NCIPC Board of Scientific Counselors
Open to the Public
July 16, 2021

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Atlanta, Georgia

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
BOARD OF SCIENTIFIC COUNSELORS (BSC)
Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control (NCIPC)

Thirty-Sixth Meeting
July 16, 2021

Virtual / Zoom Meeting
Open to the Public

Summary Proceedings

The Thirty-Sixth meeting of the National Center for Injury Prevention and Control (NCIPC; Injury Center) Board of Scientific Counselors (BSC) was convened on Friday, July 16, 2021 via Zoom and teleconference. The BSC met in open session in accordance with the Privacy Act and the Federal Advisory Committee Act (FACA). NCIPC BSC Co-Chairs, Dr. Amy Bonomi and Dr. Chinazo Cunningham, presided.

Call to Order / Roll Call / Meeting Process / Welcome & Introductions

Call to Order

Dr. Amy Bonomi, PhD, MPH
Co-Chair, NCIPC BSC
Faculty Affiliate, Harborview Injury Prevention and Research Center,
University of Washington, and Founder, Social Justice Associates

Dr. Bonomi officially called to order the Thirty-Sixth meeting of the NCIPC BSC at 10:00 AM Eastern Time (ET) on Friday, July 16, 2021.

Roll Call / Meeting Process

Mrs. Tonia Lindley
NCIPC Committee Management Specialist
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Mrs. Lindley conducted a roll call of NCIPC BSC members and *Ex Officio* members, confirming that a quorum was present. Quorum was maintained throughout the meeting. One conflict of interest (COI) was declared by Dr. Chou who receives funding to conduct reviews on opioids and indicated that he would recuse himself following the director’s update. An official list of BSC member attendees is appended to the end of this document as Attachment A. Mrs. Lindley introduced Stephanie Wallace, the Writer/Editor from Cambridge Communications and Training Institute (CCTI), who she explained would record the minutes of the meeting. To make it easier for her to capture the comments, Mrs. Lindley requested that everyone state their names prior to any comments for the record. She indicated that the CDC and On Par Production (OPP) Technicians would audio record the meeting for archival purposes to ensure accurate transcripts of the meeting notes. The meeting minutes will become part of the official record and will be posted on the CDC website at www.CDC.gov/injury/bsc/meetings.html. All NCIPC BSC and *Ex Officio* members were requested to send an email to Mrs. Lindley at ncipcbsc@cdc.gov at the conclusion of the meeting stating that they participated in this meeting. In addition, Mrs. Lindley explained the public comment process.

Welcome & Introductions

Dr. Amy Bonomi, PhD, MPH
Co-Chair, NCIPC BSC
Faculty Affiliate, Harborview Injury Prevention and Research Center,
University of Washington, and Founder, Social Justice Associates

Dr. Bonomi also thanked and welcomed members of the public, whose engagement is very much appreciated and is critical to the BSC's role and mission. She noted that from 2:15 PM to 4:15 PM there would be a period for public comments, at which time Mr. Victor Cabada would provide instructions to anyone wishing to make a public comment. She invited those unable to present their public comments during the meeting to submit written comments on or before July 23, 2021 to ncipcbsc@cdc.gov. Dr. Bonomi explained that because this was a board meeting, CDC staff and the public were attending in listen-only mode. Only speakers, select subject matter experts (SMEs), senior leadership, and division Associate Directors for Science (ADS) would be permitted to speak throughout the meeting. At this time, she welcome new BSC members Angela Lumba-Brown, Dr. Chinazo Cunningham, Dr. Wendy Ellis, Dr. Jeffery Michael, Dr. Elizabeth Miller, Dr. Steven Ondersma, Dr. Rosalie Pacula, Dr. John Rich, Dr. Lyle Ungar, and Dr. Bonomi herself joining as a new member and Co-Chair. Although Dr. Cunningham is not a new member, she is taking on a new role as Co-Chair for the BSC.

Approval of Last Meeting Minutes

Dr. Bonomi referred members to the copy of the minutes provided to them with their meeting materials from the February 16, 2021 NCIPC BSC meeting. With no questions or edits noted,

Dr. Bonomi called for an official vote.

Motion / Vote

Dr. Floyd made a motion, which **Dr. Liller** seconded, to approve the February 16, 2021 NCIPC BSC meeting minutes. The motion carried unanimously with no abstentions.

NCIPC Director's Update

Christopher Jones, PharmD, DrPH, MPH
CAPT, US Public Health Service
Acting Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

CAPT Jones noted that he typically serves as the Deputy Director of NCIPC, but is now stepping into the Acting Director role as Dr. Houry transitioned to her new role as Acting Principal Deputy Director for CDC. Dr. Derrick Gervin, who currently serves as Director of NCIPC's Extramural Research Program Office (ERPO), will step into an acting capacity in CAPT Jones's regular Deputy Director role. CAPT Jones expressed his hope that it would be a meaningful day of information sharing, learning, and public feedback as they discussed the draft of the updated opioid prescribing guideline. He expressed gratitude to everyone on the BSC and CDC staff who took time out of their day to help advice NCIPC on critically important topics. He especially thanked the members of the OWG (OWG) for their thoughtful report outlining key considerations for the CDC guideline update. He was able to review the report once it posted the previous day and was looking forward to discussion and ultimately the BSC recommendations that would follow.

CAPT Jones stressed that the BSC's insights and recommendations would be invaluable as NCIPC works to update the guideline. He also thanked CDR Melanie Ross for serving as the Designated Federal Official (DFO) for the OWG. She has put in a great deal of time to help coordinate that effort. It is important to note that while the OWG was charged with reviewing the draft guideline and developing a report, the BSC is the body that will review the report and OWG considerations and ultimately make recommendations to CDC. That process would begin during this meeting with the discussion. CAPT Jones thanked the new BSC members for joining, noting that he had worked with some of them very closely in the past and looked forward to hearing their feedback during their tenure on the BSC. He also expressed gratitude to new Co-Chairs, Drs. Bonomi and Cunningham, for their leadership in advancing injury and violence prevention. This is an incredibly important time for the Injury Center and he looks forward to engaging with each of them as well during their tenures on the BSC.

Before getting to the main focus of the meeting, the OWG report on the guideline, CAPT Jones shared a few brief updates on the Injury Center. On May 28, 2021 the Administration released the full President's Budget Request for Fiscal Year (FY) 2022. This follows what was a high-level budget outline that was released in April 2021. The topline request for CDC / Agency for Toxic Substances and Disease Registry (ATSDR) is $8.7 billion in discretionary spending, which is an increase of $1.6 billion over the FY 2021 enacted budget. For the Injury Center specifically, the budget requests more than $1.1 billion in discretionary spending. This is an increase of more than $420 million over FY 2021. There are no proposed reductions to any of NCIPC's current funding lines. Highlights of some of the proposed increases in the President's Budget Request for the Injury Center include the following:

☐ *$240 million for opioid overdose prevention and surveillance*: With these additional resources, NCIPC intends to increase investments and innovations to reach more of the nation's largest cities, counties, and smaller communities heavily impacted by the overdose crisis while continuing to support all 50 states, territories, and local jurisdictions to track and prevent overdose deaths. The additional resources also will enable CDC to support investments in prevention efforts for people at highest risk, such as supporting harm reduction and access to medication for opioid use disorder (OUD) for people transitioning from alternate residences such as jails and prisons, treatment facilities, and homeless shelters.

☐ *$100 million for community and youth violence (YV) prevention*: These resources will help further build the evidence for preventing community violence; modernized data systems to enhance the ability of states, cities, and communities to monitor youth and community violence in real-time; and support communities most impacted with resources to implement evidence-based strategies. These funds also will be used to support up to 5 community-based organizations (CBOs) to support violence prevention efforts.

- ☐ *$50 million for rape prevention*: With these additional funds, CDC will increase support to state and territorial health departments to initiate, expand, or enhance effective prevention activities. These funds also will support state, territorial, and tribal sexual assault coalitions to coordinate and implement prevention activities based on the best available evidence and to collaborate with entities engaged in sexual violence (SV) prevention.

- ☐ *$12.5 million for firearm injury and mortality prevention research*: With these additional resources, NCIPC will expand on the extramural research begun during the past year to identify the most effective ways to prevent firearm-related injuries and deaths. Collection of firearm injury data also will be expanded by funding additional states beyond the currently funded 10 states that participate in NCIPC's Firearm Injury Surveillance Through Emergency Rooms (FASTER) initiative that supports rapid collection and use of non-fatal firearm injury data at the local level. States also will be provided additional funds to incorporate the new Firearm Safety Practices Module in their Behavioral Risk Factor Surveillance System (BRFSS) state surveys to help monitor and evaluate safe storage programs and practices.

- ☐ *$10 million for the National Violent Death Reporting System (NVDRS)*: These funds will be used to improve the ability of the system and its users to collect data on sexual orientation and gender identity (SOGI) so that important disparities associated with these factors can be better understood and eliminated.

- ☐ *$5 million for domestic violence and sexual violence*: With these resources, CDC will develop and implement an appropriate surveillance strategy to estimate the burden of intimate partner violence (IPV) among older adults. These additional funds also will be used to help inform updates to CDC's "Preventing Intimate Partner Violence Across the Lifespan: A Technical Package of Programs, Policies, and Practices"[1] and will work to prevent dating violence among youth with disabilities.

- ☐ *$5 million for domestic violence community projects*: Currently, CDC's Domestic Violence Prevention Enhancement and Leadership Through Alliances (DELTA) impact program funds 10 state domestic violence coalitions. With the increased funding, it will be possible to fund 20 additional recipients to build capacity to implement and evaluate proven IPV prevention strategies in their states.

- ☐ *$2.5 million in mandatory funding*: This funding would support community violence prevention dispersed across FYs 2023-2029.

The President's Budget Request lays out the priorities for the Administration, but Congress ultimately will determine its own priorities through the appropriations process. However, NCIPC got some insight earlier in the week as to how that is taking shape with the House budget mark and is encouraged that it tracks closely with what was in the Present's Budget Request for the Injury Center and also includes small increases in NCIPC's suicide and adverse childhood experiences ACEs prevention lines. NCIPC eagerly awaits to see what the final appropriations bill will contain and looks forward to sharing more information as the process moves forward. The Injury Center certainly is encouraged to see the proposed budget increase for its overdose prevention work. Prevention and surveillance activities are critical as the overdose crisis continues to worsen, which was brought into stark contrast earlier in the week with the release of the provisional overdose death data from January 2020 through December 2020 with a predicted number of overdose deaths of more than 93,000.

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[1] https://www.cdc.gov/violenceprevention/pdf/ipv-technicalpackages.pdf

The reality is that the overdose deaths have never been higher and the current epidemic is not the same as the one 2 years ago, 5 years ago, or 2 decades ago. It is important to remain nimble and flexible to the changing facts on the ground. Implementing a comprehensive multisector response to prevent further harms is critical, but it is also important to focus on preventing upstream risks. NCIPC believes that one component of this comprehensive response is helping to ensure that patients with pain are provided with safe and effective pain management. The updated guideline to be discussed during this meeting is a step toward achieving safer and more effective pain management. NCIPC also knows that the availability of timely, high-quality data is fundamental to preventing further injuries or deaths across all of its injury and violence topics.

There also has been work across the Injury Center over the past year to advance the use of innovative data science tools, methods and techniques as part of its "Data Science Strategy for Injury and Violence Prevention"[2] released last year. This includes using multiple data sources or ensembling of data and machine learning (ML) models for nowcasting and forecasting. One example is a recent publication the *Journal of the American Medical Association (JAMA) Network Open*™ in which NCIPC developed a ML model for estimating weekly US suicide fatalities in near real-time. The model combined information from 8 data streams, including health services and online data sources, to enable accurate real-time estimation of US suicide fatalities with meaningful correlation to week-to-week epidemiological trends and a less than 1% error compared with the actual counts.[3] NCIPC is excited that this represents its first effort in data ensembling and ML.

The Injury Center is now translating these methods for overdose and homicide forecasting and looking to expand this work to other injury and violence topics. Another example is using novel data sources to understand the conversations around important health topics, such as substance use. They are working on ML and natural language processing (NLP) models to better identify and explore health misinformation. A Call to Action was published the previous day titled, "Confronting Health Misinformation: The US Surgeon General's Advisory on Building a Healthy Information Environment."[4] Misinformation certainly is extending well beyond vaccines and into injury and violence topics as well, so the Injury Center is trying to better understand that and use rigorous methods to help ascertain what myths are being shared about injury topics and use that to help inform NCIPC's programmatic efforts.

Having infrastructure in place for timely data and surveillance is critical. NCIPC's partnerships and collaborations play a key role in this effort. As mentioned earlier, the Injury Center supported a small number of states to implement near real-time non-fatal surveillance data on firearms through its FASTER project. States are now engaging in those efforts and helping to break down silos by bringing diverse stakeholders together who can collectively act on the data to strengthen firearm injury and violence prevention efforts. For example, North Carolina recently convened partners to discuss approaches for disseminating the FASTER data and how they can use that information for future prevention and response efforts. This included a broad range of stakeholders such as the health department, Child Fatality Task Force (CFTF), state emergency medical services (EMS) leadership, and various advocacy organizations who were assembled to think about how best to use the data to inform prevention and response efforts.

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[2] https://www.cdc.gov/injury/pdfs/data-science/Data-Science-Strategy_FINAL_508.pdf

[3] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774462

[4] https://www.hhs.gov/sites/default/files/surgeon-general-misinformation-advisory.pdf

In terms of diversity, equity, belonging, and inclusion activities in the Injury Center, racism is known to be a serious threat to the public's health. Data show that racial and ethnic minority groups throughout the US experience higher rates of illness and death across a wide range of health conditions compared to their white counterparts. This is certainly the case with many injury and violence topics. To achieve better health and opportunities for all, NCIPC believes that it is essential to confront the systems and policies that have resulted in the generational injustice that has given rise to these health inequities not only within the work the Injury Center does in injury and violence prevention, but also within its own organization. Over the past year, a strong emphasis has been placed on NCIPC's diversity, equity, belonging, and inclusion priorities. Most recently, an external consultant was brought in to conduct a climate assessment of activities within the Injury Center related to diversity, equity, belonging, and inclusion. This included qualitative work, focus groups, key informant interviews, and a center-wide survey. Those data have now been analyzed and a series of actionable recommendations were developed by the external consultant. The next step is to present the report and its findings to all of the staff in the Injury Center and embark on developing a strategic plan that focuses on 3 main areas including workforce, workplace, and the work of injury and violence prevention and institute structural changes to the center to ensure that proper attention is applied to these critical issues and move the center forward. No doubt this will be hard work, but it is absolutely essential and necessary work.

CAPT Jones thanked the BSC for their engagement last year when NCIPC discussed how they could advance their diversity, equity, belonging, and inclusion work in particular in its extramural research efforts. The Injury Center has worked to incorporate the recommendations from the BSC into its overall efforts. One example in which they have been able to take action to address some of the recommendations from the BSC last year, this year the Injury Center signed on to the 2021 CDC / National Institutes of Health (NIH) Administrative Supplements to Promote Diversity in Research Development in the Small Business Innovation Research (SBIR) Program Announcement. This allows NCIPC to consider awarding supplemental funds to SBIR grantees to support the increased participation of populations under-represented in the extramural scientific workforce in alignment with the NIH statement on diversity. They also incorporated second level review selection criteria language in its FY 2021 funding announcements for funding consideration of applications that support Injury Center health equity and diversity, equity, and inclusion (DEI) priorities.

All 6 FY 2021 Notice of Funding Opportunities (NOFOs) for violence included language that requires applicants to reduce the disproportionate burden of violence experienced by some groups in communities or to proposed research focused on groups experiencing reduced economic stability; limited education attainment, access, and quality; and/or limited healthcare access and quality. Language also was included in all of the NCIPC NOFOs for applicants to consider conducting research in collaboration or partnership with minority-serving educational institutions. The Injury Center continues to update its research priorities. The BSC heard about NCIPC's suicide research priorities during the last BSC meeting. In a week or so, the BSC would hear about NCIPC's ACEs research priorities. The Injury Center is working very hard to thoughtfully and intentionally include a focus on health equity in all of its research priorities. When the BSC hears about NCIPC's ACEs research priorities, they should be thinking about the equity lens and how the Injury Center can be sure that they are calling this out in that work. As part of the BSC recommendations, NCIPC is working with the American Public Health Association (APHA) to support increased participation of minority researchers in injury and violence prevention research from both minority-serving and majority-serving institutions. NCIPC is holding a virtual workshop in conjunction with the APHA meeting in October 2021.

CAPT Jones closed by reiterating the importance of the work of injury and violence prevention at this unprecedented moment, recognized the challenges that everyone in attendance have faced over the past year, and acknowledged their hard work and resilience through the pandemic. Everyone has been pulled in many directions and played many roles (remote teachers, family support providers, caregivers for others who have become ill, answering questions of neighbors and others pertaining to COVID-19, et cetera) while all striving to keep the work of injury and violence prevention moving forward. He emphasized how incredibly grateful NCIPC was for everyone spending a large portion of their Friday engaging with the center and providing critical feedback.

Opioid Overdose Prevention: A CDC Priority [Video]

Rochelle P. Walensky, MD, MPH
Director, Centers for Disease Control and Prevention
Administrator, Agency for Toxic Substances and Disease Registry

Hello. I am so pleased to join this meeting of the Board of Scientific Counselors for the National Center for Injury Prevention and Control, even if only virtually. My thanks to all of you for your participation and your partnership with CDC. In particular, I would like to acknowledge the members of the BSC's OWG and extend my appreciation for their time, effort, and expertise in developing the workgroup report on the draft update up to the 2016 opioid guideline. The diverse perspectives of the OWG members including patients with chronic pain, caregivers and family members of patients with chronic pain, as well as a broad range of scientists, subject matter experts, and clinicians are invaluable as we work to develop guidelines that ensure patients receive safe and effective treatment for pain. We look forward to the report and the conversation from the full BSC throughout the presentations today and from the public during the public comment period this afternoon. This update will expand the scope of the 2016 opioid guideline to inform opioid prescribing for certain acute pain conditions, incorporating feedback and recommendations.

The process has been and will be a rigorous one and an open one as we have all been listening to numerous perspectives, examining the evidence, and taking care to get this right. We are committed to ensuring that the guideline update includes input from a number of perspectives, particularly patients, as well as clinicians, partners, and community organizations. For example, there have been two notices in the *Federal Register* to engage the community and learn more about values and preferences relating to pain and pain management. If you are a member of the public joining us today, we thank you for your commitment to these issues. Please know your voices are heard and valued. We also recognize that pain is common. One in five adults reported living with chronic pain in 2019. Pain is also complex and can be debilitating, impacting every aspect of a person's life. All too often, we hear about the many challenges that patients, family members, and caregivers face as they navigate pain management with a complex medical care system. As a physician, I know first-hand that patients need and deserve compassionate care, especially when facing persistent pain.

The evidence-based clinical practice guideline on opioid prescribing is intended to be a tool for patients and prescribers in their conversations about safe, effective pain treatment. The 2016 opioid guideline was developed in response to a significant public health crisis. Nearly 841,000 people have died from a drug overdose in the United States since 1999 and almost 247,000 of those deaths involved a prescription opioid. The 2016 guideline helped us to address that prescription opioid overdose crisis. While prescription opioids were involved in over 28% of all opioid overdose deaths in 2019, there was a nearly 7% decrease in prescription opioid-involved death rates from 2018 to 2019. States are building foundations for safer prescribing and more holistic care across health systems, including promoting evidence-based non-opioid treatments and non-pharmacologic interventions, including exercise, cognitive behavior therapy, and massage therapy. They are also increasing efforts to improve prescribing with state Medicaid programs and are more and more increasing access to non-pharmacologic pain management, such as acupuncture.

While the overdose epidemic in the United States demands a comprehensive public health strategy ranging from primary prevention to overdose response, efforts like the CDC update to the opioid prescribing guidelines remain an important part of our overall strategy From topics as far ranging as COVID-19 vaccination to STD treatment, we strive to make all of our CDC guidelines clear, valid, transparent, reliable, and able to be implemented in practice. Most importantly, guidelines must be patient-centered and focused on patients' well-being. We do want to recognize the limitations of our guidelines. These guidelines are not regulations. They are not law. They do not represent a standard of care, nor are they intended to deny access to opioid medications as an option for pain management. Again, they are simply a tool to inform patient care based on the best available evidence.

I look forward to the thoughtful deliberations of the Board of Scientific Counselors today and their recommendations to CDC and HHS based on the workgroup report. I am committed, as you are, to CDC's development of a guideline that will support effective, safe pain care for Americans and ultimately contribute to the health and well-being of the nation. Thank you.

Overview of the Process for Updating the *CDC Guideline for Prescribing Opioids*

Grant Baldwin, PhD, MPH
Director, Division Overdose Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Baldwin provided an overview of the process that was followed for updating the *CDC Guideline for Prescribing Opioids for Chronic Pain* (2016 Guideline, CDC Guideline), noting that his remarks would complement and set the stage for those that CAPT Dowell would provide. He began with the critical acknowledgement and reflection amplifying something that Dr. Walensky just said. CDC understands that pain persists and remains a problem for millions of Americans. Pain is known to be complex and is influenced by a myriad of factors, including those that are biological, psychological, and social. Pain is one of the most common reasons that adults seek medical care in the US. Pain, particularly chronic pain, can lead to impaired physical functioning, poor mental health, and a reduced quality of life. It also contributes to substantial morbidity and mortality in the US each year. Chronic pain is the leading cause of disability in the US. The economic costs are staggering at an estimated $560 to $635 billion annually.[5] A key aim of pain management then should be the provision of individual patient-centered care that focuses on optimizing function and supporting activities of daily living.

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[5] Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US); 2011.

CDC knows that the public, particularly patients with pain, were impacted by the 2016 Guideline and will be impacted by the forthcoming update if not appropriately followed. In this context, the ultimate goal is to help people set and achieve personal goals to reduce pain and improve function. CDC believes that patients with pain deserve safe and effective pain management and understands that individuals living with pain may experience many challenges. Patients need and deserve appropriate, effective, and compassionate care, especially when facing persistent pain. Guidelines like the *CDC Guideline for Prescribing Opioids for Chronic Pain* help ensure patients receive safe and effective pain treatment, including opioids when the benefits outweigh the risks. In short, CDC is working to support the lives of patients living with pain and is committed to patients obtaining personized pain management solutions and achieving positive health outcomes.

In the 2016 CDC Guideline, CDC indicated the intent to reevaluate the Guideline as new evidence became available and to determine when sufficient new evidence would prompt an update. Based on the new evidence currently available, CDC determined that an update of the Guideline and an expansion to certain acute conditions is warranted. The 2016 Guideline was developed using the best available scientific evidence and followed a rigorous scientific process. The update of the guideline is following a similar process with some additional opportunities for community and partner engagement. CDC highly values public engagement and has ensured that there are multiple opportunities to hear from and incorporate feedback from patients, caregivers, clinicians, and partners.

There are a number of sources of input for updating the Guideline, including systematic reviews summarizing the new scientific evidence related to the treatment of chronic and acute pain, community engagement via public comment and individual conversations, federal advisory committee engagement through the BSC and its OWG, federal partner engagement, opportunities for public comment during the public BSC meetings, and the opportunity comment on the draft updated Guideline later this year. Finally, the guideline will be independently peer reviewed by experts with relevant subject matter expertise. Dr. Grant discussed each of these in turn.

The first key step in the process was assessing whether there was sufficient new evidence to warrant an update. In order to identify whether sufficient new evidence was available to warrant updates to or expansion of the Guideline, CDC funded the Agency for Healthcare Research and Quality (AHRQ) to conduct 5 systematic reviews on the effectiveness of opioid, non-opioid pharmacologic, and non-pharmacologic treatments for acute and chronic pain. Three draft reviews on non-pharmacologic, non-opioid pharmacologic, and opioid treatments for chronic pain were posted for public comment in October 2019. Final versions were published in April 2020. Two reviews on treatments for acute pain were posed for public comment in August 2020. These reviews were completed in December 2020. All of these reviews will be updated when new evidence is available into 2022. Dr. Baldwin provided a high-level summary of the findings from each of these reviews.

The non-invasive non-pharmacological treatment for chronic pain review found that exercise, multidisciplinary rehabilitation, acupuncture, cognitive behavioral therapy. mindfulness practices. Massage, and mind-body practices most consistently improved function and/or pain beyond the course of therapy for specific chronic pain conditions.[6] The non-opioid pharmacologic treatments for chronic pain review found that in the short-term, improvement in pain and function was small with specific anticonvulsants, moderate with specific antidepressants in

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[6] https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research?deliveryName=DM26365

diabetic peripheral neuropathy/post-herpetic neuralgia (PHN) and fibromyalgia, and small with non-steroidal anti-inflammatory drugs (NSAIDs) in osteoarthritis and inflammatory arthritis.[7] The opioid treatments for chronic pain review found that opioids are associated with small improvements versus placebo in pain and function and increased risk of harms at short-term follow-up between 1 and 6 months. Evidence on long-term effectiveness is very limited and there is evidence of increased risk of serious harms that appear to be dose-dependent.[8]

The treatments for acute pain review found that opioids are probably less effective than NSAIDs for surgical dental pain and kidney stone pain, might be similarly effective to NSAIDs for low back pain, and might be more effective than gabapentin for acute neuropathic pain.[9] The acute treatments for episodic migraine review found that several established classes of medications such as triptans, NSAIDs, antiemetics, dihydroergotamine, and acetaminophen improve pain and function with generally mild, transient adverse effects. Three more recently FDA-approved medications with new mechanisms of action improve pain relief and are potentially lower risk than vasoactive medications in patients with cardiovascular risk factors. There is insufficient evidence for opioids in treatment of episodic migraine.[10]

Dr. Baldwin next provided an overview of two community engagement opportunities that CDC added to the guideline update development process to further inform this effort. Of note, these opportunities focus on experiences with the management of acute and chronic pain and were not specifically focused on the 2016 Guideline or this update. CDC sought to understand more about pain and pain management through community engagement and wanted to learn from the lived experiences, values, preferences, and perspectives of patients, caregivers, and the clinicians the agency serves. Each of these offers important information and insights that can inform the work that CDC does around pain, including the update of the CDC Guideline. To make the community engagement most robust, CDC followed two pathways. The first was to solicit written public comments through the *Federal Register*. The second path involved conversations with individuals via telephone and video conversations. Although the original plan was to have these sessions in person in different parts of the US, the reality of the pandemic required CDC to reevaluate its approach and resulted in a pivot to a Zoom-based strategy.

By asking people to comment in the *Federal Registry* and to participate in one-on-one conversations, CDC aimed to better understand public perspectives on and experiences with pain and pain management, especially as they relate to experiences in the following three areas: 1) managing pain, including the benefits, risks, or harms of different types of pain management options such as opioid pain medications, non-opioid medications, and non-pharmacologic treatments; 2) choosing among pain management options, including factors like each option's accessibility, cost, benefits, and/or risks; and 3) getting information needed to make pain management decisions. To answer these questions, CDC sought insights from three key groups, including patients with acute or chronic pain, patients' family members and caregivers, and clinicians who care for patients with pain or conditions that can complicate pain management such as a history of OUD or overdose.

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[7] https://effectivehealthcare.ahrq.gov/products/nonopioid-chronic-pain/research

[8] https://effectivehealthcare.ahrq.gov/products/opioids-chronic-pain/research

[9] https://effectivehealthcare.ahrq.gov/products/treatments-acute-pain/research

[10] https://effectivehealthcare.ahrq.gov/products/migraine-treatments/research

In April 2020, CDC published its first Federal Register Notice (FRN) requesting public comment. The second FRN was posted in July 2020 and solicited volunteers to participate in the second component of CDC's community engagement through individual conversations. The individual conversations were completed in September of 2020 and the insights gathered were combined with the public comments received and were analyzed for themes in October and November 2020.

In terms of the results of the first FRN published on April 17, 2020 requesting public comment regarding the management of acute and chronic pain, the comment period was open for 60 days and closed on June 16, 2020. A total of 5,392 comments were received. An overwhelming majority (N=4,150) of comments were from people living with chronic pain. Other comments included those from advocacy and industry groups (N=702), caregivers (N=431), and clinicians (N=109).

The second FRN was published on July 22, 2021 that solicited volunteers to participate in the individual conversations. The invitation period remained open for 30 days through August 21, 2020. After the FRN closed, CDC and the laboratory at the US Office of Personnel Management (OPM) randomly selected participants within each group from a total of 973 respondents. CDC and OMP conducted individual telephone and video conversations throughout September 2020 and spoke to 106 individuals, including 42 patients, 21 caregivers, and 43 clinicians. As a reminder, these interviews were conducted purely for information gathering and were not considered part of a formal research project. These conversations supplemented what CDC heard from the community during the public comment period and frankly allowed CDC to add more context to what they heard from patients, caregivers, and clinicians.

Throughout the conversations, CDC heard many perspectives and heartfelt personal stories—reinforcing the very nuanced personal and professional experience of chronic and acute pain. Among the 106 participants in the individuals conversations, 14 reported being mostly harmed by opioids, 45 reported being mostly helped by opioids, 33 reported being both harmed and helped, and 14 had unknown impacts. Participants were geographically diverse with 8 in the Northwest, 28 in the Southwest, 19 in the Midwest, 21 in the Southeast, 18 in the Northeast, 1 from the Islands, and 11 were from unknown locations.

The insights gathered were combined with the public comments received and were analyzed for themes. Two themes emerged from the public comment FRN, which were achieving reduced opioid use through diverse approaches and the impact of misapplication of the 2016 Guideline. Participants upheld the need to reduce unnecessary opioid use through varied pain management solutions. They widely supported the assertion that initial pain treatment should employ non-opioid solutions, including behavioral health interventions to help individuals manage the psychological effects of chronic pain. They also emphasized the need for patients and clinicians to make shared decisions about an individual's care plan.

In terms of the impact of misapplication of the 2016 Guideline, participants maintained that in some instances, particularly with the management of chronic pain, opioid therapy is the best and/or only appropriate treatment. The 2016 Guideline does not contradict this assessment; however, participants shared serious concerns about how misapplication was occurring by some industries, particularly pharmacies and insurers in that they impose rigid standards and regulations to enforce adherence to those standards. Caregiver and patient comments underscored how misapplication often translated to inconsistent access to effective pain management solutions. They detailed personal experiences with the challenges that this creates, including diminished capacity due to unmanaged pain and destruction to daily responsibilities corresponding to both the level of pain intensity and increased time spent navigating the healthcare system to access their desired care.

A third theme emerged from the conversations that regarded the environment and considerations impacting reception and design. Providers reported using the Guideline as a tool to educate patients and caregivers as their first go-to source for guidance because CDC is seen as a trusted and objective source of information. Regarding perceptions, many caregivers and patients described feeling stigmatized by healthcare providers. Patients, caregivers, and providers shared that for the purposes of pain management, mental health was crucial to assess alongside physical health. These themes were shared with the authors drafting the Guideline update to inform their understanding of patient, caregiver, and clinician values and preferences. The themes also will be used internally to inform the design of potential dissemination and engagement strategies once the Guideline is released.

Another key step in the Guideline update process has been federal advisory committee engagement with the NCIPC BSC. On December 4, 2019, the NCIPC BSC established the OWG at CDC's request. The OWG reports to the NCIPC BSC, which serves as a federal advisory committee. The primary purpose of the OWG is to: 1) review the updated draft Guideline for opioid prescribing as prepared by CDC; 2) provide independent, broad, external, transparent input on the diverse and complex issues involved in this effort; and 3) develop a report that will provide the OWG's findings and observations about the draft Guideline to the NCIPC BSC.

CDC held a public nomination process for prospective OWG members from December 4, 2019 through February 4, 2020. This process was announced during the public BSC meeting in December 2019 and through public and partner newsletters and the BSC website. In seeking a balance of perspectives among prospective OWG members, CDC sought inclusion of audiences directly affected by the 2016 Guideline who would be directly involved in implementing or integrating updated or expanded recommendations into current practice and those qualified to provide representation of a specific discipline, expertise, or viewpoints in alignment with the tasks of the OWG. A total of 255 nominations for the OWG were received. The curricula vitae (CVs) of nominees were reviewed and a list of prospective members created based on expertise and diversity in perspectives. Invitations to participate in the OWG were sent. For those interested in participating disclosures of competing conflicts of interest, if any, were requested and reviewed. OWG membership was then finalized and the roster was presented during the July 22, 2020 NCIPC BSC public meeting.

The OWG has 23 members comprised of patients with pain, caregivers, and family members of patients with pain. Also included are clinicians and SMEs with diverse perspectives in the following areas:

primary care	emergency medicine	plastic surgery
pain medicine	medical toxicology	dentistry
public health	obstetrics/gynecology	sickle cell disease
behavioral health	bioethics	substance use disorder treatment
pharmacy	orthopedic surgery	research

Diversity in perspective is also represented in regard to sex, race, ethnicity, and geographic region. In accordance with CDC guidance, at least 2 members of the parent committee of the BSC must be appointed as members of the OWG and the Chair of the OWG is an appointed BSC member as well. Federal partners serve as *ex-officio* members of the OWG. The OWG also has a DFO who is an SME from the NCIPC, CDR Melanie Ross. The full roster of the OWG is available on the NCIPC BSC website.

The OWG had 11 virtual meetings from October 2020 through June 2021. Prior to receiving the draft of the Guideline update, the OWG met to review the processes used for community engagement and received an overview of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Framework. This is the framework used to rate the quality of the evidence. CDC then sent a draft of the updated Guideline to the OWG in March 2021. The OWG had a series of 7 meetings to review the draft and develop their report findings and observations, which would be presented during this meeting. As a reminder, verbal and written comments are welcomed at public BSC meetings and are considered an important input to the overall process as well.

Turning to federal partner engagement, federal partners serve as *ex-officio* members of the OWG as mentioned earlier. Included in this capacity on the OWG are representatives from the National Institute on Drug Abuse (NIDA) at the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), and Indian Health Service (IHS). The BSC also includes *ex-officio* members from the following federal entities:

☐ Administration for Children and Families (ACF)
☐ Administration for Community Living (ACL)
☐ Administration on Aging (AoA)
☐ National Institute for Occupational Safety and Health and the National (NIOSH)
☐ National Center for Health Statistics (NCHS), CDC
☐ Health Resources and Services Administration (HRSA)
☐ IHS
☐ FDA
☐ SAMHSA
☐ National Institute on Aging (NIA), NIH
☐ National Institute of Child Health and Human Development (NICHD), NIH
☐ National Institute on Drug Abuse (NIDA), NIH
☐ National Institute of Mental Health (NIMH), NIH

Additional partners will be engaged throughout the Guideline update process and federal partners also will have the opportunity to review the full draft updated Guideline as part of departmental clearance.

Regarding upcoming activities and milestones, the OWG planned to present their report later in the afternoon as noted earlier. The NCIPC BSC will then review that report and provide recommendations for CDC to consider as part of the Guideline update process. CDC will revise the draft updated Guideline based upon all of the input received and obtain CDC and HHS clearance. CDC anticipates that the draft updated Guideline will be posted in the *Federal Register* for a 60-day public comment period by the end of 2021. This will provide another critical opportunity for diverse input from the public. CDC takes public comment seriously and will carefully consider this input while finalizing the updates to the Guideline. SMEs will independently conduct peer review of the draft updated Guideline concurrently during the public comment period. A peer review panel will be selected by NCIPC's ADS. Peer reviewers will be selected based upon their expertise, while ensuring a balance in scientific and technical perspectives, avoiding COIs, and ensuring independence from the Injury Center and the process of developing the updated Guidelines. In 2022 after the public comment period has closed, CDC will revise the draft updated Guideline considering public comments and peer review, and will obtain CDC and HHS clearance. CDC will develop a suite of translation and communication resources to be co-released with the Guideline publication. Release of the final updated Guideline is anticipated to occur in late 2022.

In conclusion, CDC sought input and observations from patients and clinicians through public comments, engagement of the OWG, and evidence reviews from AHRQ. CDC also garnered public input through an FRN that received over 5,000 public comments and through 106 in-depth individual conversations with patients, clinicians, and caregivers as well as the hundreds of public and written comments received through BSC meetings such as this one. This process of listening and applying related insights is still underway and demonstrates CDC's commitment to developing a guideline in a transparent community-centered way.

Draft Updated CDC Guideline for Prescribing Opioids: Background/Overview/Progress

Deborah Dowell, MD, MPH
CAPT, United States Public Health Service
Chief Clinical Research Officer
Division of Overdose Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Dowell expressed gratitude to the members of the BSC for the opportunity to provide some background, an overview, and a progress report on the draft updated 2016 Guidelines. In terms of background, most importantly, patients with pain deserve safe and effective pain management. Guidelines can help ensure patients receive safe and effective pain treatment, including opioids when the benefits outweigh the risks.

Pain is one of the most common reasons adults seek medical care in the US. Acute pain, a nearly universal experience, is a physiologic response to noxious stimuli that can become pathologic. It is normally sudden in onset and often time-limited. Chronic pain typically lasts longer than 3 months and is often interlinked with acute pain. Pain can result from an underlying medical disease or condition, injury, trauma, surgery or other medical treatment, inflammation, or unknown causes. Chronic pain is the leading cause of disability in the US. An estimated 1 in 5 US adults had chronic pain in 2019 and about 1 in 14 adults experienced high-impact chronic pain, meaning that their pain limited life or work activities most days or every day.[11]

Pain is a complex phenomenon influenced by many factors, including biological, psychological, and social factors. There are substantial differences in the effectiveness of various pain treatments depending on the underlying pain or condition. CAPT Dowell said that on a personal note, she has practiced primary care medicine since 1999 in full-time community-based clinical positions, part-time volunteer care, and deployments. She is deeply aware that prevention, assessment, and treatment of pain is a persistent challenge for clinicians and health systems. Pain may go unrecognized and patients may be at risk for inadequate pain treatment. It is

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[11] Zelaya, C. E., Dahlhamer, J. M., Lucas, J. W., & Connor, E. M. (2020). Chronic Pain and High-impact Chronic Pain Among U.S. Adults, 2019. NCHS Data Brief(390), 1-8

known that this is particularly true for members of racial and ethnic minority groups, women, older people, people with cognitive impairment, and people with sickle cell disease.

Improving the way opioids are prescribed through clinical practice guidelines can ensure that patients have access to safer, more effective pain treatment. Related guidelines existed prior to development of CDC's 2016 Guideline, but were several years old as of early 2016 and did not reflect newer evidence. The *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* was released on March 18, 2016. The 2016 Guideline focused on recommendations for primary care clinicians prescribing opioid medications for chronic pain in patients 18 years of age and older and in outpatient primary care settings. The Guideline was not intended for use in cancer treatment, palliative care, or end-of-life care.

The recommendations were grouped into 3 conceptual areas related to decisions about starting and continuing opioids for chronic pain; opioid type, dose, and duration; and assessing risk and addressing harms of opioid use. There were 12 main recommendations as follow:

Determining when to initiate or continue opioids for chronic pain
1. Opioids not first-line or routine therapy for chronic pain
2. Set goals for pain and function when starting
3. Discuss expected benefits and risks with patients

Opioid selection, dosage, duration, follow-up and discontinuation
4. Start with short-acting opioids
5. Prescribe lowest effective dose; reassess benefits and risks when increasing dose, especially to >50 MME; avoid or justify escalating dosages to >90 MME
6. Prescribe no more than needed for acute pain; 3 days often sufficient; >7 days rarely needed
7. If benefits of continuing opioids do not outweigh harms, optimize other therapies and work with patients to taper

Assessing risk and addressing harms of opioid use
8. Assess risks; consider offering naloxone
9. Check PDMP for other prescriptions, high total dosages
10. Check urine for other controlled substances
11. Avoid concurrent benzodiazepines and opioids whenever possible
12. Arrange medication-assisted treatment for opioid use disorder

CDC's implementation efforts have focused on translation and communication, clinical training and education, and work with health systems and insurers to maximize uptake and use of the guidelines. As an example, CDC developed a mobile application (app) and training to help primary care clinicians help patients manage pain more effectively and safely. CDC engaged clinicians, health systems, leaders, payers, and other decision-makers to facilitate appropriate implementation. The medical and health policy communities have largely embraced the Guideline's recommendations. Although outpatient opioid prescribing had been declining since 2012, accelerated decreases in overall and high-risk prescribing (e.g., overlapping opioid and benzodiazepines prescriptions and high dosage prescriptions) followed the Guideline's release as documented in a 2018 paper by Amy Bohnert and colleagues.[12]

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[12] Bohnert ASB, Guy GP Jr, Losby JL. Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention's 2016 Opioid Guideline. Ann Intern Med. 2018 Sep 18;169(6):367-375

Efforts to improve opioid prescribing are commendable. However, some policies and practices citing the Guideline went beyond recommendations and were inconsistent with its guidance. For example, the Guideline does not support abrupt tapering or sudden discontinuation of opioids. However, CDC heard many reports of it being inappropriately cited to justify suddenly cutting off opioids. It is known that recommendations were misapplied to patients with cancer or sickle cell disease. These reports were extremely concerning. CDC has worked to prevent continued misapplication of the Guideline. For example, a February 2019 letter to several professional societies[13] representing providers treating patients with cancer or sickle cell disease, CDC emphasized that as stated in the Guideline, the recommendations address opioid use for chronic pain outside of cancer treatment, palliative care, and end-of-life care; that guidelines specifically addressing pain control in sickle cell disease should be used to guide decisions for patients with pain related to sickle cell disease; and that clinical decision-making should be based on an understanding of the patient's clinical situation, functioning, and life context and that careful consideration should be given to the benefits and risks of all treatment options.

In a *New England Journal of Medicine* (*NEJM*) Commentary and accompanying CDC Media Advisory in 2019, CDC described how recommendations have been misapplied and highlighted advice from the Guideline that is sometimes overlooked but is critical for safe and effective implementation. As CAPT Dowell and her colleagues wrote, "Effective implementation requires recognition that there are no shortcuts to safer opioid prescribing (which includes assessment of benefits and risks, patient education, and risk mitigation) or to appropriate and safe reduction or discontinuation of opioid use. Starting fewer patients on opioid treatment and not escalating to high dosages in the first place will reduce the numbers of patients prescribed high dosages in the long term. In the meantime, clinicians can maximize use of nonopioid treatments, review with patients the benefits and risks of continuing opioid treatment, provide interested and motivated patients with support to slowly taper opioid dosages, closely monitor and mitigate overdose risk for patients who continue to take high-dose opioids, and offer or arrange medication-assisted treatment when opioid use disorder is identified."[14] To emphasize important but overlooked messages from the Guideline such as the importance of patient-centered collaborative tapering, CDC updated its tapering pocket guide[15] and collaborated with HHS, FDA, CMS, AHRQ, HRSA, and SAMHSA on the *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*.[16]

In the 2016 Guideline, CDC indicated the intent to evaluate the Guideline as new evidence became available and to determine when sufficient new evidence would prompt an update. New evidence on benefits and harms of opioids for both acute and chronic pain, comparisons with non-opioid pain treatments, and on benefits and harms of opioid tapering and discontinuation has emerged since the release of the 2016 Guideline. Also since the release of the 2016 Guideline, there have been calls from professional specialty societies such as the American Dental Association (ADA), US policymakers, and the media for CDC to provide recommendations on prescribing opioids for acute pain.

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[13] American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), National Comprehensive Cancer Network® (NCCN)

[14] Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.; No Shortcuts to Safer Opioid Prescribing; June 13, 2019; *N Engl J Med* 2019; 380:2285-287; DOI: 10.1056/NEJMp1904190

[15] https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf

[16] https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf

Prior to drafting the updated Guideline, CDC obtained input from patients, caregivers, clinicians, and the public. As Dr. Baldwin described in greater detail earlier, key themes included shared decision-making, misapplication of the 2016 CDC Guideline, inconsistent access to effective pain management, and achieving reduced opioid use through diverse approaches. As Dr. Baldwin also described, CDC funded the AHRQ to conduct 5 systematic reviews on the effectiveness of opioid, non-opioid pharmacologic, and non-pharmacological treatments for acute and chronic pain. Dr. Baldwin also reviewed the main findings.

CAPT Dowell next provided an update of what is included in the draft and an update on progress. She reminded everyone that information presented during this meeting was based on a draft that is under development. Remaining development steps include the BSC's review of the OWG's report and recommendations as the BSC, a 60-day public comment period on the draft Guideline, and independent peer review. All of this feedback is important and will be carefully considered and incorporated during guideline revision. CDC heard the concerning reports about misapplication of the 2016 Guideline and has learned from what happened. They know that there is a very real possibility that even with the adjustments, the Guideline could be misused. CDC very much appreciates the BSC's review and input as well as additional feedback in each step in the upcoming process so that they can better anticipate how the language will be read, understood, and used and so that they can most effectively maximize benefits and minimize risks of the revised Guideline update.

The purpose of the Guideline is to support clinicians and patients in working together to create and maintain safe, consistent, and effective personal treatment plans. Effective pain management requires individual patient-centered care, including proper evaluation to establish a diagnosis and a focus on optimizing function and improving activities of daily living (ADL) and quality of life (QoL) built on a foundation of trust between patients and clinicians. To achieve this, clinicians should consider the full range of pharmacological and non-pharmacological treatments for pain care. The full range of therapeutic options is often inaccessible to many patients due to inadequate clinician education, training, and guidance; a shortage of pain management specialists; insufficient access to modalities such as behavioral therapy; siloed health systems, insurance coverage, and reimbursement policies; and lack of clarity around the evidence supporting different pain treatments. CAPT Dowell emphasized that as a clinician, she is keenly aware of these challenges and knows that they can result in over-reliance on prescription opioids alone for pain management. These barriers can make opioids seem to be the easiest quick solution for pain management, even when other treatments might provide greater long-term effectiveness and patient safety.

The Guideline update is intended to improve communication between clinicians and patients; improve the safety and effectiveness of pain treatment; and reduce risks associated with long-term opioid therapy, including OUD, overdose, and death. The Guideline provides guidance only and does not replace clinical judgment and individualized decision-making. CDC is not a regulatory agency. Its guidance is recommended and not required. The Guideline is a tool to inform the decision-making process and treatment planning. The draft Guideline updates and expands the 2016 CDC Guideline and provides evidence-based recommendations for clinicians who are prescribing opioids for outpatients 18 years of age and older with acute, subacute, or chronic pain outside of sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care. The draft update includes guidance for primary care clinicians and also for outpatient clinicians in other specialties, including those managing dental and post-surgical pain in outpatient settings and emergency clinicians providing pain management for patients being discharged from emergency departments (EDs). As clinicians often work within team-based care, the draft recommendations refer to and promote integrated pain management and collaborative working relationships with behavioral health providers, pharmacists, and pain management specialists.

Based on input from patients, caregivers, clinicians, and the public as well as on new evidence, the updated guideline draft includes expanded guidance on acute and subacute pain; updated information on benefits and risks of therapies for chronic pain; and expanded guidance on opioid tapering and on pain management for patients already receiving opioids long-term. CDC updated the Guideline drawing on evidence from the systematic review as well as from other relevant studies and guidelines to address gaps outside the scope of the systematic review, such as the American Society of Addiction Medicine (ASAM) *National Practice Guideline for the Treatment of Opioid Use Disorder*,[17] very recent studies on harms associated with rapid tapering, and others.

The updated draft recommendations address: 1) determining whether or not to initiate opioids for pain; 2) opioid selection and dosage; 3) opioid duration and follow-up; and 4) assessing risk and addressing harms of opioid use. CDC developed the updated draft recommendations using the GRADE Framework as noted earlier. Recommendations considered benefits and harms; values and preferences, including values and preferences expressed through community engagement and public comments; and resource allocation (e.g., costs to patients or health systems, including clinician time). Using GRADE, the recommendations were categorized to convey the extent to which there is confidence that adherence to the recommendation will do more good than harm. For Category A recommendations, most patients should receive the recommended course of action. For Category B recommendations, advantages and disadvantages of a clinical action are more balanced. Also used in the GRADE Framework, evidence is categorized into the following 4 types:

Type 1	High-quality evidence consisting of randomized controlled trials (RCTs) or overwhelming evidence from clinical studies
Type 2	Moderate-quality evidence consisting of RCTs with important limitations or exceptionally strong evidence from observational studies
Type 3	Low-quality evidence consisting of observational studies or RCTs with notable limitations
Type 4	Very low-quality evidence consisting of clinical experience and observations, observational studies with notable limitations, or RCTs with several major limitations

Each draft recommendation is followed by a draft rationale for the recommendation, with considerations for implementation noted. As a reminder, CDC anticipates that the draft updated Guideline will be posted in the *Federal Register* for a 60-day public comment period by the end of 2021. The Injury Center has a newsletter. Anyone who would like to receive information related to the ongoing work of the NCIPC, specific to drug overdose prevention (including the ongoing response to the opioid overdose epidemic) as well as other drug overdose updates (e.g., pertaining to resources and tools) may sign up at www.cdc.gov/emailupdates and select topics of interest.

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[17] https://www.asam.org/Quality-Science/quality/2020-national-practice-guideline

In closing, CAPT Dowell emphasized that CDC's ultimate goal is to help people set and achieve personal goals to reduce pain and improve function. When rigorously developed and judiciously implemented, clinical practice guidelines can support this goal and improve healthcare quality and outcomes. She acknowledged her draft Guideline update co-authors and expressed profound appreciation to all of the patients, caregivers, clinicians, and other individuals who shared their input and experiences during the community engagement opportunities and deep gratitude to the members of the BSC and members of the OWG who have devoted countless hours over recent months to careful review and thoughtful discussion in order facilitate the updating of the Guideline.

Discussion Points

Dr. Compton thanked CAPT Dowell for a terrific and comprehensive presentation and expressed appreciation for Dr. Baldwin's presentation that clearly laid out the very careful and thought inclusion of many opportunities for comment and feedback on these very important guidelines. He noted that there was a recent workshop at the FDA regarding morphine milligram equivalent (MME) and wondered what thought had been given to considering how that workshop, which highlighted some gaps in the knowledge base around the accuracy and applicability of MME across the board in policies might be reflected in the new guidance.

CAPT Dowell said she thought the findings from that workshop provided some food for thought, and underlined the point that MME were initially developed as a proxy for pain relief and that there is some imprecision across different studies, specific medications, and even in patients in terms of how people metabolize. The MME are meant to be a rough guide so that providers have some idea to compare different pain relievers and dosages. Findings from that workshop highlight how important it is to communicate those as guides and not necessarily as absolutes. CDC is certainly looking at language in the Guideline and feedback about how to better communicate those nuances and flexibilities.

Dr. Baldwin added that while it is very nuanced, it is known that as dose goes up risk goes up. This requires careful attention in person-centered conversations as clinicians and patients make decisions together on the appropriate pain treatment.

Dr. Pacula commented that one of the things she noted in reviewing the preliminary document was that the questions and issues raised and some of the research were based on medical disease as opposed to what is understood regarding the types of pain and how opioid receptors in different parts of the body react. She wondered to what extent consideration was given in the reviews and development of the recommendations to the physiology and pharmacological responses based on the knowledge of opioid receptors in the body versus a disease state which can be different for individuals at different stages and who may have different experiences.

CAPT Dowell indicated that CDC is attentive to try to underline in the language of the guideline individualized patient-centered care and adapting to the type of pain, disease, the person, and the individual circumstances and other factors.

Dr. Pacula clarified that she was trying to express what is being learned in the biology and chemistry transmission of pain to the brain and how different pharmaceuticals act to intervene on that pain messaging process. There is science regarding the knowledge of those factors versus disease states where the disease may or may not have different expressions. She was trying to differentiate the science that is known regarding the communication of pain from receptors to the brain from a disease state and the extent to which those were differentiated in the scientific review.

CAPT Dowell indicated that increasingly more is being learned about the neurobiology of pain and how in many cases, especially with certain conditions, chronic pain can often take on a life of its own beyond the initial noxious stimuli. That understanding informed the Guideline. The studies that were used to craft the recommendations looked specifically at clinical outcomes predominantly more than pathophysiologic outcomes. Increasingly, clinical studies are informed by that increased understanding of the pathophysiologic mechanism and the very complex neurobiology underlining all kinds of pain, but especially chronic pain.

Dr. Baldwin added that CDC relied on AHRQ and their Evidence-based Practice Center (EPC) and the rigor with which they conduct their systematic reviews in terms of evaluating the current state of the evidence. That ultimately was used by CDC as the authors in crafting the Guideline itself. He recognized that Dr. Pacula raised nuances that need to be reflected when crafting recommendations and as importantly when thinking about their application and implementation.

Dr. Kaplan inquired about looking to other countries. Reviewing the presentations, he was curious about drug-related deaths in the US versus Europe. According to a chart published by the European Union (EU) that includes the natural and semi-synthetic opioids from 2000 through 2019, the deaths in Europe were virtually flat from around 2007 through 2017, while the US experienced a significant surge in drug deaths. This made him wonder what the Europeans are doing that the US is not doing, both clinically and policy-wise.

CAPT Dowell said that while she was not familiar with the specific chart to which Dr. Kaplan referred, she has seen data from Europe in comparison to the US. Other countries, with the exception of Canada, have never prescribed opioids as extensively as in the US. Falling back on her experience as a clinician and some of her remarks earlier, she thinks that there are factors in the US health system that make it very easy to rely on opioids alone as a single quick solution to a patient’s pain and certain systematic factors that make it more difficult to take a comprehensive approach and look over the long-term. Time with a patient is not well-reimbursed in the US health system. There could be better access to a full range of additional treatments, clinician time, and behavioral health service time being better reimbursed that would go a long way in improving treatment of pain in the US.

Dr. Baldwin added that some of the additional forces have to do with the elicit marketplaces that have shifted in recent years and the wider availability and use of illicitly manufactured fentanyl. As CAPT Dowell mentioned, they saw trends in the opioid prescribing decreasing beginning in 2012, but those were from an extremely elevated position. While they have decreased substantially, they still are differential to trends in other parts of the world. Like Dr. Kaplan, he is eager to learn from other developed countries what they are doing and have done to inform what might be done in the US, knowing that the US healthcare system and how medicine is practiced in the US is slightly different.

In terms of pharmacokinetics, **Dr. Ondersma** observed that the report contains a lot of information about dosage and the potential for harm. It is known that speed of onset and distribution are also associated with harm potential. He was curious whether there is a literature on that within the opioid classes and whether that might be related to risk of harm as well.

CAPT Dowell replied that there are extensive data showing that short-acting opioids seem to be less associated with respiratory depression and overdose than long-acting opioids. When they looked across different types of opioids beyond that differentiation, there do not seem to be major differences other than the key point that keeps coming up throughout many studies that risk goes up with higher doses.

Dr. Baldwin added that there is a strong literature showing that there have been decreasing trends of deaths from methadone prescribed for pain. It is well known that there are complicated pharmacokinetics with methadone given its half-life in the body and its increased prescribing at the time because of its cost-benefit ratio within the context of the health system. Certainly in the context of methadone, the pharmacokinetics are the factor driving previous trends in methadone-related deaths and is certainly something they need to be concerned about as well. Dr. Baldwin expressed his personal heartfelt gratitude on behalf of all staff at CDC. Obviously, this was a major undertaking for them and they could not do this great and important work without the insights and help from the BSC members.

Report from the OWG

Introduction

Dr. Amy Bonomi, PhD, MPH
Co-Chair, NCIPC BSC
Faculty Affiliate, Harborview Injury Prevention and Research Center,
University of Washington, and Founder, Social Justice Associates

Dr. Bonomi reminded everyone that for the past few months, Dr. Cunningham has chaired the BSC OWG. She commended the OWG for its review of the updated guideline. They have had several meetings, reviewed many documents to prepare context for the updated Guideline, and have carefully deliberated to develop their considerations for the BSC. She welcomed Dr. Cunningham to present the OWG report on behalf of all of the workgroup members.

Observations and Report of the OWG

Chinazo Cunningham, MD, MS
Chair, OWG
Co-Chair, NCIPC BSC
Executive Deputy Commissioner
New York City Department of Health and Mental Hygiene

Dr. Cunningham acknowledged the OWG, emphasizing what an extensive process this has been. The OWG has been meeting for approximately the last 9 months during which the members have had very rich discussions. She expressed appreciation for all of the time, effort, and energy everyone put into these observations. She especially thanked CDR Melanie Ross, who served as the OWG DFO, for all of her work and leadership.

Overall, an overarching theme observed by the OWG was that the Guideline was unbalanced in that most of the focus was on the risks of opioids and that there was less attention on the potential benefits of opioids or the risks of untreated or undertreated pain. Many of the OWG members also felt that key studies were missing from the text, particularly a lot of observational studies. Many of the members felt that the discussion and the text conveyed more certainty or more absolute scenarios than were warranted by the evidence. There was a substantial amount of concern for misapplication of the Guideline, which could lead to potential harms to patients. Much of the discussion was about mitigating against potential misapplication while trying to preserve the benefits of the Guideline. However, some felt that the OWG was over-correcting and so much for the potential for misapplication that it potentially could be detrimental to the greater good.

There also was a consistent tension between public health benefits versus individual patient benefits and that this was not as explicitly stated in the Guideline as it needed to be. In addition, the Guideline overall was felt not to be sufficiently patient-centered. An important point was to contextualize how providers should use the Guideline to balance individual versus public health goals. Many OWG members felt the Guideline paid too little attention to racial and ethnic disparities and inequities in how pain is perceived, valued, and managed. There was a desire for explicit discussions about how the Guideline may either contribute to or mitigate disparities and inequities.

Many OWG members were cautious about including specific opioid dose thresholds in the recommendations. Members acknowledged the importance of having benchmarks, but many felt that specific opioid dosing in the recommendations would be misapplied as absolute cutoffs or thresholds for policies or practices. Many members felt that the thresholds belonged in the supporting text where there could be a more nuanced discussion about these thresholds. There is no single standard to calculate MMEs, which was not explicitly acknowledged in much of the Guideline in addition to the sense that these thresholds are in some ways arbitrary. There was a sense of exceptionalism throughout the Guideline in that certain conditions were implied to have “real pain” or to be “worthy” of certain types of treatment. There was concern about un-named conditions and then implicitly noting that they may not be worthy of certain kinds of treatment.

Many workgroup members felt that the recommendation of Category A was overutilized in that it was used in 11 of the 12 recommendations. As a reminder, Category A basically says that the Guideline should apply to most patients, whereas Category B suggests that the Guideline should be individualized. The OWG produced an OWG Guiding Principles document of core principles including minimizing bias, ensuring scientific integrity, enhancing inclusivity, establishing patient- and clinician-centered guidance, and mitigating harms from unintended consequences. Dr. Cunningham then reviewed the OWG’s observations about the specific recommendations as follows:

Determining Whether or Not to Initiate Opioids for Pain

Recommendation #1*: Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient. (Recommendation Category: A; Evidence Type: 3)*

Observations:

- ☐ Several workgroup members recommended changing the wording of Recommendation #1, including removal of the second “only” and changing the word “preferred” to “effective”.
- ☐ Several workgroup members were concerned about the large and unclear category of Acute Pain, and felt that further clarification is needed. For example, should post-surgical pain be in this category of acute pain? Several workgroup members felt the statement was an oversimplification and there were situations or conditions that should be exceptions. OWG members also felt that categorizing pain should be based on pathophysiology or severity and not necessarily by time. Acute pain is not a diagnosis. Several members noted that it is

often unclear when acute pain transitions to subacute pain, and when subacute pain transitions to chronic pain. In addition, there is little attention to acute-on-chronic pain.

- ☐ Some workgroup members felt the recommendation does not consider shared decision-making between clinicians and patients.
- ☐ Several workgroup members were concerned that the recommendation could be misinterpreted and translated into bad policies. There was particular concern about limited access to non-opioid pain management modalities, in part due to lack of availability or lack of coverage by payers. Improving access to non-opioid pain management modalities should be a priority.
- ☐ Recommendation Category: Most, though not all, workgroup members felt this statement should be graded as Category B instead of Category A.

***Recommendation #2**: Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate. (Recommendation Category: A, Evidence Type: 3)*

Observations:

- ☐ Several workgroup members voiced appreciation for this statement because of the attempt to be inclusive and comprehensive, take into account pain and function, be realistic upfront with patients initially, and the attention to de-prescribing and exit strategies.
- ☐ Some workgroup members felt that shared decision-making should be emphasized here and in other recommendations.
- ☐ Several workgroup members noted that certain conditions for which this Guideline does not apply feels like exceptionalism in terms of what constitutes serious pain versus what is not and may reflect what types of pain conditions receive research funding or other attention. Some conditions are named and others are not. This brings back the idea of whether some conditions are more worthy or have more serious pain and thus require a different type of treatment.
- ☐ Some workgroup members felt the language in this recommendation is somewhat too strong, given problems with some of the cited evidence. Words like “are preferred” might be softened to “may be preferred” or “may be effective.” Although the harms of opioids are very well-defined, the benefits (especially long-term) are not well-understood and are difficult to study.
- ☐ Recommendation Category: Some workgroup members felt the recommendation grade should be Category B instead of Category A.

Opioid Selection and Dosage

***Recommendation #3**: When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. (Recommendation Category: A and Evidence Type: 3)*

Observations:

- ☐ Most workgroup members overall agreed with the statement. Some felt the need to define “starting” and “opioid-naïve” more clearly, particularly given patients’ historical context of prior pain management strategies.

- ☐ Several workgroup members appreciated the supporting text discussion regarding abuse-deterrent formulations.
- ☐ Recommendation Category: Most workgroup members agreed with the recommendation Category A.

Recommendation #4*: When opioids are started for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day. (Recommendation Category: A and Evidence Type: 3)*

Observations:

- ☐ Many workgroup members voiced concern about the dose thresholds written into the recommendation. Many were concerned that this recommendation would lead to forced tapers or other potentially harmful consequences. Though workgroup members recognized the need to have thresholds as benchmarks, many felt that including these thresholds in the supporting text could serve to de-emphasize them as absolute thresholds, and thus recommended removing the specific MME range from the recommendation. In addition, these thresholds are felt to be arbitrary to some degree and could be calculated differently based on different conversion formulas, but when they appear in the statement, they appear to be authoritative rather than supporting text.
- ☐ Several workgroup members appreciated the split of recommendations #4 and #5, which differentiated those who were starting opioids from those who were already receiving higher doses of opioids.
- ☐ Some workgroup members noted that the term "justify" was concerning, as it reflects legal language. To whom should providers be justifying their management decisions? Terms like "evaluating" benefits seemed more appropriate to the treatment context. In addition, some were concerned about the term "avoid" being too strong as well.
- ☐ Recommendation Category: Several workgroup members felt the grading should be a Category B, but if the specific dose thresholds were removed from the text, then the grade should be a Category A.

Recommendation #5*: For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation Category: A and Evidence Type: 4)*

Observations:

- ☐ Many opioid workgroup members appreciated the language that acknowledged the complexity of the situation.
- ☐ Similar to the observations noted for recommendation #4, many workgroup members felt that the threshold dose should be removed from the statement and included in the supporting text.
- ☐ Several workgroup members noted that the framing of this recommendation is not balanced in that it does not include the risk/benefit calculation of continuing opioids. For example, a more balanced approach is to have one sentence about continuing opioids and one sentence about tapering opioids in terms of risk/benefit analyses. Also, not fully

acknowledged is that continuing opioids and not tapering opioids avoids risks of poor analgesia, worsening functioning, and suffering, and potentially illicit opioid use.

☐ Some workgroup members felt more discussion is needed regarding working with patients or obtaining consent from patients prior to initiating and prior to tapering opioids, and limiting involuntary tapering. Others felt that consent should occur prior to initiating opioids, and that it may not be feasible to obtain consent at each point in which clinical management is changed.

☐ Some workgroup members noted that the supporting text for recommendation #5 and other areas of the guideline document flips back and forth between “harm” and “risk.” Many felt that the document should use “risk” since assessing risk is one of the biggest challenges providers face.

☐ Several workgroup members felt an explicit and fuller discussion regarding benefits to society versus individual patients was warranted with this recommendation.

☐ Many workgroup members appreciated the supporting text, but felt that key points were missing. There were some specific issues that were noted as concerning by some members, these included: never going back up in dosage during opioid tapering; lack of inclusion of observational studies showing potential dangers of tapering; minimal discussion about risk of tapering; role of patient-centeredness approach; representing the role of buprenorphine as established rather than emerging; an explicit discussion of goals of tapers is needed, particularly related to public health versus individual patient outcomes; there seems to be an underlying assumption that the goal is to get to zero MME, but perhaps it should be to get to a safer dose or better symptoms or function; a section on iatrogenic harms of tapering may be warranted.

☐ Some workgroup members were concerned that much of the discussion was about over-correcting for possible misapplication of the guideline, which could lead to the detriment of the greater good.

☐ Recommendation Category: Many workgroup members felt that a grade of Category B is more appropriate than Category A. In addition, several noted that there is a bit of a mismatch in grading. For example, when there are several caveats and individualization in the language in the statement, how can it be recommended for all people?

Opioid Duration and Follow-Up

Recommendation #6*: When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed. (Recommendation Category: A and Evidence Type: 4)*

Observations:

☐ Several workgroup members were concerned about the potential misapplication of this recommendation. Some felt that removing the last sentence would reduce risk of misapplication and questioned the evidence supporting the statement (evidence type = 4). The challenges of defining “acute pain” were noted again (see observations for statement #1 - e.g., it is not a diagnosis, it does not reflect pathophysiology), and some workgroup members felt many potential exceptions may require more than 3 days of opioids (and that “rarely” does not seem accurate). However, others felt differently, and did not want to water down this statement so much that it does not help improve excess opioid prescribing that exists.

☐ Some workgroup members wanted clarification and discussion in the text about the goal of this statement in terms of whether it is about patients versus public health outcomes.

- ☐ Some workgroup members discussed how implementation of this guideline can have differential outcomes on patients based on their sociodemographic characteristics and that this is not adequately addressed. For example, some patients will navigate the health care system to get refills as needed, while for others it will be impossible, thereby leading to potential different consequences. Several workgroup members recommended moving the last sentence into the supporting text rather than the recommendation (e.g., not including 3-7 days in the statement), or adding qualifiers like “most patients” or “many patients” or “initial prescription”, and felt that doing so would allow for more flexibility and patient centeredness.
- ☐ Recommendation Category: Several workgroup members felt that the first sentence was Category A, but not the second sentence, that Category A for the second sentence was out of step with the evidence type 4, and the qualifiers that are necessary to describe the exceptions.

Recommendation #7*: Clinicians should continue opioid therapy for subacute or chronic pain only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. (Recommendation Category: A, Evidence Type: 4)*

Observations:

- ☐ Overall, many workgroup members felt okay with the statement in general and the recommendation category. They noted that there is little evidence to support it, particularly the specific time frames of 1-4 weeks and 3 months; however, it was reasonable and reflects common practice.
- ☐ As mentioned in overall themes, several group members observed that the use of “risks” and “harms” in this recommendation is inconsistent and recommend more careful and consistent consideration of these terms. Several members felt that using the term “risk” would be more appropriate than harms, as harms are typically not currently present.
- ☐ In the supporting text, there is discussion about 50 MME, while in other places the threshold is 90 MME. 50 MME as a threshold to increase the frequency of visits is a bit arbitrary.
- ☐ As mentioned in overall themes, many workgroup members noted that the issue of health disparities and health equity should be more central in the supporting text for this recommendation. These issues, including social determinants of health, are important and have real consequences when recommending frequent visits. For example, the duration of prescriptions or the frequency of visits may need to be guided more by social determinants of health or payer issues (e.g., co-pays) than by opioid dose.

Assessing Risk and Addressing Harms of Opioid Use

Recommendation Statement #8*: Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present. (Recommendation Category: A, Evidence Type: 4)*

Observations:

- ☐ Many workgroup members noted concern about naming specific conditions that increase risk; it suggests a parity among them. There is concern that listing these conditions implies that they carry equal risk, and that other conditions that are not listed carry less risk. In addition, specifying the 50 MME dose threshold is concerning, and conveys similar risk as the other conditions. The dose threshold is arbitrary and inconsistent with other sections of the guideline (50 vs. 90 MME). As noted in overarching themes, many members recommended that these specific conditions be removed from the recommendation.

- ☐ A few members noted concerns with potential downstream effects of offering naloxone for patients of limited means, with concerns specifically about the cost of purchasing naloxone (e.g., in some areas, patients were required to fill and pay for naloxone).
- ☐ Some members noted specific conditions that were concerning:
  - ➢ Pregnancy seems to be missing as a risk factor, though there is a different framework for pregnant women with OUD. There is concern about the framing that benefits outweigh risks for pregnant patients receiving MOUD, but not those with pain, despite the fact that not prescribing opioids could lead to withdrawal. In addition, pregnancy statements were overgeneralized, and there was concern that with the supporting text, pregnant women undergoing procedures could be at risk of not receiving adequate treatment.
  - ➢ Because buprenorphine has a very high MME, it's not clear what the implications would be.
- ☐ Many workgroup members noted that the supporting text was not balanced, and a full discussion of risks and benefits are needed – that address risk/benefits of prescribing opioids and of not prescribing or limiting opioids. For example, the discussion about older adults focuses on risks of opioids, but there is no discussion about risks of untreated or undertreated pain in this population (e.g., potential worsening of blood pressure, mood, cognition). A similar point was made regarding individuals with psychiatric conditions, and the possibility of destabilization with untreated or undertreated pain. Likewise, the discussion about people with substance use disorders was unbalanced, with little discussion regarding the challenges of pain management (and buprenorphine's analgesic effect was missing). This issue of an unbalanced discussion in the supporting text is noted as an overall theme throughout the Guideline.
- ☐ Some workgroup members noted that there is little consideration about the problem of lack of access to alternative pain treatments.
- ☐ While many workgroup members noted that naloxone should remain in the recommendation, some felt that taking a more comprehensive risk mitigation approach is warranted.
- ☐ Recommendation Category: Several workgroup members noted that evidence for Category A was appropriate if the list of conditions were removed. However, if the list of conditions remains in the recommendation statement, then the recommendation should be Category B. Some workgroup members disagreed and felt the evidence category should remain A regardless of the list of conditions.

Recommendation #9*: Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for acute or chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. (Recommendation Category: A, Evidence Type: 4)*

Observations:

- ☐ Several workgroup members felt that the word "dangerous" may be too strong and too binary. Some felt words like "high-risk" may be more appropriate, noting that there are nuances to deciding whether specific combinations of medications put individuals at risk. In addition, some workgroup members noted that it would be important to check the PDMP for risks that are broader than overdose.

- ☐ There were conflicting opinions regarding checking the PDMP for acute pain. Some workgroup members felt that prior to prescribing opioids for a small number of days, checking the PDMP may not be warranted or feasible, and therefore, the word "acute" should be removed or a qualifying term like "when possible" should be added. Others disagreed and felt acute pain should remain in the recommendation statement.
- ☐ Some workgroup members expressed caution regarding potential harms of the PDMP, particularly when algorithms are used to create risk scores that lack evidence without qualifications. Some mentioned the cost to the patient-provider relationship; however, others discussed that when protocols are standardized, there is less risk to negatively impacting the patient-provider relationship and less risk of bias.
- ☐ Some workgroup members appreciated the recommendation that patients are not dismissed due to PDMP information. Perhaps this declaration should be more prominent, given this real risk to patients.
- ☐ Some workgroup members felt the supporting text needs to be re-worked, especially regarding acute pain.
- ☐ Recommendation Category: The workgroup was split regarding the recommendation category. Some felt that Category A is appropriate. Others felt Category A is appropriate only if acute pain were removed and/or if there were qualifying language like "when possible" or "when available." As with several other recommendation statements, several members of the workgroup felt it was difficult to assign a recommendation category to the statement while recommending changes to the statement. It becomes unclear if the category would/should be applied to a modified statement or the existing statement.

Recommendation #10*: When prescribing opioids for chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. (Recommendation Category: B, Evidence Type: 4).*

Observations:

- ☐ Illicit drugs are not defined, which is particularly problematic for cannabis. The issues around cannabis create challenges for providers, which vary by state. Perhaps cannabis should be approached similarly to alcohol, which is not routinely tested among individuals taking opioids. However, providers may not have control over the specific panels of tests, and often fentanyl might not be included. This could lead to false assurance. A discussion of these nuances of urine drug tests is warranted.
- ☐ Interpretation of urine drug tests results can be complicated, and many providers lack this knowledge, which can lead to inappropriate negative consequences. In addition, because most urine drug tests are screening tests, false positive or false negative tests are not uncommon. Such inaccurate tests could lead to punitive action. Confirmatory testing is important but can also lead to financial issues for patients. Several workgroup members felt these potential harms are not fully addressed in the supporting text. In addition, the concept of a screening test should be included (e.g. with false positives and negatives).
- ☐ As mentioned in the overall themes, there are biases and disparities in which patients have urine drug tests. Several workgroup members felt that this issue should be more centrally addressed, as the recommendation statement could have substantial disproportionately negative consequences among Black and Latinx patients.
- ☐ Because substance use is associated with serious stigma, some workgroup members recommended reviewing the supporting text to ensure non-stigmatizing language is warranted (e.g., should the term "recreational drug" be used instead of "illegal drug?").

- ☐ Several workgroup members discussed the importance of providers' discussing why and how urine drug tests are used, and not taking a punitive approach. There is a potential ethical tension if the role of the provider is to police the patient behavior, as the provider's duty is to the individual patient, and the policy makers' duty is to the public.
- ☐ Some workgroup members were cautious regarding conducting urine drug tests prior to prescribing opioids, especially if this were to delay care. Some also felt that the recommended frequency of urine drug tests and the use of opioid dose to guide the frequency were arbitrary.
- ☐ Some workgroup members were cautious about patients' potential financial implications of frequent urine drug testing and confirmatory drug testing.
- ☐ Recommendation Category: This is the only recommendation that is graded Category B. Category B is appreciated, though others felt that a Category A potentially could reduce bias and disparities in which patients' clinicians order urine drug tests.

***Recommendation #11**: Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants. (Recommendation Category: A, Evidence Type: 3)*

Observations:

- ☐ Several workgroup members felt the words "avoid," and "whenever possible" are problematic as they can be interpreted as "never." Some proposed that a more appropriate phrase may be to use extreme caution. In specific situations, benzodiazepines can be beneficial, and stopping benzodiazepines can be destabilizing. Additionally, benzodiazepines may serve as a marker for risk of overdose due to underlying conditions. It's also important to differentiate between chronic stable prescribed use versus erratic unpredictable non-prescribed use.
- ☐ Some workgroup members felt including an entire class of medications such as central nervous system depressants was far-reaching and could lead to unintended negative consequences. Some of these medications can be beneficial and if stopped or abruptly decreased can be destabilizing.
- ☐ Some workgroup members felt that this recommendation statement is not appropriate for the acute care setting.
- ☐ Including the FDA warnings regarding benzodiazepine use among people prescribed opioids and among people with opioid use disorder should be included in the supporting text.
- ☐ Recommendation Category: Several workgroup members recommended a recommendation Category B.

***Recommendation #12**: Clinicians should offer or arrange treatment with medication for patients with opioid use disorder. (Recommendation Category: A, Evidence Type: 2)*

Observations:

- ☐ Many workgroup members agreed with the strong language of the recommendation, specifically the word "should."
- ☐ New regulations regarding buprenorphine prescribing should be included in the supporting text.
- ☐ Several workgroup members noted that the supporting text should better distinguish opioid agonist versus opioid antagonist treatment and questioned the framing as the medications being equal options. Opioid agonist treatment has stronger evidence for better outcomes,

doesn't require abstinence, has less challenges with inductions, and is much more widely utilized.

- ☐ Some workgroup members noted a conflation regarding management of problematic opioid use versus OUD in the supporting text. Reassessing pain is important prior to deciding whether to taper or discontinue opioids.
- ☐ Several specific details about OUD treatment were felt to be inaccurate in the supporting text, and additional review by an OUD expert is warranted.
- ☐ Some workgroup members felt the evidence type should be 1.

Introduction and Conclusions Sections of the Guideline

Observations:

In addition to the overarching observations, additional comments and observations specific to the introduction and conclusions sections included the following:

- ☐ The discussion regarding health equity and disparities is not until the end of the document. Many workgroup members recommended that this discussion be much earlier in the guideline. In addition, attention to health equity and disparities should be throughout the entire document, and a discussion about how the recommendation may impact equity and disparities is warranted.
- ☐ Many workgroup members felt there should be an explicit statement that the guideline is a clinical guideline, and not payer or governmental policies. Similarly, the tension between risks and benefits for individual patients versus the public health should be explicitly addressed. A patient-centered approach should be strongly encouraged.
- ☐ A few workgroup members noted issues with authorship and reviewers. Specifically, there are a small number of peer reviewers who are not identified, input from patients and providers was solicited but it was not clear how their input was factored into the guideline, and many of the included references have a lead author who is also an author of the guideline. In addition, providing the areas of expertise of the OWG members is suggested.
- ☐ When describing benefits and harms, it is important to recognize real-world patients' lack of access to many non-opioid pain management strategies.

Discussion Points

Dr. Bonomi thanked the OWG for such a thoughtful and comprehensive review. She requested that BSC members keep in mind as they discussed the OWG report that they would like to come to consensus at the end of the day and have a vote on whether to endorse the OWG report as is or include additional recommendations and/or modification to the report. If there are no further asks of the OWG, there also will be a vote pertaining to whether to sunset the OWG. She then invited the BSC members and ex officio members to provide comments and questions.

Dr. Staffa pointed out that since the 2016 Guideline was issued by CDC, a number of other clinical guidelines have been issued by different groups such as the Mao Clinic, Johns Hopkins, and a variety of others. She wondered whether any thought had been given to where these guidelines would fit into the current environment. FDA has received a lot of feedback that it can be confusing for practicing clinicians when there are multiple guidelines with seemingly conflicting recommendations, and she asked whether any thought had been given to that. As this churns further along toward being published, perhaps this could be addressed in some sort of preamble CDC could consider.

Dr. Cunningham indicated that some of the conflicting recommendations or issues were brought up during the discussion, particularly the FDA's statements about some of the things that should have been included. The OWG was given a very specific charge, which Dr. Baldwin reviewed earlier in the day. They were given materials beforehand upon which the draft Guideline was based and most of the OWG discussions focused on those. Dr. Cunningham noted that while she commented to some extent about the introduction and conclusion, the Guideline is quite large with a large introduction that walks the reader through the process and the materials that were provided, so that becomes clear in those sections.

Dr. Baldwin thanked Dr. Staffa for the suggestion and indicated that CDC would take that into consideration as they reflect on how in the introduction or conclusions they contextualize what this Guideline is and is not.

Dr. Staffa recalled a comment about one of the recommendations in terms of subtext relating to abuse deterrent formulations and a suggestion that the OWG was acknowledging that they thought this to be appropriate language. She requested further information regarding what that was about and how it was handled. She noted that FDA had a public meeting about one of these abuse deterrent formulations, Oxycontin, in September 2020 during which the observation was made that there may be some effects of these formulations, but it is not really a panacea. She also appreciated the comments of the OWG about removing a lot of the language around specific thresholds of MMEs or dosing from guidelines. The FDA also has found in their work that even though there certainly is an association between increasing daily dose and increasing risk of overdose, the thresholds are not actually supported by a lot of data. They are often based on arbitrary cut-points that are used by necessity in research. FDA worries about the implications of implying that 89 MMEs per day is safe and 90 MMEs are not. There still seems to be some room in the Guideline for using cut-points, but moving them into subtext. She wondered if there was a reason behind that.
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Dr. Cunningham indicated that under one of the recommendations, there was discussion about abuse deterrent formulations and opioids. OWG members appreciated that the discussion was there, but also observed that these do not completely reduce the risks in terms of what the data show with regard to the abuse deterrent formulations when thinking about the risks and benefits. That discussion was very much appreciated and it was nuanced about reducing some but not all of the risks, and the importance of taking that into consideration. Much of the OWG's discussion focused on the MME thresholds, and they understand the data in terms of the risks of negative consequences rising with dose and also recognize that these are somewhat arbitrary. The OWG felt that making that clearer in the discussion is important. As a practicing primary care provider, having some sort of benchmark is helpful. However, having MMEs front and center makes it seem absolute in the recommendation statement versus putting it into some sort of text so that there can be a much more nuanced discussion about it seems appropriate. In general, most of the OWG members recognized the need to have some sort of benchmark, but also felt that there could be a more nuanced discussion about that if the thresholds were moved from the actual recommendation statement and placed into the supporting text.

Dr. Pacula was curious about the recommendations made by the OWG for categorizing Recommendations 1 and 2 as Category B instead of Category A, given that their focus is on the initiation of opioid therapy and the first decision for a new persons. She requested further explanation as to why this was viewed to be something that should be more selective rather than available to everyone as a guideline. One thing that stood out to her was that in some of the other recommendations, the grading was modified based on how the recommendation may or may not reflect some of the other proposals offered, such as taking out certain words would make it a Category A versus a Category B. That context was not provided on these two particular recommendations, which made her interpret that recommendation as being much stronger and more supported than in some of the other ones.

Dr. Cunningham indicated that in general, there was a sense that the Guideline needed to be more patient-centered. Category A reflects that most patients should receive the therapy, while Category B indicates that it should be individualized. For example, for Recommendation 1 about acute pain there was concern that there are some types of acute pain in which opioids are necessary. Particularly emergency room physicians on the OWG felt that there are enough situations in which it would be the exception. Part of this also comes from the definition of what constitutes “acute pain” and a desire to focus more on the pathophysiology and severity rather than the number of days and that it is difficult for providers to know what that will be. Part of the lack of clarity around how “acute pain” is defined led into the fact that people felt like there were enough potential exceptions, that a Category B grade was warranted. She emphasized that the OWG did not reach consensus, nor was that their goal. In the actual report, there are statements that most but not all of the OWG members felt that it should be a Category B. The report has more nuanced language, given that there was not a goal to reach consensus.

Dr. Ondersma requested more context as to the concerns of some of the members pertaining to over-correcting and the dissenting opinion in that regard. Regarding the suggestion to perhaps move MME to the subtext and 1 to 3 days or no more than 7 days to the supporting text, there seemed to be a general feeling that if what might be perceived as absolute quantitative pieces in the recommendation were moved, that would strike that right balance.

Dr. Cunningham clarified that many of the OWG members were very concerned about misapplication of the Guideline, given the historical context. The lens of how these recommendations could be misapplied was a focus of many of the observations. In a perfect world, if the Guideline had not been misapplied, there would have been a very different group of observations. Given that we do not live in a perfect world, this was the lens through which many of the OWG members were providing observations. Others were worried that there would be so much focus on the potential misapplication, that perhaps they were missing the bigger picture and the tendency to over-correct for potential misapplication made actually reduce the potential good for the greater good. There was tension throughout a lot of the OWG discussions that reflects the real-world that people live in of patients, payers, and policies that came about after the 2016 Guideline was published. Both of those perspectives were definitely present. In general, there was a feeling that the framework was focused largely on the harms of opioids without fully appreciating the potential harms of under-treated pain, stopping other medications, and provider and patient relationships. The sense of an unbalanced approach in the overall framing was part of this as well.

Dr. Liller emphasized the importance of equity and disparity information. Public health is having to incorporate this into programs and all efforts. She noted that the document the members were given to read suggests that this is going to be addressed and wondered whether there would be particular recommendations for equity and disparity or if they would just be included in the subtext. Her hope was for discussion at the outset of the document and then within each of the recommendations.

Dr. Cunningham indicated that the OWG had discussions about exactly that question. In general, the OWG’s approach was not necessarily to propose how to fix the problem. Instead, they highlighted the problems they observed. In general, the OWG felt that issues around inequities was not present in the way that it should be and that it felt somewhat like an afterthought. There are so many instances in which the recommendations can be applied in ways that lead to more inequities or not, and the updated Guideline offers an opportunity to reduce inequities and disparities. Attention to that is needed throughout all of the recommendations in addition to more broad statements.

Dr. Baldwin reminded everyone that one of the things CAPT Jones mentioned earlier in the morning was CDC's commitment to diversity, equity, inclusion and belonging. CDC and the Injury Center are thinking more broadly of issues of health equity as a guiding principle for everything the agency does. There are absolutely ways that they can think more holistically about how to incorporate and infuse the understandable need for and commitment to attending to issues on health equity across the entirely of the Guideline.

Dr. Pacula agreed that the issues of disparity and equity are very important, as is the acknowledgement of the lack of access to non-opioid pain management as an overarching theme and goes back to the first couple of recommendations related to initiations of opiate therapy. In some ways, she thinks that explicit recognition of the lack of access to particular types of non-opioid pain management is an acknowledgement that healthcare markets are inadequate. That is correlated in the research with some of the disparities and inequities with differences due to demographic compositions in certain communities as well as rural and urban settings. She asked why the statement focuses more on the need to pay attention to disparities in that there is a market environment in which services are being offered that may be differentially available to certain populations. In a recommended guideline to clinical providers nationally, the encouragement to discuss non-opioid pain management options could actually lead to a change in the availability of these options. If there is not a discussion and awareness with the patient and the doctor of the lack of availability made explicit, then there is not going to be an incentive to change it. The concern in the first couple of recommendations about lack of access to non-opioid pain management as a tool in the considerations of that recommendation is one of the ways that the Guideline can help nudge availability and provide greater equity and access to alternatives. One of the opportunities of the Guidelines is to educate providers in areas where some things might be available but not accessible to all patients.

Dr. Cunningham emphasized that a lot of OWG members had similar feelings, while some were more pessimistic. In a perfect world, that is what they are hoping for. In the real-world, there are doubts that that is how it will play out.

Dr. Baldwin added that one of the ways CDC is hoping to attend to some of this is in the implementation and dissemination work in which they can pay particular attention to this. There are also efforts HHS-wide across the other operating divisions within HHS to work together on various working groups to help attend to the issues Dr. Pacula raised that are both resonant in the Guideline. Addressing them in a meaningful, pragmatic, real-world way as Dr. Cunningham mentioned requires CDC to work across other operating divisions and with state and local partners in implementation work.

Dr. Staffa applauded CDC and the OWG on the transparency of this effort in terms of the plan, timeline, and various mechanisms for accessing input for so many different groups. She believes this will be appreciated by many people.

Dr. Greenspan expressed her appreciation to the OWG for all of the thoughtful review and comments. She noticed that there were a couple of participants in the public with their hands raised. She reminded the public that this discussion period was devoted to a conversation of the

BSC, which is the governing body that will be making recommendations. She emphasized that the public would have 2 hours to make comments from 2:15 to 4:15 PM and expressed gratitude for all of the interest from the public.

Dr. Compton seconded some of the comments made earlier about this being a very inclusive and thoughtful process. He expressed appreciation for Dr. Cunningham's leadership of the OWG. It was certainly his honor and pleasure to help contribute to the recommendations. The discussion that this was not a consensus-building group is an important aspect of the conclusions from the OWG. There were a few things they agreed on, which are reflected. Most of the discussion reflected a wide variety of thoughts and opinions, which he thinks is consistent with the state of the field and makes this a difficult process for CDC as they plan to launch the Guideline. It makes him appreciate that they are taking quite a bit of time in developing the Guideline, including the public comment and external review. Those are very helpful processes to assure that it will not be perfect, but that will be as strong as possible. The NIDA looks forward to working with CDC to understand the impact of this and other major changes in the field and doing everything they can together to make sure that they provide the benefits that are hoped for without adding to concerns.

CAPT Jones expressed appreciation for the comments made by Drs. Staffa and Compton from the federal family perspective. Their agencies also will have the opportunity to review the full Guideline in the clearance process. The FDA and NIDA also have struggled to strike the right balance in how to advance evidence-based pain care in a world of uncertainty about which patients will benefit from which therapies. He appreciated the OWG's report, because it is reflective of the tensions they are trying to work through. He requested that as the BSC is contemplating the report from the OWG and the process that Dr. Baldwin laid out earlier for how CDC is trying to be inclusive in perspectives from different people who are impacted or providing care or caregivers, thinking about whether there are other avenues through which CDC could engage in the process to ensure that they are getting reflections from people who will be impacted and providers who will be asked to provide care in a world of uncertainty.

Dr. Ondersma noted that there is a small but perhaps modestly encouraging literature in patient education, especially when it syncs with messaging from the provider in terms of reducing pain and possibly in terms of reducing opioid prescription-related harm. He was curious about that literature in terms of this Guideline and whether it was considered too weak to be included. This literature includes materials and videos that easily could be incorporated into technology-delivered formats that standardize the patient education process and make it more ubiquitous to avoid situations in which the discussion is missed early on and things exacerbate from there.

Dr. Cunningham indicated that there was not anything specific on patient education. There was more attention paid toward up front discussions with patients, which the OWG members appreciated. One of the recommendations pertained to shared decision-making in terms of talking about explicit goals, potential risks, potentially reducing or stopping opioids, tapering, and attention to harms with forced or involuntary tapers even before starting opioids. More of that language was in the Guideline versus the prior Guideline, which the OWG definitely appreciated. At the same time, some of the discussions were around that being the easy part and the harder part being when people present who have had opioids for 10 years with whom these discussions never occurred. Then providers are trying to figure out what the best thing is for patients. While in general the idea of trying to have more upfront discussions about how the course of treatment would occur and shared decision-making in the draft Guideline is appealing and appreciated, providers are still going to face additional challenges. CDC has done a lot of work in the area of patient education.

Dr. Baldwin added that an individualized and patient-centered focus was something CDC placed at the heart of the Guideline itself. CDC tried to be attentive to being integrated and multi-modal in the Guideline. There will not be a one-size singular solution. It is likely that multi-modal therapies will be the way forward.

Dr. Greenspan recalled that with regard to the introduction and conclusions sections, one of the OWG observations pertained to a few un-named reviewers. She emphasized that this process is ongoing. She asked Dr. Cunningham whether there are any specific perspectives the OWG thinks CDC should be considering as they contemplate reviewers in terms of specialties or gaps.

Dr. Cunningham indicated that there were a couple of suggestions about this. Someone who has expertise in health disparities and inequities would be an excellent addition. In addition, the last Guideline focused on those with SUDs and OUDs and there was a lot of inaccuracy in some of the supporting facts. It seems like an expert in that field is also warranted to help with that discussion. There were specific comments about pregnancy and the need for additional help in discussions about pregnancy. There were some differences around opioid management for pain and management for OUD. It is nuanced, but there were OWG members who felt like the Guideline did not take a more nuanced approach specifically for pregnant women. Overall, her sense was that the OWG members worked very well together, respected each other, had various perspectives, came from different parts of the country, et cetera. Thus, the range of perspectives led to very rich discussions.

Dr. Bonomi emphasized the need for a focus on the broader structural level in terms of addressing and tackling inequities. In terms of thinking about health disparities experts, there could be an even larger bolus of individuals who are tapped to provide this expertise to help think about making these guidelines as equitable as possible.

Dr. Baldwin noted that one example is that as part of CDC's response to the COVID-19 pandemic, an entire infrastructure was set up led by a Chief Health Equity Officer, so they are much more thoughtful and attentive than they have ever been. With Dr. Walensky's leadership and her commitment to addressing health inequities across everything the agency does, he is confident that they can bridge in the expertise needed to ensure that the Guideline in the end is fully reflective of that perspective and the broad structural factors that Dr. Bonomi rightly pointed out are at play when thinking about issues around access and how it intersects with inequities.

CAPT Jones emphasized that a clinical practice guideline cannot be expected to change all structural barriers, but CDC hopes that it can be a call for changing that. The follow-on work that will occur within the agency, private insurers, health systems, and others will be critically important in helping to bring that to reality.

Dr. Pacula said she was very struck by Recommendation 10 of the 2016 Guideline that recommended using drug testing before starting opioid therapy. She noticed that the draft updated Guideline recognizes that interpretation of urine drug testing can be very complicated, particularly if not done in the same fashion in different settings. There was not grading, so she wondered what the OWG's thoughts were. She would be okay with a drug testing recommendation if very narrowly applied to ED doctors who might not have a familiarity with a patient or know their circumstances and need to know how to treat immediately. The logic there is understandable in that EDs would have a concern in over-prescribing in the former opioid epidemic when prescription drugs were a major driver. From a criminal justice drug testing background, this seemed to her like a very odd and perhaps particularly damaging recommendation in a primary care or ambulatory setting with a regular doctor, given that it can breed mistrust and other negative consequences that would diminish the patient-doctor relationship instead of improving it. She asked for more information from the OWG and about the range of ability to say something about specific recommendations.

Dr. Cunningham said there were definitely some mixed feelings about this. The OWG might have taken a somewhat opposite perspective from Dr. Pacula, which is that at least for the ED setting, the idea of getting drug testing before starting opioids could lead to delays in treatment. There were mixed conversations about primary care settings. The role of PDMP is similar in terms of monitoring for other controlled substances or illicit drug use in the sense that having objective data is important. Others felt that doing the PDMP check could change the relationship between the provider and the patient. A lot of the discussion also focused on considering how the information would be used. Part of the Guideline specifically states that patients should not be dismissed, at least for the PDMP. The OWG members appreciated those kinds of explicit statements about using this information in a way to help the patients, but not in a negative pejorative/policing way. While this is challenging, that was the kind of framing that was necessary when discussing these recommendations and being very clear about the potential benefits and harms with attention to race, ethnicity, and gender as well. There was not consensus and there were specific areas people pulled out that they thought needed more discussion or more of an explicit statement regarding how the information should be used.

Dr. Pacula said that it was interesting to hear the different perspective and interpretation of this. She generally thinks of an ED as needing to know how to respond to a patient who might be unconscious or in a mentally altered state because of a concussion or some other issue, for whom the only way to ascertain the risk of administering an opioid is through a test because it might be possible to get a full assessment from the patient. EDs generally have laboratories on-site that can get this done very quickly versus a doctor's office that has to send it out. The idea of addressing the patient's needs she would have thought of very differently, though she recognized that she is not an ED doctor and might be thinking of this in terms of bigger city EDs versus more rural EDs. Drug testing and how it could be misused is an interesting point because it is a potentially dangerous thing that could be held against patients when used outside of very narrow circumstances.

Dr. Liller emphasized the importance of working with the colleges, Prevention Research Centers (PRCs), and all of the centers that are funded in terms of social marketing. As she reviewed the Guideline, it looked like a lot of effort was made to move away from particular prescriptive information and handling people on a more individual basis. She asked whether there was any concern among the OWG members that too much of that was done and now there is too little guidance. She wondered whether that would work for physicians or if it needed to be a little more prescriptive.

Dr. Cunningham indicated that there was discussion about that and there were mixed feelings among the members. There were definitely OWG members who felt that perhaps the groups was over-correcting and that could reduce the benefits for the greater good. A lot of this was about forecasting this misapplication and there were differences of opinion about how governments, payers, and practices would potentially take the topline statements and run with them regardless of what the supporting text says. That had much to do with the lens that people have lived with and were bringing to the table. Again, they did not come to consensus but that was not their charge.

Dr. Kaplan commented that some years ago he wrote a piece on drug testing as a form of social control. Every time that comes up, it raises a lot of issues in his mind about who is being tested, whether it is fair, if it is random, and so forth. He suggested that they need to incorporate the views of bioethicists on issues surrounding drug testing, given the huge ethical questions.

Dr. Cunningham indicated that the OWG had a bioethicist as a member, so that was part of the discussion. Some of the ethical concerns are reflected in the report. In terms of drug testing, this related to how the results would be used, what the goal is in terms of public health versus the individual patient, providers not being charged with policing, et cetera. Ethical considerations were absolutely part of the OWG's discussions. Though they may not have made it to this presentation specifically, they are definitely in the report.

Dr. Floyd noted that it was his privilege to be part of the OWG and emphasized that it was a very diverse panel with input from various perspectives. In particular, there was robust discussion on the urine drug screening that he also was a part of. By way of background, he is a medical director, a practicing internal medicine specialist, engages in a lot of pain management with a number of his patients, and routinely employs the urine screening at least annually of his patients who are on opiates. He is a believer in the process as he indicated to the OWG. The vast majority of his patients do fine, accept this, and he rarely has issues. The reasons he is a proponent of urine screening is that there are times that it is very revealing. For example, a new patient presented to his practice with chronic back pain who said he was on Percocet and declined to provide his prescriptions until his urine screening test came back positive for cocaine and methamphetamine. Therefore, Dr. Floyd declined his prescriptions. There is clearly a role for urine screening, but there are a lot of limitations as pointed out in the OWG. Cost was raised as a potential issue for patients. At least in his experience, that has seldom been an issue. He suspects much of the cost when patients cannot afford it is actually absorbed by healthcare systems rather than patients, though he has not seen data on that. Accuracy can certainly be an issue. It is necessary to be aware of things that can create false positives and ensure that a high quality laboratory is being used. When urine screening is deployed, there are a lot of things clinicians have to keep in mind for it to be done correctly. Regarding the ED, speaking in terms of local practice and his own observations, patients presenting to the ED with acute pain is not the focus of this Guideline. Acute pain patients need their pain treated with the appropriate modality and there should be no role in his mind for urine drug screening in that situation. The question arises with regard to the patient who is leaving the ED, such as someone who presents with intractable headaches. Though not an ED physician, his observation is that if an ED clinicians believes that there is an appropriate use, they will discharge patients with a short-term supply consistent with what is seen in the Guideline and then have them follow-up with their primary care clinician to determine next steps. In the ED, he sees urine screening as being appropriate when there are issues such as mental status changing. He agrees with the draft Guideline and thinks it is excellent. One thing that gives him pause as a primary care clinician for which he expects there will be some negative feedback is that clinicians cannot or should not discharge patients based on the results of their findings on PDMP checks and urine screening. There needs to be an element of trust both ways in a patient-doctor relationship such that if the clinician finds that their patient is getting their medication through multiple providers, that trust is severely eroded. In one case, he saw a patient who was getting her pain medications from across the state line. He told her he would no longer prescribe her pain medicines and she left his practice after that. A number of clinicians are going to have a hard time accepting that particular component.

Dr. Lumba-Brown indicated that she is an ED physician and could say that caring for acute pain in the ED is unique, but just as unique as it would be in caring for chronic pain in an outpatient setting. In determining recommendations and best practices, the setting of where the patient is presenting is also important to take into account. Regarding urine drug testing in the ED, she thinks consideration must be given to the fact that regardless of what urine drug testing shows, that patient still could be in pain and their pain needs to be treated. For her, a urine drug test result in the ED would be moot if she has a patient presenting with pain.

Dr. Pacula added that she was thinking that a urine test could be used as a clinical tool to identify preferred ways of managing pain in light of what is in a patient’s system as opposed to a treat/no treat tool. If someone presents with a lot of a certain drug in their body, there could be interactions.

Dr. Lumba-Brown responded that the urine drug testing is not quantitative, nor does it give clinicians a very definitive understanding of what timeframe a substance might have been used or exactly what substance was used. For her as an ED clinician, the best decision about what pain medicine might be appropriate for a patient begins with asking the patient what has worked for them in the past, the qualities of the pain they are experiencing in that moment, and understanding the cause of that pain.

Dr. Cunningham noted that this did come up in the OWG discussions. She pointed out that in medicine, objective data are obtained all of the time and many pieces of information are used (e.g., laboratory tests, patient history, physical, et cetera) to help guide the management strategy. The thought that this is so different from everything that is done in medicine is exceptional. It is one piece of information just like the PDMP is one piece of information. As providers, they assemble all of this information to form a treatment plan. The challenges regarded whether the goals were about the patients in front of them or about society. This goes back to the ethical consideration. As a provider, it is the patient. As a public health agency, it is society. What are the goals of the Guideline? That arose repeatedly in the discussions. That tension needs to be much more explicit in the Guideline, because that is what providers across the US are struggling with. It is critical to be explicit in addressing the goals of the Guideline, which is what many OWG members were struggling with.

CAPT Dowell acknowledged the tension between whether the goal of the Guideline is to focus on individual-level or public health-level recommendations. From CDC’s perspective, a big emphasis and major part of the background that they cannot ignore is public health. However, these are clinical guidelines with an overall goal for safe and effective pain care and to maximize the benefits and minimize the risks of opioids in pain management in general. Taking this a step further, CAPT Dowell said she could not express enough appreciation for the thoughtfulness, hours, and care that went into reviewing and providing observations on the draft Guideline. CDC also wants to maximize the benefits and minimize the risks of the Guideline itself. The various perspectives have been invaluable in looking at the language and providing feedback about how the Guideline might be read, understood, used, misused, et cetera. As Dr. Compton said earlier, there is no way this can be perfect. However, CDC is trying to get it as right as possible and very much appreciates all of the time that has gone into this.

Dr. Bonomi took a moment to briefly summarize what she heard thus far. There is a great appreciation and applaud for the transparency of the effort and diversity of the panel mentioned by several commentors. The report reflects a wide range of opinions and addresses some nuances, and through the additional comment period following this session, the report will be as strong as possible. Concerns persist with regard to potential over-reach, forecasting, and misapplication. Efforts made to move away from prescriptive recommendations are appreciated by some, but concerns were expressed that now there may be too little guidance for physicians. There is appreciation for consideration of nuances of the language pertaining to specific dosing. While benchmarks are helpful, more nuanced discussion and recommendations would be helpful. For drug testing, considering societal impacts is key. One reviewer was struck by Recommendation 10 regarding drug testing before starting opioid therapy and wanted to hear more from the OWG around that issue. Patients should not be dismissed when we consider drug testing, with attention paid to gender, race, and ethnicity. Comments were made about equitable issues around who is being testing, if it is being done fairly, and the need to incorporate the bioethicist view (which was reflected on the OWG). There are times when testing is relevant, but there are some barriers related to cost. Certainly, the settings where patients are presenting is key to consider in terms of testing. Related to that, regardless of what testing shows, there is a key consideration that patients may still be in pain and must be treated. In terms of issues related to equity, the BSC wanted to hear more about equity and disparities and whether there will be something overarching and integrated throughout each recommendation and subtext. Related to that are structural issues and whether there is an awareness of the lack of availability of non-opioid medications. If there is not a discussion about that, there will be no incentive to change it. Consideration to looking at that across disparity lines can lead to better equity in these practices. There were good comments from the BSC in terms of wanting to hear more about patient support and shared decision-making, clarity about the abuse deterrent regulations, questions about whether other guidelines were considered before the 2016 Guideline, clarity around Category B versus Category A in the recommendations, and suggestions for reviewers in the future to ensure that health disparities and equity reviewers' input is reflected. Dr. Bonomi added her gratitude for the thoroughness and work the OWG, Dr. Cunningham, and colleagues put into this to provide a comprehensive overview.

Public Comment Session

Victor Cabada, MPH
Office of Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Mr. Cabada thanked everyone for their participation in the BSC meeting and indicated that all public comments would be included in the official record and would be posted on the CDC website with the official meeting minutes at CDC.gov/injury/bsc/meetings.html. He also indicated that while they would not address questions during this public comment period, all questions posed by members of the public would be considered by the BSC and CDC in the same manner as all other comments. Given that a large number of people registered to speak, there may not be time to hear from everyone who asked to speak. Those who do not get a chance to speak may submit their comments in writing to be included with the meeting minutes along with the comments of those who speak in person.

Amy Partridge
Patient Advocate & Person with Intractable Pain
Member, National Pain Advocacy Center Community Council

My name is Amy Partridge. I have no conflicts of interest. I suffer from intractable pain and I'm a member of the National Pain Advocacy Center (NPAC) Community Council. These comments are my own. Before I begin my actual comment, I must say that the comment made earlier today that the MME limits in the Guideline were intended as a rough guide is absurd. A Tolman et al found that from 2016-2018, 527 new federal and state opioid-related policies, including statutes, rules regulations, and guidelines, were approved. The Drug Enforcement Administration (DEA) is also using these limits to target and prosecute physicians. The foundation of both the 2016 Guideline and the revision is on arbitrary dose caps or MME values, which is not even a valid scientific method as discussed during a recent FDA meeting. The process is once again very much shrouded in secrecy. Peer reviewers have not been released and we're not provided access to the Guideline. Though we do have the workgroup comments, it's tough to tie the two together when we don't have the actual guideline. It feels as if we're being only given a small piece of a very large puzzle. The lack of transparency is increasingly concerning. Finally, what we do know is that Roger Chou, who has multiple significant conflicts of interest, was charged with leading the evidence review at AHRQ and based on one of the slides shared today, is one of the revised Guideline's authors. It is wildly inappropriate and unethical that someone with strong ties to the anti-opioid industry and who has significant financial conflicts of interest be leading this process. The evidence review and Guideline revision are both, therefore, inherently biased and should be struck in their entirety. The BSC needs to ensure that qualified experts in pain, pain scientists, neurobiologist, palliative care physicians, et cetera who are independent and don't have conflicts of interests are immediately brought into the process. Thank you.

Gary Franklin, MD, MPH
Medical Director, Washington Department of Labor and Industries
Research Professor, University of Washington

Dear Chair, ladies and gentlemen, I'm Gary Franklin, Medical Director of the Washington State Department of Labor & Industries (L&I) and Research Professor at the University of Washington. It is my honor to represent the public agencies in Washington State in support of the updated 2022 CDC draft Opioid Guideline. In 2005, we reported the first deaths in the US in a peer-reviewed journal related to prescribed opioids. These were 32 injured workers who received prescribed opioids through Workers Comp. None had any illicit drugs or alcohol on board. We also found a huge increase in opioid doses starting in 1999 with the so-called "Intractable Pain Regulations" that made opioid prescribing inappropriately permissive based on false information on opioid safety. This was the start of the flood of opioids in Washington. The US is still far ahead of all other developed nations in prescribed opioids. So even today, even with all the terrible fentanyl-associated mortality, 28% of deaths are still associated with prescribed opioids. In addition to the morbidity and mortality, we and others have found a sharp increase in work disability among those prescribed opioids early on following a routine injury. In a Class I prospective cohort study, we found that just 2 prescriptions, or more than 7 days of an opioid, in the first 6 weeks after an injury doubled the risk of disability 1 year later. Thus, the heightened emphasis in the 2022 CDC Guideline on acute and subacute prescribing is totally appropriate. The opportunity to prevent inappropriate or simply inadvertent transition from short-term to long-term opioid use, both after acute injuries and post-operatively, is perhaps the most important component of both the 2016 and draft 2022 Guidelines. Finally, there's been a lot of discussion about the dosing thresholds. We have seen huge odds of mortality in our Medicaid population from combinations of opioids and benzos and sedatives, even between the 50 and 90 MMEs [dropped off, Victor invited him to post any additional comments].

Adriane Fugh-Berman, MD
Physician & Professor, Georgetown University Medical Center and
Health Professionals for Rational Opioid Prescribing

Hi there. I'm Adriane Fugh-Berman. A Physician and a Professor at Georgetown University Medical Center (GUMC) where I direct PharmedOut, a research and education project that promotes rational prescribing. I'm also on the Executive Committee of Physicians for Responsible Opioid Prescribing (PROP) and I serve as a paid expert witness in state and local government litigation against the opioid industry. The 2016 CDC Guideline has been crucial in decreasing inappropriate and dangerous prescribing of opioids. The revised Guidelines will be just as important. The US Still prescribes more opioids than any other country and this contributed to the 93,000 overdose deaths in 2020. Yes, many deaths are due to fentanyl-laced heroin, but was heroin users started with prescription opioids. The OWG comments perpetuate myths disseminated by opioid manufacturers complaining that the guideline focused heavily on the risk of potential harms of opioids, while less attention was focused on the potential benefits. This is certainly an industry-friendly view. The OWG assumes that opioids are effective for chronic pain, although best evidence does not support this, and objects to calling non-opioid options "preferred" even though non-opioid treatments are often as or more effective than opioids and are safer. Several statements from the OWG are just wrong, including the claim that continuing and not tapering opioids avoids risk before analgesia, worsening functioning and suffering. In fact, chronic opioid use results in both tolerance and hyperalgesia and chronic opioid use is associated with depression and decreased functioning. In line with industry, the group opposes recommended limits on dose or duration. Although no risk of opioids are acknowledged, the OWG is concerned about putative risks of tapering. A proven role of buprenorphine in medication-assisted therapy (MAT) is termed "emerging" rather than "established." Citing tensions between public health benefits and patient benefits is bizarre. Public health benefits are patient benefits. The OWG substitutes sentiment for evidence and flies in the face of both science and medicine. The 2016 CDC Guideline can be credited with decreasing opioid over-prescription in the US. We hope and expect the new Guideline to continue to uphold the highest standards. Thank you.

Anne Fuqua
Hospital & Health Care Professional
Pain Patient Advocate

My name is Angie Fuqua. I have no COI. I was troubled that Drs. Baldwin and Dowell failed to mention suicide in pain patients and don't seem to recognize the extent of suffering that the CDC prescribing cuts following the Guideline. CDC never sought to track adverse effects of their Guideline. The private registry I maintain contains 576 reports of suicides in pain patients. Over 500 have occurred since the initial draft was released. Family, friends, or suicide notes explicitly states that a physician cited the CDC Guideline as the reason to taper or stop meds in many of these instances. CDC sent an EpiAid (Epidemiologic Assistance) team to Palo Alto when 12 adolescents committed suicide unrelated to agency action. I would think they would want to investigate when their own guideline is believed to have played a role in hundreds of deaths. CAPT Dowell asked us to believe that the CDC has learned from the previous Guideline and asked us to trust this new Guideline would be better. Even the agencies working with HHS though were unable to quote the Guideline accurately and were unable to respect the cautionary guidances against misapplication offered by the CDC itself. The documents from CMS and OIG show that cautionary statements on dose thresholds were not honored or utilized by the HHS Department of the OIG and its work with law enforcement agencies. CDC has been silent on the fact that the HHS 5-star rating system rewards prescribers whose patient panels have few patients receiving greater than 90 MME. Further, CDC staff have yet to acknowledge or demonstrate the issues related to assessing MMEs—CDC says treatment should be patient-focused, but they also say that it is a Guideline to affect the larger population. A Guideline directed at the means should not overtly harm the extremes. The CDC guidelines have seriously impacted patients' access to treatments that are effective for them as individuals. Drs. Baldwin and Dowell repeatedly state that patients should have access to safe and effective pain treatment.

Gena L. Struna, MS
Chronic Pain Patient

I'm a chronic pain patient. I have been for 6 years. I'm representing the real world. My access to compassionate care and pain management has fluctuated over time. I've gone from being the one who's held my family's functioning together to being a burden when pain management is inadequate or absent altogether. I thank you as a group for acknowledging that pain, specifically chronic pain, is a significant issue in our society. However, unfortunately the scope, definition, and application of these guidelines are highly problematic overall. Dr. Cunningham did allude to the dynamic in the workgroup between the ideal world and the real world. Sadly, the real world is full of problems as a result of the guidelines. We see one of the problems, and I'm speaking for many different pain patients from various groups that I'm a part of, thousands and thousands of pain patients—we have a problem with the way that pain patients are lumped in the very same category as people with addiction illness. We feel that all of these people deserve help in the correct manner, but the problem is that pain patients are having to suffer for policies that don't apply to our condition. We need prescription pain medication to function at a very minimal state. People with addiction illness are dealing with a much different situation. Lives have been ruined for chronic pain patients and their families. Even though you'll see data with distinctions in the type of community represented, sadly in the dialogue, we don't hear those differences. The overall riding assumption is that all opioids are always bad. Even our doctors have these assumptions. We have a hard time finding doctors. We would like to appeal to Dr. Walensky, and we know she has a reputation of fidelity to scientific data and she pledges to keep politics out of the influence of the CDC, so we rely on you to help people in pain. Our suicides have gone up. We hear about people that we care about having a suicide plan every day. Our conversation has gone from the best types of treatments to what our suicide plan is like when we are untreated. The situation is desperate. We thank you for your time.

April Kapu, DNP, APRN, ACNP-BC, FAANP, FCCM, FAAN
American Association of Nurse Practitioners (AANP)

Thank you for the very informative sessions today. I am Dr. April Kaku, and I am the President of the American Association of Nurse Practitioners (AANP). With over 325,000 Nurse Practitioners (NPs) in the US today, we strive to advocate and elevate the voice of the Nurse Practitioner and our commitment to high-quality, accessible patient care. As a Nurse Practitioner, I greatly appreciate your inclusion of the NP perspective in these discussions. NPs across the US see over 1 billion patients per year. Over 70% are certified in primary care and many work in rural and underserved communities. In addition, we appreciate the consideration of NPs in the discussions around medication-assisted treatment for opioid use disorder as the updated guidelines have supported NPs in providing quality, safe, and equitable care. Since the passage of Comprehensive Addiction and Recovery Act (CARA), studies have found that NPs have greatly increased access to MAT in rural and underserved communities. In rural communities, NPs and PAs were the first waived clinicians in 285 rural counties covering 5.7 million residents. The Medicaid and CHIP Payment and Access Commission (MACPAC) found the number of patients with opioid use disorder treated by NPs increased substantially in the first year NPs were authorized to obtain their data waiver, particularly in rural areas and for Medicaid beneficiaries. However, MACPAC found that NPs in restricted practice states were less likely to obtain their data waiver than NPs and full practice authority states. Today, we would like to highlight the importance of retiring barriers to practice on the state and federal levels to ensure NPs practice to the full extent of their education and clinical training. This is in line with the recent National Academies of Science, Engineering, and Medicine (NASEM) *The Future of Nursing Report* recommending that all relevant state, federal, and private organizations enable nurses to practice to the full extent of their education and training by removing practice barriers that prevent them from more fully addressing social needs and social determinants of health, improving healthcare access, quality, and diversity. Thank you so much for allowing us to comment today.

Elliott Warren, MBA
Medical Device Manufacturers Association (MDMA)

Elliot Warren here with the Medical Device Manufacturers Association (MDMA). MDMA represents innovative and entrepreneurial medical device companies. I lead our Pain Working Group, which is comprised of members that develop cutting-edge innovations that help patients manage their pain symptoms. We’ve appreciated the opportunity to collaborate with this group and provide comments on the appropriate role of FDA-approved evidence-based pain management and opioids-sparing medical device technologies as you work to update the CDC Guideline for Prescribing Opioids. Past efforts have included oral and written comments for meetings such as these, as well as responding to the CDC request for comment on the management of acute and chronic pain where we provided a list of technology types within our membership that can aid in the management of acute and chronic pain and also serve as an alternative to opioids in certain instances. In conversations with our members two main issues are continually highlighted as barriers to access for these technologies for pain patients. Those barriers are: 1) education of patients and providers who are simply not aware of certain interventions available to them; and 2) economic reimbursement policies, including coverage and payment, can disincentivize the use of these technologies where they should be appropriately utilized in the clinical setting. We believe the BSC is well-positioned to break down both of these educational/reimbursement-related patient access barriers and we appreciate observations in the Opioid Workgroup’s report that acknowledge these reimbursement challenges for non-opioid pain management modalities, as well as clarifying certain types of pain. However, we maintain our past and current position that any update to the CDC Guideline must explicitly reference medical devices and their appropriate role as a part of the multi-modal approach to pain management, not just as open-ended non-pharmacological alternatives. We appreciate the opportunity to comment today and look forward to continuing our work with you on behalf of pain patients. Thank you.

Renee Blare
Chronic Pain Alliance of the West (CPAW)
National Pain Council (NPC)
Rare Disease Legislative Advocates (RDLA)
National Organization of Rare Diseases (NORD)
Reflex Sympathetic Dystrophy Syndrome Association (RSDSA)
Wyoming Rare Disease Advocacy for NORD

Thank you for calling my name. Thank you for the opportunity to comment today. My name is Margaret Renee Blare. I am from Newcastle, Wyoming and I represent the Chronic Pain Alliance of the West (CPAW) and the National Pain Council (NPC). I am a 25-year licensed Pharmacist for the State of Wyoming and I became disabled in July 2019 from Complex Regional Pain Syndrome Type II (CRPS II) or Causalgia. My frontline clinical experience includes the VA, Indian Health Service, retail hospital staff, Ad Pack, and managerial. I am practiced with veterans, Native Americans, and most races and cultures in this country. My comments today come from the viewpoint as a health care provider and rare and severe pain patient. I am open for questions whenever you need to ask me. In 2015, the CDC released the 2016 Guideline being revised and discussed here today. They impacted the veterans, Native Americans, and public health care similar to the implementation of the Fifth Vital Sign in the late 1990s with devastating consequences: escalating suicides and overdose rates; misapplication of the guidelines by political, state, and federal agencies, including the DEA; and the traumatic impact of chronic severe pain patients in America, including rare disease, post-surgical, and disabled patients. The last 7 years have led to the destruction of Wyoming's severe pain and rare disease health care. The medical patient in this class has little to no options or access to care. While specialists have retired, left the state, stopped practicing, been incarcerated by the DEA, or ceased to prescribe opioids at all due to restrictions to DEA license. In addition, the suicide rate of Wyoming has climbed to 17% in this year alone. No matter the intent, goal, or method that the CDC may desire with these guidelines and their purpose with the American healthcare system, the DEA will still manipulate them to serve their way. As long as they exist, they can and will be misapplied. I think that the way to stop the harm to patients, providers, and the system is to repeal the guidelines and trust the system. Publish, advise and do not regulate. Thank you for your time.

Kristen Ogden
Co-Founder
Families for Intractable Pain Relief

Good afternoon. My name is Kristen Ogden. I am the Co-Founder of Families for Intractable Pain Relief. I have no conflicts of interest. I speak today on behalf of a small subset of chronic pain patients who suffer from severe, constant, intractable pain with cardiovascular and endocrine complications, a condition we describe as intractable pain syndrome. When intreated, this condition has devastating effects on cardiovascular and endocrine systems and can lead to premature death. For these patients, MME-based prescribing policies have not worked. The result of the 2016 CDC Guideline and related policies has been an increase in patient harm, not improvement in patient care. These policies have caused incalculable harm to patients, families, physicians, and pharmacists. High doses are needed by some intractable pain patients as a last resort treatment when all else has failed. These patients often suffer from extremely painful, incurable illnesses that involve neuroinflammation such as arachnoiditis and connective tissue disorders, such as Ehlers-Danlos Syndrome (EDS). Efficacious doses for some patients are in the 2000 to 3000 MME range, including my husband, Lewis Ogden, whose efficacious dose is about 2900 MME—a dose some believe must be too high. If a high-dose opioids regimen succeeds in meeting goals for pain control, functional capability, and quality of life, patients should not be tapered off medications that work for them. Bottom line. MMEs should not ever be used as a threshold for prescribing or dispensing medications, or for targeting and disciplining doctors. We need to restore physician discretion to diagnose and prescribe. Failure to do so will allow the continuation of preventable harm. In effect, this amounts to torture of intractable pain patients. Freedom from pain to the extent achievable is the most fundamental of all human rights. My husband should not have to suffer because an arbitrary number, MME, is thought to be too high. Thank you for the opportunity to comment and for releasing the report prior to the meeting.

Lauren Deluca
Founding President and Executive Director
Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG)

Thank you for allowing me to comment today. My name is Lauren Deluca. I am the Founding President and Executive Director of Chronic Illness Advocacy & Awareness Group, (CIAAG), a national nonprofit focused on patient rights and access to medicines, particularly for those with painful illnesses and diseases. I'm also what is often referred to as "collateral damage" to the nation's attempt to regulate drug overdoses by restricting access to opioid medications. Despite years of conducting these meetings with the CDC and other federal agencies, patients continue to suffer egregiously due to the policies changes and even laws that are being supported by the CDC guidelines. There is ample evidence of severe patient harms that directly stem from these guidelines. And instead of taking action, we have seen the CDC claim misapplication, yet make no further efforts to rectify the situation. Even this rewrite we see taking place right now is only being done because it was federally mandated to be reviewed after 5 years. Simply updating the Guideline with more politically correct terminology while aligning with preordained goals of promoting multimodal and often inadequately researched modalities as a solution to the systemic issues these guidelines have created is wholly inadequate—not just for the people with painful conditions, but for the entire nation given the Guideline's far-reaching application into the acute care setting to surgical care treatment of individuals with rare, debilitating conditions, and even individuals in their last days of life in hospice care. The committee has even acknowledged in their observations the competing goals of population health versus individual health. How can we expect improved public health outcomes when we are actively sacrificing individual health care rights? If it is not good for the individual, then it is not good for overall society. I've never seen two goals pitted against one to the other for constitutional rights sacrificed for the greater good. Whose greater good? The CDC and all committee members have a responsibility to the entire nation for the work they are tasked here today. The citizenry deserves better. Thank you.

Dr. Felix Brizuela

Thanks for having me. First of all, I'd like to comment on a subject that was brought up earlier in terms of why we have more patients on opiates that in other countries—because we have a bad health care system. Physicians are very reluctant to make diagnoses of Lupus rheumatoid arthritis, which causes most of patients to have chronic pain, because they're afraid of being ridiculed, being called a "quack," or even being terminated by their employers. As a result of that, these conditions cause a process known as facilitation. Facilitation leads to release of what they call—I don't want to get into too many details, but inflammatory mediators that lower the pain threshold—the body's way of saying, "Hey, I'm in pain. Do something about this." There is no such thing as opioid-induced analgesia. That's been discredited. That was made clear in a publication early in 2020 in *Practical Pain Management*. What you're actually seeing is the chronic pain itself, the lower pain threshold, so I just wanted to make that clear. In the early

2000s, this alleged opiate crisis started. Like many others, I bought into this opioid crisis propaganda. Then they started criminally prosecuting doctors. Eventually that led to me being prosecuted. I was prosecuted and convicted because I did not take patients with chronic diseases who were on low-dose opioids out of my practice because they had mild indiscretions in the urine drug screens. I made it clear that I follow CDC guidelines, but they didn't want to hear it saying that "You don't kick patients out of a practice simply because they have some impropriety if that they have real medical conditions." I got sentenced to 28 months in prison. I served 7 months and luckily, I won my appeal. But the deception by the DEA and the Federal Bureau of Investigation (FBI) harassing patient, telling patients to speak against me, threatening them that if they don't speak against me that they would be prosecuted was completely unlawful. Every day we read about some physician, mid-levels such as nurse practitioners, and even nurses being prosecuted just for doing their jobs. Patients who suffer from chronic pain due to various conditions are being told that they are lying and being labeled as addicts and doctors who are helping them are going to jail. The government, the FBI, the DEA have taken on the role of doctor with absolutely no medical training. Anyone else doing what they are doing would be accused of practicing medicine without a license and facing legal action. There are 60 million people in the United States suffering from chronic pain. That's over 10 times more than those suffering from addiction—addiction being defined as those who take drugs like opiates for non-medical reasons—in this case pain. The data from the 1990s absolutely without a doubt show that there was never a rise in prescription drug abuse. Modern-day analysis shows that less than 3% of drug abuse has involved prescription drugs. Data from the 1990s, the government told us that we must address suffering, calling this the Fifth Vital Sign. Then sometime in the 1990s, they started prosecuting doctors. Let me just finish off by saying in the short time that I have, let's give doctors back our power so that we can fix this.

Jay Kuchera, MD, FASAM
Board Certified Addiction Physician
Director, Specialized Opioid Support Services

I am a Physician, Board Certified Addiction Medicine by the American Board of Addiction Medicine (ABAM). I am the Director of Specialized Opioid Support Services. We have about 3,000 opioid patients. We are seeing a very significant problem with the referral of problematic, high-risk, complex opioid patients into pain medicine driven by the CDC guidance. There are 400,000 primary care providers in the United States. The CDC guidance has had a profound influence on the prescribing habits. In at least 8 places in the current 2016 CDC guidance, there is a call for referrals of problematic patients to pain medicine. This externalizes pain medicine. There's only 4,800 pain providers in the United States. This is putting a tremendous amount of stress. So everything that we have heard about all the issues, all the problems, and all the controversy, and the tremendous patient care conundrum that opioids are posing right now are being focused on pain medicine. We do not have adequate policy support for pain medicine. If you look at the NIDA website, they support 19 separate specialties and provider types. Pain medicine is not one of them. The Providers Clinical Support System (PCSS) is a wonderful consortium, but it really doesn't focus on pain medicine. Because the CDC guidance is regarding pain medicine as external, we really are stuck. I certainly hope that a subsequent iteration of the guidance realizes that you are perpetrating the idea that pain medicine is an ideal destination for problematic opioid prescribing. Please address this. It deserves every attention. Do not perpetrate this.

Kristin McGarity
National Council on Independent Living (NCIL)

My name is Kristin McGarity. I represent the National Council on Independent Living (NCIL). We are the nation's largest organization run by and for people with disabilities, with Centers for Independent Living (CILs) serving people in every state, district, and territory in the US. Our members have suffered disproportionate harm from misapplication of the 2016 CDC Guidelines. These harms include medical abandonment, forced tapering, loss of flexible individualized care, loss of function and quality of life, and heightened barriers to accessing health care. Even since the CDC has welcomed clarification in 2019, the Guideline continues to be misapplied by insurance companies, legislators, Medicare, Medicaid, state agencies, pharmacy benefit managers, and law enforcement. Our members continue to suffer. In updating its guidelines, we hope that the CDC takes seriously its ethical obligations to the full range of people living with pain, including those not well-represented by the evidence reviews. Evidence reviews primarily focused on moderate pain from common conditions, not on severe pain or pain from rare conditions or diseases. In closing, we reiterate our comment from June 2020 asking the CDC to recommend replacing dosage and duration thresholds with care optimized to the individual. CDC has a role to play in preventing overdose deaths and the CDC also has a duty to protect people with disabilities from further harm. Thank you very much for your time today.

Leah R. LoneBear
Volunteer Managing Director
Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG)

My name is Leah LoneBear. I am the Volunteer Managing Director for Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG). As we are here again revisiting the opioid guidelines that were established in 2016, we remind you that since the inception of the guidelines, patients have begged and pleaded for mercy to maintain their quality of life, avoid medical collapse, refrain from going to the streets for relief, and/or commit suicide. You as a group began this atrocity in 2016 and here in 2021, you have allowed the death and the suffering to continue unabated with the idea in mind that it may be the end of 2022 before you update your guidelines. All of your actions have caused this loss of quality of life, medical collapse, death, and suicide, and destroyed lives and families. You have exponentially increased the black market and the number of patients who will seek it as a last resort. You have turned people to disability. Whereas before they were functioning and working as long as they were medicated for pain, they can no longer function. Pain medication has been ripped from patients in mass. I have witnessed speeches by pediatric surgeons pleading for people to understand the necessity for pediatric pain control. You say that adverse childhood experiences have to do with whether or not a person becomes addicted. I cannot imagine a more adverse childhood experience than going through cancer surgery, or treatment, or pancreatitis without adequate pain control. If you need a vivid and clear example, then hear this. Erin Gilmer was a chronic pain patient and attorney who worked in health law. She, in fact, worked with and for Stanford University, PICORI, and AHRQ. Due to the insanity of the environment that we are now surrounded by in regard to pain and pain patients, last week Erin killed herself. So your creation has come home to roost and landed at your own door. You've killed one of your own by deprivation. Thank you.

Adrienne Shapiro
Axis Advocacy

Hello. I'm Adrienne Shapiro with Axis Advocacy, an organization that works with adults living with sickle cell disease. There are going to be other advocates for sickle cell disease speaking, so I'm just going to talk about a little bit of what we like. In the 2016 report, sickle cell disease was listed as one of the conditions that the report did not apply to. It didn't matter. As a matter of fact, it was ignored. We had discussions with the CDC. They then added in their second report that sickle cell should not be looked at as something included under this report. It didn't matter. At this point now, I'm looking at the report you have now, and I'm saying to you it won't matter. I'm asking that on each page, really, if you have groups that are excluded and you have to publish this, add a tag line on the bottom of each page that lists the conditions that are not included as a start, right. So if it's end of life, it's cancer, if it's sickle cell, you have to do that because people are not reading it. They take one look at us and make all these decisions about who we are and what we deserve. And, you know, the thing is this, we are getting good pain treatment, but it is actually at end of life. It doesn't have to be that way. It shouldn't be that way. I know it's not the way you intended it to be, but that's how it is. Thank you.

Scot Faulkner
Photobiomodulation (PBM) Foundation

Thank you very much. I'm Scot Faulkner with the Photobiomodulation Foundation, PBM Foundation. We applaud the CDC's newly revamped opioid and drug overdose websites in your recent publication *Safely and Effectively Managing Pain Without Opioids*. We enthusiastically support the CDC's policy of encouraging non-pharmaceutical therapies to manage pain. The PBM Foundation recommends that the CDC add photobiomodulation, PBM, to your list of options for pain management and consider this therapy as adjunctive to existing treatments, as well as helping patients scale back their opioid use. Photobiomodulation is red and near-infrared light directed at the body with the right intensity to stimulate mitochondria repair, restore cell function, and reduce inflammation. It is non-invasive and is a natural process aiding a natural process. PBM is an FDA-cleared medical technology that successfully manages pain. It is widely used in veterans hospitals and leading medical centers, including Harvard, MD Anderson, St. Jude's. PBM has been used in over 100 million patient treatments without any documented side effects. There is an overwhelming body of evidence proving PBM therapy's efficacy. This is supported by over 750 randomized clinical trials; 8,000 research studies, and many published in leading scientific journals. All those suffering from acute and chronic pain should be made aware of PBM's effectiveness and cost-effectiveness. PBM's ease of use, lack of side effects, and low cost will save lives and help achieve clinical equity throughout our healthcare system. Thank you.

Syndee Damrosch
DPPR C-50
American Pain & Disability Foundation

My name is Syndee Damrosch. I don't want to repeat anything that anybody else has said already. I agree with many of the comments about the harms that were committed. I did want to thank the workshop for recognizing the harms done and for listening to the public comment. In 2017, I suffered a traumatic brain injury (TBI). While I was recovering from that, in 2018 the pain management doctor I had been seeing for many years was raided by the DEA and I had one day to find a new doctor. That first doctor didn't even examine me. He cut my dose in half. In my next visit, he advised me I was going to be tapered off all together with no alternatives and without physical examination. He cited the CDC Guideline. The next doctor wanted to do surgery. Again, CDC Guideline's alternative therapies, which are great. But, as I understand best practices, they're not patient-centric enough in that what works best for one group isn't going to work best for everyone. There can't be a one-size-fits-all. My quality of life has been diminished. I just want to know how many more friends I have to lose from excruciating chronic pain committing suicide, suffering betrayal trauma from their doctors who have thrown them out. I was forced tapered and I want to make sure that these recommendations are going to be taken to heart and actually applied, because in 2019, HHS Opioid Task Force Best Practices for Pain Management had a wonderful plan that was ignored by Congress. The harms are happening now. They are ongoing and we need to stop this. We can do better. Thank you.

Wendy Sinclair
Founder
Oregon Pain Action Group

Hi. I'm Wendy Sinclair. I live with a chronic painful condition and I'm the Founder of Oregon Pain Action Group. Our group of over 500 members is filled with patients who are losing their pain care and thereby their function and their quality of life. Before I say anything else, I ask you to listen to the concerns and suggestions of the Opioid Workgroup and that you amplify them. The misapplication of the CDC Guideline has dramatically changed the prescribing climate for chronic pain patients. Regardless of the intent of the guidelines, in practice they are repeatedly used as a reason to force taper pain patients, especially by decision-making groups, including the Oregon Medical Board. They forgo clinical judgment or individualized medical care treatment in exchange for hard limits, asserting that they are adhering to the CDC guidelines. And those guidelines are taken even further in Oregon with the push for an anti-opioid state. It is very difficult to allow individualized care when the MME thresholds are taken as the rule of law and expanded upon. Oregon is in crisis. Our Medical Board is radically misapplying the CDC Guideline as well with hard limits to providers, including pain specialist, regardless of clarifications. They cite the guidelines as their reason. They have mandated many providers to taper all of their patients to hard limit threshold of 90 MME and it is generally known to be what is expected. These forced tapers happen without any data on patient harms. This is not patient-centered or individualized care. Intention or not, the guidelines have created an avalanche of tragedy directed at the people they are supposed to protect. Patients become casualties and the harms are escalating. As disabled patients, we are somehow in a different class and don't have the same rights as other patients. Another huge problem is the commingling of us with addiction patients, which have very different needs. Neither group is served appropriately with this commingling. Pain patients deserve proper treatment for their conditions, not for addiction. Thank you for your time.

Michael April, MD
Board Certified Specialist in Physical Medicine Rehabilitation
American Academy of Pain Medicine

My name is Michael April. I want to thank Dr. Walensky for her comments. I'm a Board Certified Specialist in Physical Medicine Rehabilitation. I treat very complex chronic pain patients that have seen numerous providers and have been through numerous treatments. Unfortunately, the issue is addiction and we haven't been able to separate out the chronic pain patients from the addiction patients. I find very few of my patients have problems with opioid medications. They function better in most cases, but because of the guidelines in 2016, irreparable damage has occurred with my patients. Many of them are having to reduce their medication or go off medication. It has affected my practice and my ability to practice medicine. I'd like to get to some of the comments Dr. Walensky made. The guidelines have been used as standard of care. I have personal knowledge of this. Insurers have used the guidelines to reduce patient's medication. Pharmacists frequently used the guideline as a way to not fill prescriptions. I get calls probably two to three times a month from pharmacists who will not fill prescriptions on patients that have been on opiates for 10, 15, 20 years. Their argument is that I'm outside the guidelines, which I'm not. And secondly, they say that they're going to have respiratory depression. It looks like we've lost all sense of science here. I know many of my colleagues won't treat pain patients anymore because of the guidelines from 2016. So, I hope that the 2022 guidelines will make significant changes.

Lewis Hsu, MD, PhD
Chief Medical Officer
Sickle Cell Disease Association of America (SCDAA)

Hello. I'm Dr. Lewis Hsu. I'm Chief Medical Officer with the Sickle Cell Association of America. I'm a practicing physician and prescribe opioids for children with sickle cell disease and cancer. I applaud modifying the guidelines with attention to pain care and want to advocate for implementation of the guidelines to do better than 2016 for sickle cell pain. Sickle cell pain is among the most severe pains known and can start from infancy. Even with the best current medical treatment, sickle cell pain is unpredictable with acute recurrences. Therefore, opioids are part of the standard of care for sickle cell multi-modal pain management. Studies show that sickle cell patients do not have high rates of fatal opioid overdose. The science also shows that sickle cell pathophysiology is different from other types of pain. Sickle cell pain management was therefore put outside the scope of the 2016 CDC opioid prescribing guidelines by a single sentence as mentioned by Adrienne Shapiro, but that single sentence was widely ignored. Restrictions were misapplied to sickle cell pain and increased suffering by delays in authorizations and caps on the number of doses and medicines. These implementation dissemination problems for individuals with sickle cell and cancer are described by an expert panel report in 2020. We suggest more assessment of implementation dissemination. Build in early corrections and do not wait 5 years to do a reassessment of health equity. Keep the capacity to act on stakeholder feedback by keeping the Opium Workgroup available for a year after the guidelines will help. We also strongly urge more research on effective pain management options that are alternatives to opioids. We urge collecting data on opioid safety when prescribed for pain treatment in chronic diseases like sickle cell disease. I thank the working group for their efforts. We appreciate the opportunity to make public statements and I'll conclude there. Thank you very much.

Angel Mason
Pain Support Specialist
American Chronic Pain Association (ACPA)
Foundation for Peripheral Neuropathy
US Pain Foundation
Chicago I Hurt Chronic Pain

My name is Angel Mason. Here in Chicago, I'm a Pain Support Specialist. I work with the American Chronic Pain Association (ACPA). I have also worked with the Foundation for Peripheral Neuropathy and now the US Pain Foundation. These guidelines are killing us. I'm a chronic pain patient. Chronic pain started for me more than 30 years ago. In the past 8 years, I have been on opiates. We have pain clinics here that are telling the patients that these guidelines are law. They're force tapering without regard to anything as to whether they're helping the patient or not. I'm tired of going to funerals. It's good that these guidelines are being revised. But next year? What about the people dying today because of this? Doctors are afraid to even prescribe medication and afraid to help us because they're afraid of being sued. This is madness—what it's done to us. I will be in pain for the rest of my life. There are no other treatments for me. Opiates have worked. The biggest side effect I've ever had was constipation. We're supposed to look at all medications as benefit outweighing risk. Well those of us without risk are still being forced off these medications. That's making the opiate crisis worse and it is making the suicide rate higher because of what's it is doing. Thank you for letting me speak.

Peter Pischke
Independent Health and Disability Reporter
Primarily with the *New York Daily News*

Hello. My name is Peter Pischke. I am an Independent Health and Disability Reporter, primarily working with the *New York Daily News*. Thank you for allowing me to join public input and for not playing games. The last meeting, your "click the invisible mute button trick" during the meeting in February was manipulative and cowardly. I'm glad this session's public comments are working as they should. I only hope the words of the honest and good reach the hearts and minds of those here. From this meeting and document released yesterday, we know the CDC has learned few lessons on the perfidy and world domination that is the 2016 CDC Guideline. It is evident to anyone paying attention that your workgroup is divided between a small faction that understands rightly that the guidelines have led to millions of deaths, suffering, inequity, and bigotry against disabled Americans. Standing against them are the NCIPC members leadership prefers. This group ignores the harm caused by the guidelines. Instead, they are concerned to protect the prohibition created or worst, feel this does not go far enough. This is outrageous and morally bankrupt. Every step, study, meta-analysis shows this is broken. Addiction rates up. Overdose deaths up. Access to medications at an all-time low since arguably the Civil War. We've gained nothing for that cost. We have lost people like Erin Gilmer, a disabled human rights lawyer with a professional record across journalism and law. I know this is an inflammatory statement, but I share because it is true. That death is at least partially on the hands of you guys. Not only them, but to all those oh so benevolent activist hoping to strip patients of access to opioids. Lastly, I implore those scientist with actual influence and authority, especially Dr. Roger Chou who admitted at previous meetings that even he, the very creator of the guidelines, got attacked by his hospital for using them. Please stop this. This is wrong, insane, evil. You all know better. Thank you for your time and have a good day.

Terri Lewis, LCSW
Independent Patient Advocate and Care Partner
Social Scientist and Clinical Educator

Hi, I'm online. My name is Terry Lewis. I have no conflicts of interest to report. I am an Independent Patient Advocate, a Care Partner, and I work with patients across the country. I'd like to address something that others have not addressed, and that is the evidence basis that has submitted and underlies these guidelines. One of my concerns as a social scientist and as a clinical educator is that the evidence that we constantly refer to must be well-crafted and representative. But in looking at the most recent submissions of evidence in the comparative effectiveness review for both 229 and 227, there are some very serious problems of bias and representativeness. I want to briefly address my major concerns and I will submit the rest in my written comments. First of all, the random controlled trials that are reflected in these reviews do not represent the patients who are most affected by the guidelines across the Nation. The demographics are unclear, the conditions that are represented are very narrow, and they do not reflect the range of conditions that must be addressed by primary care and community care clinics across the nation and the providers who treat them. That's a very serious problem. Another problem is that the evidence that underpins the guidelines don't reflect the settings under which these doses and materials are delivered to patients. I will submit the rest of my comments in writing, but I think we need to pay very close attention to looking closely at the evidence basis. Thank you.

Jessica Minerd-Massey
Pain Patient

My name is Jessica Minerd-Massey. I'm a 53-year-old divorced single mother of two and used to be an artist. In 2003, I was injured at my full-time job which resulted in being put on Worker's Comp and 15 major surgeries between 2004 and 2013. Almost half of these were emergency revisions and I almost died more than once. This led to a new diagnosis of Post-Traumatic Stress Disorder (PTSD), which has only been exacerbated by years of repeated forced tapers, fighting for treatment and pain relief from my Failed Back Surgery Syndrome (FBSS), current broken hardware, bone-on-bone vacuum phenomenon, spondylolisthesis, ruptured discs in my neck and back, and too many more to name here, including my never-ending severe pain. I've tried almost every alternative therapy there is, including aqua, physical therapy (PT), acupuncture, biofeedback, and meditation—pretty much anything except an intrathecal pump as I refuse to be cut open again for any of the 5 surgeries I'm told I need. I was a legacy patient on over 1,000 MME and could cook, shower shop, do small art projects, take care of my children, occasionally travel to visit family, and even thought I'd go back to work at one point. Against my doctor's orders and despite several phone calls and letters on my behalf, the Workman's Comp insurance company forced me down to 98 MMEs citing the CDC guidelines. Thanks to a compassionate law judge, I didn't lose them completely. I'm running out of time and won't go into the horror of withdrawal from 500 MME, but both my children witnessed it. They watched me fight to come back after every surgery, through force withdrawals, and to keep living in spite of the pain. One day my younger son came to me and tearfully and quietly told me how much he loved me, but he would understand and forgive me if I decided to kill myself. Can you imagine how that felt? Pain does not only hurt the patient. Even the CDC has admitted there have been harms done to patients and I am far from the only one. My son is now 25. I do have a suicide plan and have talked openly with my family about it. I agree with most of the suggestions made by the workgroup and beg you make the necessary changes to the guidelines so the DEA cannot weaponize it against doctors, patients, and pharmacists and we can all go back to living instead of just existing in a world of pain and fear. Thank you.

Annette Maxwell, PMP
Healthcare Advocate
Don't Punish Pain Rally

My name is Annette Maxwell. For the last 40 years, I have been a Business Consultant working on business programs and operations, and I hold the Project Management Professional (PMP) Certificate. I am also suffering from a painful chronic condition for which there is no cure, so I have become a Healthcare Advocate. Now it's 2021 and I find myself providing feedback for the third time on a document that has 2016 in its title. I'm wondering what the CDC isn't getting, so I'm going to be somewhat direct here. But first, you broke the project management cardinal rule of successful programs. You failed to identify and get feedback from your stakeholders early on. We're trying to do this downstream and you can tell we're having a hard time. You didn't get feedback from your stakeholders. You have no success metrics. And in fact, the data that you have is—I don't want to call it junk, but I think it is junk. It's hurt us. It violated our human rights. It's killed some of us. It's caused some of us to commit suicide. In project management there's a saying if “the only tool you have is a hammer, every problem looks like a nail.” So if you’re writing a document about drugs and the only people you consult are from substance abuse and emergency medicine, you’re going to get a document with the substance abuse slant. It’s called “group think” and it’s another mistake that will sink a program. This document should have been written from a place of compassion for people in pain, providing guidance for how to gauge pain, tools that can help, how to get patients back to work and back to a normal life. Where is the section on quality of life? You’re not going to be able to fix this without a completely different group of consultants. There are people for who opioids are the only treatment left and use opioids according to their doctor’s instructions. These are responsible patients. They will use opioids for the rest of their lives. Addiction has no meaning. We need a document that provides guidance for the prescribers to be responsible patients, but what we’ve created is a system where pharmacists, veterinarians, and everybody can overturn a pain doctor’s decisions. So, closing statement. My advice is to get a different group of consultants, including successful pain management doctors, chronic pain patients, advocacy groups, Purple Heart veterans groups, myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and fibromyalgia advocates and have 2022 guidelines and include the right topic. Include the basic human right to live without paying and the problem when pain goes untreated, undertreated, or undiagnosed. The worst thing that could happen is you’ll have a missing first task of the 2016 guidelines. Thank you.

Cammie LaValle
Palliative Care Pain Patient

Thank you for this opportunity. I first want to thank the Opioid Workgroup for doing their thorough review and the recommendations. I want to be blunt here and say the situation is dire and as people who have spoken prior to me had indicated, we have a lot of suicides on our hands. We have forced disability due to forced tapers. There is a taper frenzy almost in every state. I happen to live in Minnesota. Before anyone questions, I do not have any conflict of interests. I know that there was an indication that there was not going to be any questions answered, but in one of my questions is will imperative action be taken in the interim to intervene with state health and human service departments, insurance industries, PBMPs, Medicaid, our Administration to pause what they’re doing with their own guidelines and their own policies. I’m wondering if the CDC is going to do more than put out a publication asking their patients and advocacy groups to actually disseminate their clarification to the policymakers and legislators of their state, which I personally think was unacceptable. I believe the CDC could have done better, should have done better, and I hope they take the opportunity to do better this time. We took the clarifications I can say in Minnesota to our policymakers and they just blatantly disregarded it and doubled down. I’m a palliative care patient, rare disease patient, no FDA indicated treatments, disabled, and I’m facing another forced taper on palliative care. So, I am asking for millions of patients in this country to actually do something and take our concerns seriously, act, and not just do a publication asking to not misinterpret these guidelines. Thank you so much for the time.

Elizabeth Hrycak
Chronic Pain Patient

Hi. Thanks for having me. My name is Elizabeth Hrycak. I’m a 30-year old chronic pain patient. I started my experience with chronic pain when I 20 years old. I developed a rare autoimmune disease that affects the spinal cord called transverse myelitis (TM). My disease was well-treated through the first few years on opioids. Then a little bit after 2016 when my doctor left the practice, I was forced to find a new doctor. This new physician did not examine me. He cut my dosage by 75%. At my next visit, he informed me that he will be fully tapering me off these medications. Since then, my life has been absolute misery and hell. I've attempted suicide. My mother is also in the same position at 65 years old. Her mental health in in peril because she does not have access to adequate pain management. I used to be able to work effectively on opioid medication, but since then, I'm causing the country money being forced on disability and not being able to work. If I was able to have my chronic pain medication, I would be able to finish my Nursing degree. I'd be able to raise a family. So please consider what your impact is on the general public and the people who these affect. Thank you for letting me speak today.

Tamera Lynn Stewart
P3Alliance

Hi. Thank you for giving me this opportunity. Let me see if I have this straight. Chou's been involved in calling for opioid guidelines or restrictions since around 2011. The CDC gets funding for these guidelines. The CDC pays AHRQ to write reviews on which of these guidelines are going to be based. AHRQ not only contracts with Dr. Chou to conduct reviews of the opioid studies, but Chou also helps set the AHRQ priorities. Chou is one of the 5 authors who wrote the drafts of the guidelines based on the reviews he was paid to create. Last but not least, Chou is on the Board of Scientific Counselors which approves or denies any opposition comments from the working group, and being on the BSC. Chou has a say in the final approval of the guidelines themselves. All this and there's no mention of a conflict of interest until today, July 16th around 9:00 AM. Even then, the source of that conflict isn't revealed in order to determine whose interest Chou is serving. This is not managing conflicts of interest. This is sufficient enough information that P3Alliance insists the process is corrupted and the draft guidelines ought to be considered illegitimate and biased. Any further effort on this guidelines draft should be abandoned. We further call for Congressional investigation in the institutional conflicts of interest due to ongoing lack of transparency. Finally, the P3Alliance insists any further actions on opioid guidelines best practices be removed from the CDC, placed where transparency and stakeholder involvement will be guaranteed and respected, and that the scientific pursuit of truth trump the pursuit of financial interest on the part of the guidelines creators and editors. Thank you for that opportunity.

Pat Corley, RN
Cayenne Wellness Center
Axis Advocacy
International Association of Sickle Cell Nurses And Professional Associates IASCNAPA

Good afternoon. Pat Corley and I'm actually a retired nurse who lives in the sickle cell community. I'm just kind of a piggyback on what Adrienne Shapiro and Dr. Hsu talked about earlier and it's our community. First of all, I want to thank you guys for all the work that you've done on the guidelines, but I also want to say that the guidelines have not been helpful to our community. Instead, they've probably made living in the sickle cell more complicated and more painful for people living with sickle cell disease, an inherited red blood cell condition that is punctuated by pain and suffering. From the time that babies are born with sickle cell disease, they have potential for pain. Some of the things that have happened in our community are denial of medication, mistreatment of patients, rudeness on the part of healthcare providers, judgment as a result of having sickle cell disease. Actually, the fact that you share that you have sickle cell disease closes all the doors to getting effective and good pain management as our patients navigate the community. And so I would ask that you guys number one rethink these guidelines, if there are going to be guidelines, that you include people who would be more in tune to what's going on out in the pain community, which includes nurses, which also includes people who are living with other conditions that cause pain, and also to educate healthcare providers so that they understand the plight of people with pain and the suffering that they experience—not just the person who is experiencing it, but their entire community and their family. I would encourage that you guys do more education with doctors and make mandatory for certification some education related on an annual basis. Thank you.

Joseph Kramer
Pain Patient

First of all, I want to say I have no conflicts of interest. One thing I would like to bring up to the group today is that the guidelines have raised the cost of care astronomically. Okay. Until you get the DEA out of the doctor's office, no doctor where I live is going to prescribe and I've already been told that. All right? My doctor said, "good luck." My primary doctor. Do you have any idea what a failed policy this has been? Why would PROP be involved in the first guidelines when they want to restrict opiates? Okay? Because they've made a ton of money off of this. When they have interest in Phoenix House sending people to treatment, I mean, isn't that a conflict of interest? The Vice President of that group was ordered—his job was to clean up the heroin epidemic, but it's been a failed policy. Failed job. He should be fired. Okay? The damage that has been done—there's no doctors where I live to get care anymore. Okay? The other doctor already told you how many pain doctors are across the country. So you want to say now what recommendations you have for people that have been left to suffer, because you've done so much damage. Suicides? I mean, really, come on. You caused a health crisis across the country—a mental health crisis. All right? Then then these people say, "Oh, people don't want to work." Well, let me tell Mr. Franklin that Workman's Comp, if you are medication, they wouldn't pay your claim if you went back to work and got hurt. You better rethink the policies because it's been terrible. That pain management doctor who spoke up, thank you, because they can't do their job like they want to, okay, because of the 2016 guidelines and probably the ones are going to come out next. Thank you for letting me speak.

Andrea Andis
National Pain Advocacy Center (NPAC)

I'm Andrea Andis speaking on behalf of the National Pain Advocacy Center (NPAC), a nonprofit that takes no industry funding and advocates for people living with pain. Our group includes people with a wide range of pain conditions, such as cancer, multiple sclerosis (MS), CRPS, spina bifida, and many other high-impact pain conditions. The broad implementation of the 2016 Guideline by payers, legislatures, Medicare and Medicaid, state agencies, pharmacy, benefit managers, and law enforcement has all resulted in immeasurable harm to the patient and clinician communities. Our members, and those we hear from almost daily, have been forcibly tapered off medications they require to function. Others confront mounting barriers in filling their prescriptions and too many are unable to find a provider who is willing to treat them at all. These devastating results, which have destabilized their health and lives, continue unabated despite the 2019 clarification. We thus urged the CDC to heed the workgroup's recommendations in this update to strongly correct course and act to protect patients who require prescribed opioids from ongoing stigmatization and outright harm. We also note especially that studies in the AHRQ report focused on only mild to moderate pain from common conditions, not on severe pain or rare conditions that many of our members experience. Yet the policies that result affect them disproportionately. We are also concerned about MME thresholds, which failed to account for variability in metabolics, disease processes, and methods of MME calculation. Evidence presented at the FDA examining underlying CDC data found wide variation in MME conversions. The same medication given at the same interval can be translated in MMEs at either or above these 50 are 90 MME thresholds. Yet, they are standards of care embedded in

EHRs and PDMPs with significant consequences for both patients and providers. In closing, we urge that CDC come out clearly against hard limits and in favor of careful prescribing that allows for individualized, patient-centered care. Thank you.

Gabrielle Johnston

Thank you for letting me have this opportunity to speak in front of this panel. Actually, the comments that I have today already have been forwarded by public comments by some of the people within the panel. So, I would like to yield my time, I guess, and let somebody else have this time to make a comment. Thank you.

Julie Glatczak, RN
Chronic Pain Patient
Board Member, Range Suicide Prevention Council

What I want to bring up is some of the points that have already been brought up, but I want to say that as somebody had previously just stated, she's a resident of Minnesota. I live in Michigan. In Michigan, BlueCross BlueShield (BCBS) is actually offering surgeons kickbacks in payouts for not prescribing opiates post-op. I just think that is so wrong. I'm a nurse. While disabled right now, and I'm also a chronic pain patient. I'm also a board member of the Range Suicide Prevention Council. I know that many have talked about the suicides that have been created because of the guidelines, but nobody has ever said the percentage and I want to let you know that I've attended different workshops and webinars in that the actual percentage in the chronic pain community of suicides is 47% since the 2016 guidelines. And if that doesn't frighten you, it is 57% in the Veterans Administration and suicides related to untreated pain. Now, I'm not going to go into what is wrong with me, but one thing I think that it is important is we need to refine and define palliative care, because where I live in a rural community in Michigan, and a lot of others complain that it is considered the same as hospice. And even though chronic pain patients, many of them meet the criteria for palliative care, it is not an option for us. And we need to do something before 2022, because the suicide rates are just enormous. I just want to say that being a board member myself of the Range Suicide Prevention Council and me having suicide thoughts myself, it is sometimes difficult for me to stand and talk to somebody about suicide prevention, but I do it. And I think that's what has kept me alive so far. I want to thank you for letting me talk.

Shirley Buck
American Pain & Disability Foundation

My name is Shirley Buck. I'm with APDF, American Pain & Disability Foundation. I have no financial conflicts of interest or responsibility. First off, I'd like to say that the CDC should not be involved in this matter at all. The CDC Guidelines should become re-worded as the "Malfunctioning CDC Guidelines." If the CDC wants to be responsible for this issue, then they need to be held responsible for all the suicides and the damages that have been caused as well. Patients have experienced extensive issues with pharmacies and insurance companies, unable to get their prescriptions or turned away. Neither one of them want to fill it or pay for it. It's imperative that you specify when you do these new guidelines that chronic pain patients, cancer patients, hospice patients, and sickle cell patients will not be counted in the CDC Guidelines. This must happen. We've already had entirely too many suicides and people are dying. These are family members. This is wrong. Pain patients are also not being appropriately represented by the CDC. There's entirely too many representatives on the board with major conflicts of interest. One from last year was on the board and also on the board of PRI. That's a huge conflict of interest, but it was ignored like nothing ever happened. Also, most of the board all have ties with rehabilitation businesses. Why is that? That has nothing to do with us. Why are we tied into this? Also, the members of the boards need to have many more pain management doctors and actual chronic pain patients involved in those instead of so many rehab doctors. It's ridiculous. Actually, the 90 MME is not even scientifically backed but is being pushed on all patients. Drug overdose deaths have gone up 1406% and that's mainly through illicit street drugs. It's a disgrace. The CDC Guidelines have been nothing more than a disgrace and they obviously aren't working. I highly recommend this issue be placed back into the hands of the FDA.

Joseph Adams, MD
Board-Certified Addiction Medicine Physician and Internist
American Society of Addiction Medicine

Hi. I'm a Board-Certified Addiction Medicine Physician and Internist. Opioid use disorder is a terrible epidemic and is a common cause of death. It's well known that the majority of people with opioid use disorder developed a problem after using prescription opioids. I ask every patient with OUD, opioid use disorder, how the problem started and 70% to 80% tell me it started with a prescription opioid. That's consistent with what we know from the literature. Now, illicit opioids are the number one cause of opioid overdose death, but that in no way suggests that prescription opioids are no longer driving the epidemic. Prescription opioids have always been the driver of the epidemic. They still are. The US continues to have a much higher rate of opioid prescribing than any other country in the world. Over-prescribing is common in my own community. Until we address the underlying cause of opioid use disorder, over-prescribing, we are not going to be able to change the course of this epidemic. In terms of thresholds in the guidelines of 50 and 90 morphine milligram equivalents for 3 days will often be sufficient. Some have argued that there is not enough evidence for these particular thresholds. There is adequate evidence that there are significant increased risks that are dose-related. We need these thresholds. Without them, the guidelines would not offer practical guidance and would lose their effectiveness. Once a person already develops physical dependence on opioids, tapering is extremely risky. Decisions on whether to taper opioids should be voluntary. Individual guidelines exist on how or whether to consider a trial of tapering only if it is appropriate. It is hard to control what an individual provider does, but the CDC opioid guidelines are consistent with precautions around tapering decisions. Concerns about tapering should not be a reason to reverse the significant gains of the 2016 guidelines. Thank you very much.

Andrea Ortiz
Don't Punish the Pain Patients

My name is Andrew Ortiz and I am calling in representation of the Ehlers-Danlos Syndrome (EDS) Community of Western New York, a community not many doctors are familiar with. We have a connective tissue disorder syndrome disease and it causes major pain throughout the body. And each of us, though we have the same disease, we each have different issues with this disease. Many doctors want us to join pain management and in Western New York, that is almost an impossibility. They call us "liabilities" and they say they our syndrome is way too complex and they do not want to risk their licenses taking on such complex patients. Our condition limits us to PT care, chiropractic care, and even surgeries are less life-threatening. I often end up in the ER where most refuse to even treat me because according to them, I'm a chronic pain patient and need to be in a pain center, which I cannot get into. I have called 11 different pain management centers, and before I can even get them to see me, right away, they say they only will use interventional medicine, shots, therapy, steroids—things that I am not allowed to use in my condition. They will not give me instant pain relief and most often send me home in horrible pain. Before the CDC Guidelines in 2016, I was able to function and play with my kids until my doctor said he can no longer prescribe any opiates because of the change and discontinued all of his patients. From then on, it has been one doctor to another, which now pegs me as a “doctor shopper.” At one point, I was tricked to go on to SUBOXONE®, calling it the new pain treatment, which now I am pegged from a chronic care patient to a opiate addiction user. I am 41 years old. I have a whole life ahead of me and I shouldn’t have to live it lying in bed being afraid to go to the ER or a doctor because at most points, they make me feel like I have no other choice but to jump off a bridge.

Jay Joshi
Daily Remedy

My name is Dr. Jay Joshi. I am a primary care physician who was convicted under the Controlled Substances Act after establishing an award-winning National Committee for Quality Assurance (NCQA) primary care practice in Northwest Indiana. I have no conflicts of interest. I would first and foremost like to thank everybody who has been brave enough to share their experiences and discuss the implicit moral hazards that have come to define the 2016 CDC Guidelines. What I would like to add to everything that has already been discussed is an awareness on how the guidelines are implemented. It is one thing to implement and establish guidelines in a clinical setting. It is another thing on how they are interpreted in the legal setting and the public policy setting. And so I would like the committee to be extremely leery on how the interpretations are set for in the different contexts and possibly even set forth guidelines on how the interpretation could place in the legal setting and the public policy setting knowing full well that the guidelines, although ascribed for individual patient-physician encounters, will inevitably be implemented, or revised, or possibly recontextualized into settings that are not intended for its original use. And it is this particular reinterpretation that has led to the implicit moral hazards, that has caused, so many patients, so much grievance that has led to so much suicide. So I would strongly urge the committee, the intelligent well-intentioned folks who are speaking who are attending this, to recognize that there will be reinterpretations on the guidelines set forth. Address how those reinterpretations will take place within the legal setting, within the criminal setting, within the DEA, with the Department of Justice (DOJ) and understand how you can address that to standardize interpretation to help everybody and address the implicit moral hazards. Thank you for your time, sir.

Maria Higginbotham
American Pain & Advocacy
End Pain Stigma P3

First, I want to thank you for taking the time to let me make a statement. Pretty much everything that I had to say has been stated today. I want to beg all those that are involved in these guidelines to consider that someday this could be them. It could be you that gets a diagnosis of a rare disease. It could be your family member that gets in an accident that ends up with a painful condition that will take much pain medicine to treat. Most of us that have gotten to the point where we are on opioid treatment have tried every other treatment available and have found that those did not successfully treat our pain. Opioids have been the last resort. There have been bad practices that have happened years ago, but right now to try and find a compassionate ethical doctor to treat your pain is almost impossible. Those of us that live with these conditions are watching our lives go by out a window. We are forced to live in agonizing pain, either to choose suicide over a life of agonizing pain or go to the streets for drugs for pain relief when we were being watched by a physician and cared for. The CDC Guidelines have hurt millions of Americans and this is not the country that I was taught to love and respect. We need to take care of our people. And that's pretty much everything I need to say. Think about this. It could be you. Thank you.

Kelly Brooks
Pain Patient

First, I want to say thank you for allowing me the moments to speak here today. I hear you guys echoing over and over again that the CDC Guidelines are guidelines and that they weren't meant to do any of this stuff. However, in my hand, and I will be sending it in with my comments, in my hand, I'm holding an actual form from my doctor's office. I got this one and 2018 and I have to sign it every single year and it says, "Due to the fatal risk of overdose with co-prescriptions of opioids and benzodiazepine compliance with CDC guidelines, these medications will not be prescribed together at this practice." Then right underneath that is the actual CDC Guideline Number 11, "Clinicians should avoid prescribing opiate pain medication and benzodiazepines co-currently whenever possible." This is a document I have to sign every single year. So to tell me or to tell anybody that these are not being put into hard practice is first incorrect and second of all, the problem that is happening here is that you guys are not addressing the issues the way they should be. Addiction is a completely separate issue of pain management and you have continued to lump us together. Continuing to lump us together has resulted in us being treated like criminals. Now, I am a pain patient with intractable pain and have been on medication for 11 years. I was stable until recently when I got diagnosed with RA and now I require more medication to keep me from—so that I can actually get out of bed. And I also in live in the State of California and we have some serious intractable pain laws and I have to sign a contract every year. I get piss-tested randomly. And so all of these things that you guys are trying to implement I understand and I get because I also went to school to be a surgical tech. So, I have a little knowledge on the medical side that some people might not. I get the gravitas of the situation with these medications. The problem is that we don't have enough pain management. Second of all, I am tired of talking about "let's take the pain medication away" when you're not talking about what causes the addiction and that's a trauma. Why are we not focusing on providing therapy and getting people the therapy that they actually need when they are hurt and just the first trauma that propels them into addiction. It's not the opioid that propels into addiction. It's the trauma and you guys have overlooked all of that all because of this pill. Pushing SUBOXONE® on us is never going to work. And I'm going to tell you as a pain patient, I will never go back to the days where I go to the ER every other day because my pain is that bad. I will never go back to those days, and I will be one of those patients that ends up in the back end of the black market because you guys forced it and that's not fair because I didn't ask to be sick. None of us asked for this and if it happens to you or your family member, it's going to be too late for you to do anything about it. Thank you.

At the close of this session, Mr. Cabada thanked the members of the public for providing comments. He reminded those who did not get a chance to speak or who had additional comments to make to submit written comments to ncipcbsc@cdc.gov no later than 5:00 PM on July 23, 2021. All public comments will be included in the official record and will be posted on the CDC website with the official meeting minutes at cdc.gov/injury/bsc/meetings.html

Discussion and BSC Recommendations

Dr. Amy Bonomi, PhD, MPH
Co-Chair, NCIPC BSC
Faculty Affiliate, Harborview Injury Prevention and Research Center,
University of Washington, and Founder, Social Justice Associates

Dr. Bonomi thanked the public for their extremely thoughtful comments and reflections on the draft Opioid Guideline and for taking the time to attend this meeting. It certainly will help the BSC members in thinking about how this moves forward. At this time, she requested that the BSC discuss the information that they heard throughout the day as well as the public comments in order to develop recommendations that can be passed along to the CDC. She explained that at the end of this discussion session, they would be making two motions. One would be to endorse and/or amend the OWG group report and the second would pertain whether to sunset the OWG. Dr. Bonomi first provided a general reflection of what she heard during the public comment period. The comments ranged from support for the report to some concerns. Some of the concerns regarded the importance of thinking about how to interpret this across various contexts (e.g., legal, healthcare provider, public health). There are certainly concerns about mental health, certainly in terms of suicidality, trauma, and biases/labeling. Concerns were raised regarding diseases and making sure that specific diseases are considered, such a sickle cell, and differences of the manifestations of diseases across the chronic pain treatment spectrum. Commenters also raised concerns about backlash from providers prescribing.

Discussion Points

Dr. Floyd observed that they heard from a number of patients with chronic pain who had to switch clinicians for one reason or another. There is a dynamic that he did not think had been, but should be, addressed. Many, including himself as he has been an internist for 37 years, through the time when the dynamic was that pain is the fifth vital sign, pain is being under-treated, there are great opiates that are safer but are being under-utilized, et cetera. Those who lived through that dynamic and had implemented it are now retiring as time goes by. A number of those clinicians are leaving and that is leaving a lot of the patients who came through that era "high and dry." He is still practicing and sees this with patients presenting to his office. Clinicians who are practicing in this new era are on the opposite side of the pendulum where opiates are bad, harmful, and risky. They fear if they prescribe, the DEA will come after them That is a very real dynamic that Dr. Floyd strongly believes is underpinning a lot of the comments they are hearing. He expressed his hope that the CDC would address in the write-up that these guidelines being reviewed should be considered on an individual basis as patients are being transferred into practices, especially patients who have been on chronic pain medications long-term. He recalled some references in the write-up that he read, but he thought there ought to be some reference to this particular dynamic. This is huge in his area and he is seeing it a lot, and is sure it is huge nationally.

Dr. Cunningham noted that a lot of the issues she heard during the public comment period were issues that the OWG discussed. There are a lot of challenges and various perspectives. Because the data are not that great in a lot of ways, it comes down to opinions and perspectives, which is unfortunate. Trying to strike the right balance between individual patient care and public health is really the challenge that they have in front of them. As Dr. Floyd mentioned, a lot of the comments she was struck by during the public comment session were by people who have been on opioids for years. Some of the guidelines were "easier" for people to agree on, while others were much more challenging. For instance, some of the early recommendations in the Guideline about when to start opioids felt easier than what to do among the group of individuals who have been prescribed opioids since long before the 2016 Guideline came along. That scenario is by far the most challenging for patients and providers. It seems that there will have to be a lot of attention on long-term patients, which they heard loud and clear from the public.

Dr. Staffa, from FDA, thanked all of the public commenters. She acknowledged that it could be very challenging with the technology to hang in there and make sure to get to comment. She also thanked CDC for all of their efforts to make that happen. They heard a lot of really heartbreaking stories. The thing that resonated for her the most regarded the MME thresholds. The OWG has made the observation that they should take the thresholds out of the recommendations, but still continue to perhaps reference them in the supporting statements. Based on the comments they heard from the public, that seems to be a common source of misperception in terms of applying these guidelines. She asked that the OWG, BSC, and CDC further consider the approach to that issue. Perhaps a more evidence-based approach might be to talk about the data that really do support the increasing daily dose and the risks associated with that rather than having thresholds, which can be too easy to pull out and apply inappropriately as they have heard has happened. While she recalled hearing at the beginning of the day that Dr. Chou recused himself from this discussion, there clearly continues to be some question or confusion about his involvement. It might be a good idea to double check and to clarify that so that people do understand that situation, his conflicts, and how that has been canceled.

Dr. Bonomi asked Dr. Staff for clarification about whether she was asking for a specific change regarding the MME thresholds or just to have it be reflected as a group who stated it that there is a threshold, but there are some nuances in that threshold.

Dr. Staffa said while it is not clear that the data support these thresholds, the data do support the continuous measure of increasing daily dose along with a number of other factors, which clearly needs to be assessed for patients. Perhaps they should drive the thinking in a direction that may be a more helpful way of thinking about patients, their own situations, and how their own risk factors contribute to that risk—combined with their daily dose. Including numbers again that were based on arbitrary cutoffs from researchers lend themselves very well to policies that are not patient-centric. Given that the committee and CDC are trying to support more patient-centered decision-making, perhaps removing the concept of thresholds at all and talking about daily dose and how to consider it in a different way may be helpful.

Dr. Cunningham agreed and noted that this aligned with the observations from the OWG. She was not clear about the conversation they were having in terms of whether it was about adoption of the observation and the report as a whole, or if they were meant to go into particular aspects of the report that they were asked to comment on.

Dr. Bonomi indicated that her understanding was that the BSC could vote to endorse as is or vote to endorse with minor amendments and these considerations can be included should the CDC choose to make the revisions. She called upon Dr. Greenspan for further input.

Dr. Greenspan confirmed that the task for the BSC was now to vote on whether to endorse the OWG's report in its entirety, and determine whether there were any parts of the report that the BSC did not want to endorse or wished to be amended. The considerations, report, and recommendations from the BSC would then go to the CDC and the HHS Secretary to consider as they are revising the Guideline. The BSC's task was to endorse, or not, the OWG's report based on their review of the Guideline—not the Guideline itself.

Dr. Pacula echoed her thanks to the public speakers for sharing their stories and assured those who spoke who feel a sense of despair because there is a lack of understanding from the 20 members of their experiences that some of them do live with those same experiences, whether themselves or with their immediate family members, and that has been motivation for doing the research that they do. She also echoed the sentiments expressed by Dr. Staff about the specifics regarding the MMA thresholds. From a scientific perspective, using a continuous measure for understanding dosage and the concerns in increasing dosage, in particular situations not all situations, is warranted to raise as a decision that should be taken seriously as opposed to heeding what is known to be poor science regarding no harm from doing that. That does not mean that it should be done. It means that it needs to be considered scientifically on a case-by-case basis. She thought that was echoed in the recommendations made by the OWG. In terms of endorsing this or not, she noted that she was mindful of the fact that this is a problem that pertains to the following analogy. There is a spigot flowing into a pool and the pool is overflowing with use. The use of the swimming pool is great and needed until it is overflowing and causing damage everywhere. There are two problems that these guidelines are trying to address, this spigot being turned on and the genuine need to have some people in that pool that are appropriate for the pool. She thought the members of the BSC reading the guidelines clearly understand that there are recommendations for acute new opioid naïve users that are appropriate. Some statements were made that there has been good done by past 2016 recommendations—so that spigot problem. But it has done harm to the people in the pool. She found the recommendations to be mindful of both of those purposes. In order to endorse this going forward, the BSC members need to be mindful of how the guidelines got misinterpreted in the past, which has been clearly echoed. Maybe one of the recommendations they as a board could make would be for the CDC to do a better job of intervening when the interpretation of the guidelines is focused on the pool rather than the spigot and inappropriately so on the pool. It is not just a matter of creating the guidelines and putting them out there, but that constant education that she heard Acting Director Jones reference, that perhaps they could do a better job so that it is not so commonly misinterpreted.

Hearing no further discussion, **Dr. Bonomi** indicated that she would entertain a motion. **Dr. Greenspan** indicated that only BSC members could motion and vote.

Dr. Compton pointed out that *ex officio* means a member of a committee based on his/her role or job—it does not mean non-voting.

Dr. Cattledge confirmed that the voting protocol is set forth in the NCIPC BSC charter, which indicates that members vote and *ex officios* and federal partners are non-voting members. If there are not at least 10 BSC members present, then the *ex officios* can vote.

Dr. Compton requested that the minutes reflect "*ex officio* and non-voting" because it is unclear and atypical for the definition of *ex officio*, though he did indicate that he considered this to be a minor point.

Motion / Vote

Dr. Liller made a motion, which **Dr. Cunningham** seconded, to endorse the Opioid Workgroup (OWG) report and the considerations and observations of the recommendations made and discussed by the BSC during this meeting. The motion carried unanimously with no abstentions.

Motion / Vote

Dr. Ondersma made a motion, which **Dr. Pacula** seconded, to sunset the Opioid Workgroup (OWG) as the work of this group has concluded. The motion carried unanimously with no abstentions.

Closing Comments / Adjournment

Dr. Bonomi thanked Dr. Cunningham and her team for the incredibly hard work they undertook to ensure a comprehensive report. She thanked everyone for participating in this meeting and reminded all BSC members and *ex officios* to send an email to Mrs. Tonia Lindley stating that they participated in this meeting, including the date and a note about how they voted for each motion to ensure that both votes were captured completed. She thanked the CDC Audio Technician, Cambridge Communications, and On Par Productions. This meeting would not have been possible without the CDC staff, including Mrs. Tonia Lindley, Dr. Arlene Greenspan, Dr. Gwen Cattledge, and Mr. Victor Cabada. The next BSC meeting will be held on July 29, 2021.

With no announcements made, further business raised, or questions/comments posed, **Dr. Bonomi** thanked everyone for their attendance and participation, wished everyone a wonderful weekend, and officially adjourned the Thirty-Sixth meeting of the NCIPC BSC at 5:00 PM.

Certification

I hereby certify that to the best of my knowledge, the foregoing minutes of the July 16, 2021 NCIPC BSC meeting are accurate and complete:

September 29, 2021

Date

Amy Bonomi, PhD, MPH
Co-Chairs, NCIPC BSC

September 29, 2021

Date

Chinazo Cunningham, M.D., M.S.
Co-Chairs, NCIPC BSC

Attachment A: Meeting Attendance

NCIPC BSC Co-Chairs

Dr. Amy Bonomi, PhD, MPH
Co-Chair, NCIPC BSC
Faculty Affiliate, Harborview Injury Prevention and Research Center, University of Washington, and
Founder, Social Justice Associates
Michigan State University

Chinazo Cunningham, MD, MS
Co-Chair, NCIPC BSC
Executive Deputy Commissioner
NYC Dept. of Health and Mental Hygiene

NCIPC BSC Co-Executive Secretaries

Gwendolyn Cattledge PhD, MSEH
Deputy Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Arlene Greenspan, DrPH, MPH
Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

NCIPC BSC Members

Roger Chou, MD
Professor of Medicine, Oregon Health and Science University
Departments of Medicine, Medical Informatics and Clinical Epidemiology

Wendy Ellis DrPH, MPH
Assistant Professor, Global Health
The George Washington University
Founding Director, Center for Community Resilience

Frank A. Franklin, II, PhD, JD, MPH
Principal Epidemiologist and Director
Community Epidemiology Services
Multnomah County Health Department

Frank Floyd, MD, FACP
Medical Director
United Health Service Medical Group

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Julie Eschelbach	Aisha Mahmood	Diakima Thomas-Davis
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Valerie Godoshian	Melissa O'Grady	Shannon Woodward
Rose Gomez	Kierstyn Oldham	LCDR Marcienne Wright, PhD
		Kun Zhang

Public Attendees

Taiwo	Omirinde	A Better You
Arlene	Remick	ACOG
Tom	Norris	ACPA
Jennifer	Hoque	ACS CAN
Kirsten	Tullia	AdvaMed
David	Davido	Advanced Energy
Cammie	LaValle	Advocate
Robert	Vangelisti	Advocate Bob
Marie	Cleary-Fishman	AHA
Verena	McGinnis	Alexandria VA
Amy	Goldstein	Alliance to Advance Comprehensive Integrative Pain Management
Lynn	Martin	Allscripts Healthcare LLC
Bryn	Rhodes	Alphora
Daniel	Blaney-Koen	AMA
Linda	Paul	American Academy of Pediatrics
Britinia	Galvin	American Academy of Physical Medicine and Rehabilitation
Adam	Horgan	American Association of Nurse Practitioners
April	Kapu	American Association of Nurse Practitioners
Jeanne	Tuerk	American Association of Oral and Maxillofacial Surgeons
Angel	Mason	American Chronic Pain Association
Jeffrey	Davis	American College of Emergency Physicians
Ryan	Crowley	American College of Physicians
Angela	Mickalide	American College of Preventive Medicine
Alonso	Carrasco-Labra	American Dental Association Science & Research Institute
Amanda	Latimore	American Institutes for Research
Amy	Cadwallader	American Medical Association
Sandy	Marks	American Medical Association
Bobby	Mukkamala, MD	American Medical Association
Brian	Williams	American Medical Society for Sports Medicine
Sana	Syed	American Muslim Health Professionals
Aroona	Toor	American Muslim Health Professionals
Anne	Burns	American Pharmacists Association
Matthew	Goldan	American Society of Anesthesiologists
Ashley	Walton	American Society of Anesthesiologists

Kylie	Clark	Americorps
Barbara	Marino	Angel’s Medical Clinic
Joseph	LaCavera	AOA
Lois	Trakas-Zaremba	APCA Group led by Angel Mason
Shirley	Buck	APDF
Jessamyn	Butler	APDF
Les	Fisher	Apha icehs section
DENISE	MOLOHON	Arachnoiditis Society For Awareness & Prevention
David	Harden	Arizona Dept. of Health Services/Bureau of EMS & Trauma System
Jessica	Pough	Association of State and Territorial Health Officials
Marcus	Plescia	ASTHO
Richa	Ranade	ASTHO
Rachel	Redding	ASTHO
Sis	Rock	ATIP
Kathleen	McFadden	Atlantic Prevention Resource
Avrom	Brown	Avrom S Brown, DO, FAAFP, FIAIME
Adrienne	Shapiro	Axis Advocacy
Barabra	White	BA
Mancia	Ko	BDSI
Beth	Larson	Beth
SAGIE	DE GUZMAN	BEVERLY HOSPITAL
Gabrielle	Nichols	Big Cities Health Coalition
Stefan	Kertesz	Birmingham VA Medical Center
Amanda	Bishop	Bishop Consulting
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Francie	Killebrew	Brunet-Garcia
Rachel	Bruce	Brunet-Garcia
Kimberley	Collins	Brunet-Garcia
Eugenia	Johnson	Brunet-Garcia
Francie	Killebrew	Brunet-Garcia
Petalia	Johnson	Brunet-Garcia Advertising, Inc.
Louis	Kattie	BryteHealth
Justin	Minyard	BSC
Rebekah	Tamburine	BSW Sunnyvale
Anna	Zepeda	Butte County Public Health

Stephanie	Wallace	Cambridge Communications & Training Institute (CCTI)
Victoria	Albright	CamBright Research
Tom	Hayashi	caregiver/advocate
Pat	Corley	Cayenne Wellness/Axis Advocacy
Archana	Vedavyas	CB STRAT
Alexander	Tin	CBS
Grace	Mbuya	CHC
Sarah	Diwan	Chicago ACPA Support Group
John	Keilman	Chicago Tribune
Natalia	Pane	Child Trends
Koa	Kai	Chronic Disease Coalition
Lauren	DELUCA	Chronic Illness Advocacy & Awareness Group, Inc.
Renee	Blare	Chronic Pain Alliance of the West
Janet	Clendenin	Chronic Pain Patient
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Lori	Ravelli	Chronic Pain Patient
Annie	Shoger	Chronic Pain Patient
Veronica	Kramer	Chronic Pain Patient Advocate
Lynda	Rollins	Chronic Pain Patient Outreach
Steven	Maniaci	CIAAG
Leah	LoneBear	CIAAG.net
William	Sims	CMS
Lynn	Thorpe	CMS
Mia	Hunter	Coalition Of Health Services Inc (TX) (2820)
Steven	Passik	Collegium Pharmaceuticals
Cheryl	Hale	Comanche County Memorial Hospital
Carol	Benack	CPP News Source
Leah	Sies	Cppns
Eryn	Pandorican	CPPUNITED
Katherine	Ventura	CRPS Sufferer
Johnathan	Duff	CRS
Shahnaj	Safi	CSTE
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Jane	Gallup	Don't Punish Pain Rally (DPPR)
Misty	Hoffman	Don't Punish Pain Rally (DPPR)
Brooke	Kocher	Don't Punish Pain Rally (DPPR)
Paula	Lehmann	Don't Punish Pain Rally (DPPR)
Bev	Schechtman	Don't Punish Pain Rally (DPPR)
Andrea	Ortiz	Don't Punish Pain Rally (DPPR)
Beverly	Diaz	Don't Punish Pain Rally (DPPR)
Gordon	Ess	Don't Punish Pain Rally (DPPR)
Lauren	Nava	Don't Punish Pain Rally (DPPR)
Sandi	Slezak	Don't Punish Pain Rally (DPPR)
Nancy	Wheeler	Don't Punish Pain Rally (DPPR)
Syndee	Damrosch	Don't Punish Pain Rally (DPPR) C-50 AP&DF
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Bryan	Ruggery	Drug Enforcement Administration (Contractor)
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Jessica	Hill	DVP, CDC
Sheryl	Heron	Emory
Pamela	Curtis	End Pain Stigma
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Joseph	Kramer	Families for Intractable Pain Relief
Kristen	Ogden	Families for Intractable Pain Relief
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Nancy	Chang	Food and Drug Administration
Ling	Chen	Food and Drug Administration

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Jana	McAninch	Food and Drug Administration
Tamra	Meyer	Food and Drug Administration
Sheheryar	Muhammad	Food and Drug Administration
Mallika	Mundkur	Food and Drug Administration
Bic	Nguyen	Food and Drug Administration
John	Rhee	Food and Drug Administration
Victoria	Sammarco	Food and Drug Administration
Amy	Seitz	Food and Drug Administration
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Michael	Weiss	Food and Drug Administration
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Menglu	Yuan	Food and Drug Administration
Christina	Greene	Food and Drug Administration
Danielle	Molnar	Food and Drug Administration
Caroline	Huang	Food and Drug Administration
Catherine	Dormitzer	Food and Drug Administration CDER OSE
Jennifer	Naples	Food and Drug Administration OSE DPV-II
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Rebecca	McCray	Freelance reporter
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Adriane	Fugh-Berman	Georgetown University Medical Center
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Kathleen	Marriott	Health Professionals for Responsible Opioid Prescribing

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Rosie	Gomez	HHS - ACF
Costas	Miksis	HHS/ACL
Mera	Choi	HHS/ONC
JaWanna	Henry	HHS/ONC
Lolita	Kachay	HHS/ONC
Stacy	Perchem	HHS/ONC
Jon	doe	High Impact Pain
Nancy	Rene	HOPE Foundation LA South Chamber of Commerce
Lillian	Ramírez-Cruz, MSN	Hospital Menonita Guayama
Diane	Pilkey	HRSA
Lennon	Maclean	Human Being
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Chris	Freedman	Maximus
Elizabeth	Habermann	Mayo Clinic

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Annette	Maxwell	Mings Healthcare Repair
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Helen	Rich	N/A
Martha	S	N/A
CHERYL	SCRIBNER	N/A
Bill	Slezak	N/A
Amy	Stevens	N/A
Melanie	Baccus	N/A
Randy	Cabral	N/A
Dee	Smith	N/A
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Deborah	Tucker	National Center on Domestic and Sexual Violence
Kristin	McGarity	National Council on Independent Living
Courtney	Wheeler	National Indian Health Board
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Leslie	Bythewood	National Pain Council
Joy	Maxwell	National pain Council, don't punish pain rally
Jennifer	Werth	National Safety Council
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Jamie	Osborne	NIOSH
Michael	Rieders	NMS Labs
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Tami	Caldwell	None
Jeanie	Clemens	None
Tracie	Dixon	None
Janice	Garland	None
Troy	Haslam	None
Ruth/john	Koznecki	None
Kari	Kruska	None
Penny	Kunkel	None
Serina	Matteson	None
Dena	McGugan	None
Candi	P	None
Melissa	Quackenbush	None
Svetlana	Shargorodskaya	None
DAWN	VEEK	None
Robin	Washburn	None
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Melissa	Ringer	Not Available
Andrea	Anderson	NPAC
Lelena	Peacock	NPAC
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Lisa	Papa	NYS DOH DITC
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Kate	Nicholson	Opioid Workgroup
Larissa	Joassaint	ORAU

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Wendy	Sinclair	Oregon Pain Action Group
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Chad	Kollas	Orlando Health
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Tamera Lynn	Stewart	P3Alliance
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Jacqueline	Schneider	PA ACIP (PA Alliance for Chronic Illness & Pain)
Ashley	Rodgers	Pa Alliance for Chronic Illness and Pain
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Michael	April	Pain & Injury Ctr Greater Washington
DP		Pain Advocacy Coalition
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Pat	Anson	Pain News Network
Katherine	APARICIO	Pain Patient
Celinda	Colling	Pain Patient
Xav	Kovaks	Pain Patient
Gena	Struna	Pain patient advocate
Ishwaria	Subbiah	Palliative Care physician
Heather	Covey	Patient
Kathy	Fleming	Patient
Lynne	Hall	Patient
Carrie	Judy	Patient
Susan	Leighton	Patient
Heather	Whitehurst	Patient
Richard	Lawhern	Patient Advocacy - An Informal Collaborative Network
Kathy	Sapp	Patient Mind Inc.
Ann	Cataldo	Patients
Mary	Wade	Paulding County School District
Scot	Faulkner	PBM Foundation
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Sandi	Massingill	Personal
James	Spurling	Personal

Gregory	Suskind	Personal
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Judy	Butler	PharmedOut
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Alan	Rozen	Platinum Palliative Care, LLC
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Jim	Feelely	POV Media
Nancy	Crudele	PPLP
Leslie	Barker	PPU
Shawn	Boyne	Private Citizen
Felix	Brizuela	Private Solo Practice
Remy	La'Sapienza	Public Health Research
Emmetta K	Harris	Public Health/Black Infant Health
Kelly	Arthur	Qlarant
John	Gallagher	Quality Insights
Deborah	Vick	RareABILITY
Douglas	McVay	Real Reporting Foundation
Michelle	Caccamisi	Registered Nurse
Weston	Kaszer	Research College of Nursing
Jay	Kuchera	Resolute
Cathy	Callaghan	Retired
Richard	Draut	Retired CDC contractor
Wendy R	Burnett	Retired OTR, CHT
Lisa	Kronus	RN
Kelly	Brooks	RSD Sisters
Joshua	Borg	RSDSA
Sheryl	Freed	RSDSA
Julie	Keenan	RSDSA
Jessica	Cance	RTI International
Bhupinder	SINGH	RUMC
MURIEL	BRAZEAU	Safe haven
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Amy	Partridge	Self
Cindy	Ali	Self
Caroll	Arevalo	Self
CHARLES	BEYER	Self
Fred	Brown	Self
Victor	Cabada	Self
Joel	Cohen	Self
Julie	Glatczak	Self
Irene	Hansen	Self
Darren	Hill	Self
Edward	Ivy	Self
Gabrielle	Johnston	Self
Wendy	McAninch	Self
Roger	Minton	Self
Megan	Rivera	Self
Walter	Wrenn	Self
Sara	Gehrig	Self-Employed
Donna	Zucker	Self-Patient Nurse IP Diagnosis 33yrs
Francine	Prescott	Sgu
Lewis	Hsu	Sickle Cell Disease Association of America
Amy	Bonomi	Social Justice Associates
Doreleena	Sammons Hackett	Society for Public Health Education
Brett	Opie	SOLVD Health
Beth	Darnall	Stanford
Carol	Jacoby	Starshine Advocacy
Fusheng	Wang	Stony Brook University
Christina	Creech	STOP Inc.
Louise	Schwartz	Stop the Pain
Teresa	Murphy	Strategic Solutions
Louise	Bryde	Stroudwater Associates
Abdel-Halim	Ahmed	Student - GIMPA
Galaxy	J7 Sky Pro	Swan Studio
Kimberly	Rockwell	Teladoc
Terri	Lewis	Terri Lewis Consultant
Robert	Fortier	The American Chronic Pain Association
Stacey	Fields	The National Chronic Pancreatitis Support Network
Valarie	Pompey	The Ohio State University
Hannah	Kelman	Thorn Run Partners
Ron	Phelps	Traders Plus
Jill	Duggins	Treatment Associates, Inc.

Jenifer	Stevens	Twisted Sisters
Cindy	Steinberg	U.S. Pain Foundation
Anne	Fuqua	UAB
Qing	Li	UC Denver
Mark	Kaplan	UCLA
Deanna	Ferrell	UDOH
Frank	Floyd	UHS
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Laisha	Blair	University of Colorado Denver - NURS 6070 Policy and Politics in Health Care Student
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Lindsey	Hammerslag	University of Kentucky
Monica	Roberts	University of Kentucky
Mary	Sau	University of Kentucky
Svetla	Slavova	University of KY
Mark	Bicket	University of Michigan
Stephen	Marshall	University of North Carolina Injury Prevention Research Center
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Michelle	Shirey	University of Pittsburgh
Jeanne	Sears	University of Washington
Gregory	Terman	University of Washington
William	Simmons	UPS
Tamara	Haegerich	US Department of Veterans Affairs
Wendy	Bullock	US Pain Foundation
Gwenn	Herman	US Pain Foundation
Gwenn	Herman	US Pain Foundation
Paula	Perry	US Pain Foundation
Maria	Padilla	US Pain Foundation volunteer.
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Karen	Liller	USF
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Sherrie	Pace	Utah Poison Control Center
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Gabriel	Pimsler	Venn Strategies
Andrew	Friedman	Virginia Mason Medical Center/AAPM&R
Anns	Phelps	Volunteer
Laura	Veach	Wake Forest School of Medicine
Barbara	Hastie	Walther Global Palliative Care & Supportive Oncology
Rose	Bigham	Washington Patients in Intractable Pain
Gary	Franklin	Washington State Department of Labor and Industries

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Attachment B: Acronyms Used in this Document

Acronym	Expansion
AANP	American Association of Nurse Practitioners
AAPM	American Academy Of Pain Medicine
ABAM	American Board of Addiction Medicine
ACEs	Adverse Childhood Experiences
ACF	Administration for Children and Families
ACPA	American Chronic Pain Association
ADL	Activities of Daily Living
ADS	Associate Director for Science
AHRQ	Agency for Healthcare Research and Quality
AoA	Administration on Aging
APDF	American Pain & Disability Foundation
APHA	American Public Health Association
ASAM	American Society of Addition Medicine
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology
ATSDR	Agency for Toxic Substances and Disease Registry
BCBS	BlueCross BlueShield
BSC	Board of Scientific Counselors
BRFSS	Behavioral Risk Factor Surveillance System
CARA	Comprehensive Addiction and Recovery Act
CBO	Community-Based Organization
CCTI	Cambridge Communications and Training Institute
CDC	Centers for Disease Control and Prevention
CFTF	Child Fatality Task Force
CHIP	Children’s Health Insurance Program
CIAAG	Chronic Illness Advocacy & Awareness Group, Inc.
COI	Conflict of Interest
CPAW	Chronic Pain Alliance of the West
CRPS II	Complex Regional Pain Syndrome Type II
DEA	Drug Enforcement Administration
DEI	Diversity, Equity, and Inclusion
DELTA	Domestic Violence Prevention Enhancement and Leadership Through Alliances
DFO	Designated Federal Official
DIP	Division of Injury Prevention
DOJ	Department of Justice
DOP	Division of Overdose Prevention
DPPR	Don’t Punish Pain Rally
DVP	Division of Violence Prevention
EDS	Ehlers-Danlos Syndrome
EMS	Emergency Medical Services
EPC	Evidence-based Practice Center
EpiAid	Epidemiologic Assistance
ERPO	Extramural Research Program Office
ET	Eastern Time
FACA	Federal Advisory Committee Act

Acronym	Expansion
FASTER	Firearm Injury Surveillance Through Emergency Rooms
FBI	Federal Bureau of Investigation
FBSS	Failed Back Surgery Syndrome
FRN	Federal Register Notice
FY	Fiscal Year
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
GUMC	Georgetown University Medical Center
HHS	(Department) Health and Human Services
IHS	Indian Health Service
IPV	Intimate Partner Violence
JAMA Network Open™	*Journal of the American Medical Association Network Open™*
MACPAC	Medicaid and CHIP Payment and Access Commission
MAT	Medication-Assisted Treatment
MDMA	Medical Device Manufacturers Association
ML	Machine Learning
MME	Morphine Milligram Equivalent
MSI	Minority-Serving Institution
NASEM	National Academies of Science, Engineering, and Medicine
NPAC	National Pain Advocacy Center
NCHS	National Center for Health Statistics
NCIPC	National Center for Injury Prevention and Control
NCCN	National Comprehensive Cancer Network®
NEJM	*New England Journal of Medicine*
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIOSH	National Institute for Occupational Safety and Health
NLP	Natural Language Processing
NOFO	Notice of Funding Opportunity
NORD	National Organization of Rare Diseases
NP	Nurse Practitioner
NPC	National Pain Council
NSAID	Non-Steroidal Anti-Inflammatory Drug
NVDRS	National Violent Death Reporting System
OPM	Office of Personnel Management
OPP	On Par Production
OUD	Opioid Use Disorder
OWG	Opioid Workgroup
PA	Physician Assistant
PCSS	Providers Clinical Support System
PDMP	Prescription Drug Monitoring Program
PICORI	Patient-Centered Outcomes Research Institute
PHN	Post-Herpetic Neuralgia
PBM	Photobiomodulation
PROP	Physicians for Responsible Opioid Prescribing
PT	Physical Therapy

Acronym	Expansion
PTSD	Post-Traumatic Stress Disorder
QoL	Quality of Life
RCT	Randomized Controlled Trials
RDLA	Rare Disease Legislative Advocates
RSDSA	Reflex Sympathetic Dystrophy Syndrome Association
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIR	Small Business Innovation Research
SDOH	Social Determinants of Health
SME	Subject Matter Experts
SOGI	Sexual Orientation and Gender Identity
SV	Sexual Violence
US	United States
USPHS	United States Public Health Service
YV	Youth Violence

Attachment C: Written Comments

From: abembenek2
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 3:19:14 AM

As a long time chronic pain patient, with a rare neurotube defect, that was cut off all prescription painkillers in 2017, I need to stress that pain didn't go away because some patients were over prescribed. I am still in such a level of pain, that suicide has been a serious consideration.

I never once failed a drug test, ask for a "replacement" prescription, or for an increase in dosage. I've been to physical therapy, tried alternative medications, and went from having a functioning life, to rarely spending more than an hour or two at a time out of bed. When asking about possibly being prescribed some painkillers, not even for daily use, I'm marked as drug seeking and an addict. After over 3 years of suffering. The pain management clinic system in my half the state went bankrupt, leaving no place to even be referred to.

Pain is real. Yes, painkillers should be monitored, but I have done everything ever ask of me, and still I suffer. My condition is incurable. I have no issues with mandatory drug tests, more physical therapy, and any other treatment that may help, but short of a miracle, I will be in debilitating pain for the rest of my life. I'm a victim of the opioid crisis, not a cause.

Compassion and common sense should be part of the new guidelines. Instead of making doctors scared of loosing their licenses, and leaving patients like myself with no hope of ever having a functional life again. I beg you to take people like myself into consideration when drafting the new guidelines. No patient should have to choose between endless suffering, or ending their life. Doctors should not be afraid to write a prescription that is in the best interest of their patients. Because companies put profits over patient care, and some bad seeds were too ready to treat everything with a painkiller, I suffer. I did nothing wrong and cannot be cured. And I suffer. I can't believe that is the goal of the guidelines, and yet that is the result. What do people like me do? Or has it become a culture of survival of the fittest, and I don't qualify? When did my life stop mattering? While I've been abandoned by the healthcare system that is supposed to do no harm.

Please let me have some sort of functional life back, instead of punishing me for having chronic pain I neither want or did anything wrong in seeking relief for. Because I have no life, and I'm being punished for not my actions, but the actions of others.

Sincerely,

Anne Bembenek
7743 Krause Lane
Almond Wisconsin 54909

Sent from the all new AOL app for iOS

From:	Angee B
To:	NCIPCBSC (CDC)
Subject:	Updated Draft Opiod Prescribing Guidelines
Date:	Friday, July 23, 2021 4:23:48 PM

To Whom It May Concern,
My name is Angela Biney and suffer from many chronic illnesses three of which cause me pain. Fibromyalgia, Lupus SLE, and Gastroparesis. Due to the negative stigma of opiods and the discrimination I faced for being on them I was forced to wean myself off. I now have no options for pain relief because NSAIDS are contraindicated for my Kidney Disease.
These proposed guidelines sre necessary because everyone is different snd deserves different considerations. Living with chronic pain daily is debilitating and we need releif. Free of stigma and flexible. Our government can not continue to allow everyone to suffer for the actions of a few. Thank you for taking the time to consider my comment.
Angela Biney

From: Anita Borthwick
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:10:57 PM

Being a ANA+ Polyarthritis, Sjogrens, Degenerative Disc Disease, Multifocal Headache Syndrome, Major Depressive Disorder, General Anxiety Disorder patient, I can no longer get the relief from opioids that I need. I am in excruciating pain on a daily basis. I live at a 6-7/10 pain rating on a daily basis. That's as low as I get with the regime I am on at this time. I am no longer reliable to work any kind of job. However, I have been denied disability. My daughters are 21 and 19. I can no longer go do things with them to make memories. I have had no positive results from alternative sources to decrease pain.

Please consider patients like me who are also in excruciating pain on a daily basis and get no relief. Pain is pain, no matter what patient it is diagnosed with. It is imperative that the guidelines include patients such as myself. Our suicide rate is increasing daily because people can no longer live with the pain they are afflicted with.

Thank you for your time and consideration,

Anita Borthwick
Pain patient without relief
--
Anita

From: conover@preventopioidabuse.org
To: NCIPCBSC (CDC)
Subject: POA.OEFA.CDC Guideline Comment
Date: Friday, July 23, 2021 4:55:20 PM
Attachments: CDCGuideline.Comment.POA.OEFA.pdf

Hello,

Attached please find a comment on the CDC Opioid Prescribing Guideline from Elaine Pozycki, Chair and Founder of the Opioid Education Foundation of America and Prevent Opioid Abuse.

Thank you,

Angela Conover

PREVENT
OPIOID ABUSE

PREVENTION EDUCATION KNOWLEDGE
OPIOID
EDUCATION FOUNDATION
OF AMERICA

July 23, 2021

Dr. Chinazo Cunningham
Chair of the Opioid Workgroup of the Board of Scientific Counselors
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
VIA Email

Dear Dr. Cunningham:

On behalf of Prevent Opioid Abuse and the Opioid Education Foundation of America, I am writing to provide comments on the update to the 2016 Guideline for Prescribing Opioids.

These guidelines are important and lifesaving recommendations to help prevent opioid dependency and addiction.

There isn’t a family or community untouched by the opioid crisis, including my own. And, like so many other families, my son was introduced to opioids through a prescription from his doctor after a sports injury, which ultimately led to his dependency, addiction, and death.

I urge the Centers for Disease Control and Prevention to include in the guidelines the requirement for a conversation informing all patients, and/or the parents of patients, of the potential for dependency and addiction to an opioid. It is vital this discussion occurs before an opioid is prescribed, and it must include information to make patients aware of alternatives to opioids that exist for their acute pain.

These conversations can help reduce the number of new opioid prescriptions written, whether for a broken hand, wisdom tooth extraction or any other acute pain, as evidenced by research. They will also help to identify the signs and symptoms of dependency and encourage patients to properly secure these powerful drugs within the home to prevent diversion.

Every American has the right to be warned about the highly addictive qualities of opioids, as well as effective non-opioid pain relief alternatives, and to receive this information at the time it is most needed: right before an opioid is prescribed. I once again urge the CDC to include patient notification and discussion of alternatives to the updated guidelines.

Sincerely,

Elaine Pozycki
Founder and Chairwoman
Prevent Opioid Abuse and Opioid Education Foundation of America

From: Abbie Cunha
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:13:53 PM

I suffer from Persistant idiopathic facial pain since 2004 been on n off pain medication through out the years it comes n goes pain medication plus Lyrica is the only thing that makes me able to function through out my day I’m 68 heading for a back fusion also there r times in my life where I asked God to take me my facial pain is also referred to as suicide pain please don’t stop doctors from treating us that need pain control thank you

From:	Adam Horgan
To:	NCIPCBSC (CDC)
Cc:	Frank Harrington
Subject:	AANP Comments
Date:	Friday, July 23, 2021 10:08:48 AM
Attachments:	AANP CDC Opioid Prescribing Comment.docx

Good morning,

On behalf of the American Association of Nurse Practitioners, attached are comments in reference to the opioid working group observations. We appreciate your consideration of these comments, and if there is any further information we can provide, please let us know.

Adam Horgan
Regulatory Affairs Analyst
American Association of Nurse Practitioners
1400 Crystal Drive, Suite 540
Arlington, VA 22202
ahorgan@aanp.org

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July 21, 2021

U.S Department of Health and Human Services
Public Health Services Board of Scientific Counselors (BSC)
Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control (NCIPC)

RE: Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids

To whom it may concern,

The American Association of Nurse Practitioners (AANP), on behalf of the over 325,000 nurse practitioners (NPs) across the nation, appreciates the opportunity to provide comment on the observations of the opioid workgroup on the updated CDC guideline for prescribing opioids. As you are aware, NPs provide a substantial portion of pain management to patients across all care settings, and we appreciate the inclusion of NPs in these observations. We also appreciate your continued commitment to engaging with stakeholders on this important topic and look forward to continued engagement with the CDC.

NPs are advanced practice registered nurses who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and backgrounds. Daily practice includes assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs hold prescriptive authority in all 50 states and the District of Columbia (D.C.) and perform more than one billion patient visits annually.

NPs practice in nearly every health care setting including hospitals, clinics, Veterans Health Administration and Indian Health services facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), skilled nursing facilities (SNFs) and nursing facilities (NFs), schools, colleges and universities, retail clinics, public health departments, nurse managed clinics, homeless clinics, home health care settings and mental health facilities.

Nurse practitioners provide a substantial portion of the high-quality[1], cost-effective[2] care that our communities require. As of 2019, there were more than 163,000 NPs billing for Medicare services, making NPs the largest and fastest growing Medicare designated provider specialty.[3] Approximately 40% of Medicare patients receive billable services from a nurse practitioner[4] and approximately 80% of NPs are seeing Medicare and Medicaid patients.[5] NPs have a particularly large impact on primary care as approximately 70% of all NP graduates deliver primary care.[6] In fact, NPs comprise approximately one quarter of the primary care workforce, with that percentage growing annually.[7]

The pharmacodynamics, therapeutics and management of controlled drugs including opioids is an integral part of both baccalaureate and graduate advanced practice nursing education. NPs are qualified pain

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[1] https://www.aanp.org/images/documents/publications/qualityofpractice.pdf.
[2] https://www.aanp.org/images/documents/publications/costeffectiveness.pdf.
[3] https://www.cms.gov/files/document/2019cpsmdcrproviders6.pdf
[4] https://www.cms.gov/files/document/2019cpsmdcrphyssupp6.pdf
[5] NP Fact Sheet (aanp.org)
[6] 6 https://www.aanp.org/about/all-about-nps/np-fact-sheet.
[7] 7 Rural and Nonrural Primary Care Physician Practices Increasingly Rely On Nurse Practitioners, Hilary Barnes, Michael R. Richards, Matthew D. McHugh, and Grant Martsolf, Health Affairs 2018 37:6, 908-914.

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management practitioners who have the clinical preparation to provide excellent health care across practice settings to patients suffering from a wide range of conditions involving acute and chronic pain. NPs are educated in pharmacologic, pathophysiologic, psychologic, and sociologic aspects of pain management that includes the diagnosis and treatment of patients with addictive diseases.

We appreciate the considerations of the workgroup and agree with members who stressed the importance of guiding principles such as addressing health equity and creating patient and clinician centered guidance. NP-led care focuses on treating the whole patient, including the integration of primary care, behavioral health, and the importance of both opioid and nonopioid medications. As providers of care in rural areas and areas of lower socioeconomic and health status, NPs understand and address issues of health equity as part of their daily practice.[8],[9],[10] Below are our comments on specific recommendations from the workgroup.

Recommendation #1: *Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient. (Recommendation Category: A; Evidence Type: 3)*

We generally agree that nonopioid medications and treatments should be used as first line therapy to treat pain and that all clinicians should understand the use of nonopioid medications and treatments in the management of pain. Use of nonopioid alternatives can lead to a decrease in opioid use and subsequent addiction. We also agree that addressing insurance coverage policies should be a priority for increasing access to alternate treatments such as complementary and integrative health care.

Unfortunately, many non-pharmacological therapies for chronic pain are not covered by the Medicare and Medicaid programs. Thus, clinicians have difficulty prescribing complementary and integrative health care modalities due to a lack of available payment options. Treatments such as acupuncture and therapeutic massage should be available for patients who seek non-opioid treatments for their chronic pain, but without Medicare or Medicaid coverage they cannot afford to obtain these treatments. Recommending the coverage of these treatments in the Medicare and Medicaid programs and through commercial payers, would increase utilization of these alternative treatments. These recommendations should be consistent among all applicable entities (e.g. health plans, CMS, FDA) to increase the availability of non-pharmacologic pain treatments.

Recommendation #2: *Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate. (Recommendation Category: A, Evidence Type: 3)*

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[8] Davis, M. A., Anthopolos, R., Tootoo, J., Titler, M., Bynum, J. P. W., & Shipman, S. A. (2018). Supply of Healthcare Providers in Relation to County Socioeconomic and Health Status. Journal of General Internal Medicine, 4–6. https://doi.org/10.1007/s11606-017-4287-4.

[9] Xue, Y., Smith, J. A., & Spetz, J. (2019). Primary Care Nurse Practitioners and Physicians in Low-Income and Rural Areas, 2010-2016. Journal of the American Medical Association, 321(1), 102–105.

[10] Andrilla, C. H. A., Patterson, D. G., Moore, T. E., Coulthard, C., & Larson, E. H. (2018). Projected Contributions of Nurse Practitioners and Physicians Assistants to Buprenorphine Treatment Services for Opioid Use Disorder in Rural Areas. Medical Care Research and Review, Epub ahead. https://doi.org/10.1177/1077558718793070

We agree with the importance of clinicians discussing treatment options, goals, and strategies to initiate or discontinue opioids with their patients and ensuring that patients are educated and involved in their clinical decision making, as well as the importance of including other therapies in a patient's treatment, as appropriate. This is an essential component of the patient-centered health care practiced by nurse practitioners.

Recommendation #12: *Clinicians should offer or arrange treatment with medication for patients with opioid use disorder. (Recommendation Category: A, Evidence Type: 2)*

We agree with increasing access to medication-assisted treatment (MAT) for patients with opioid use disorder (OUD) and recommend that the guidelines reference the importance of including counseling and behavioral health in this treatment. With the passage of CARA in 2016, NPs were temporarily authorized to provide MAT for the treatment of OUD after taking the necessary training and obtaining a DEA waiver. Since CARA passed, SAMHSA has reported that over 20,000 NPs have obtained a MAT waiver. This was recognized by Congress in the SUPPORT Act by making the authorization for NPs to obtain MAT waivers permanent. MAT has been proven to be an important treatment regimen that decreases opioid use, opioid related deaths, criminal activity, and infectious disease transmission.[11]

Studies have found that NPs have greatly increased access to MAT in rural and underserved communities, but that restrictive practice environments in some areas are associated with fewer NPs being able to obtain MAT waivers.[12] In rural communities, NPs or physician assistants were the first waivered clinicians in 285 rural counties covering 5.7 million residents.[13] The Medicaid and CHIP Payment and Access Commission (MACPAC) found that the number of NPs prescribing buprenorphine for the treatment of opioid use disorder (OUD) and the number of patients with OUD treated with buprenorphine by NPs increased substantially in the first year NPs were authorized to obtain their MAT waiver, particularly in rural areas and for Medicaid beneficiaries. However, MACPAC found that NPs in restrictive practice states were less likely to obtain their MAT waiver than NPs in full-practice authority (FPA) states.[14]

This disparity between FPA states and non-FPA states is in large part due to federal regulations stipulating that if a state requires an NP to maintain a collaborative or supervisory agreement with a physician, that physician must also have completed the MAT certification course or be board certified in addiction medicine or addiction psychiatry for the NP to provide MAT. This has reduced the ability of many NPs to provide MAT to their patients as it is more difficult for NPs to locate physicians with these qualifications in rural areas. Despite the proven success of NPs, this barrier to practice decreases access to this medically necessary treatment.

Removing barriers to practice such as these promote health equity and are consistent with the National Academies of Science, Engineering and Medicine report *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity* report which recommends that "all relevant state, federal and private organizations enable nurses to practice to the full extent of their education and training by removing practice barriers that prevent them from more fully addressing social needs and social determinants of health and improve health care access, quality, and value."[15] The World Health Organization's *State of the World's Nursing 2020* report also recommends modernizing regulations to authorize APRNs to

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[11] https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.

[12] https://jamanetwork.com/journals/jama/fullarticle/2730102?widget=personalizedcontent&previousarticle=2737024.

[13] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2019.00859.

[14] https://www.macpac.gov/publication/analysis-of-buprenorphine-prescribing-patterns-among-advanced-practitioners-in-medicaid/

[15] https://www.nap.edu/resource/25982/FON%20One%20Pagers%20Lifting%20Barriers.pdf

practice to the full extent of their education and clinical training, noting the positive impact it would have on addressing health care disparities and improving health care access within vulnerable communities.[16] Removing barriers to practice for NPs is an important step towards improving access to care for underserved populations.

We thank CDC for its continued engagement with stakeholders and appreciate the opportunity to provide these comments. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

Jon Fanning, MS, CAE, CNED
Chief Executive Officer
American Association of Nurse Practitioners

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[16] https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf

From: Anthony & Lauren Nava
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Friday, July 23, 2021 2:50:02 PM

I am writing to address the CDC opioid prescribing guidelines and how they have directly effected me as a chronic pain patient. To give a little background on myself, I am 33 years old and work full time as a pediatric occupational therapist and have for almost 13 years. In order to continue to do my job efficiently and accurately, I require opioid medications to control my pain. A little over 8 years ago, I was a passenger in a 2013 Chevy Silverado tha rear ended a fully loaded lumber truck at 72 mph. As a result of this I was hospitalized for almost a month in ICU on life support and I live with constant, nonstop pain. The 2016 CDC guidelines have negatively effected me by making it more difficult to find a pain management doctor who will appropriately treat my pain secondary to the 90 MME limit that almost all pain management doctors are now feared into enforcing on chronic pain patients. I kindly request that the CDC and the AMA reconsider the guidelines to be exempt for chronic pain patients such as myself.

Anthony & Lauren Nava

From: Aliina Laine
To: NCIPCBSC (CDC)
Subject: Opoiod usage
Date: Thursday, July 22, 2021 10:24:10 AM

To whom it may concern at the CDC,

It is my understanding that you are collecting comments on opioids. I understand that there is a problem with opioid addiction in this country but there are many people who need opioids to function or to exist in this country. There are many medical conditions that cause severe pain and there is no other way to live comfortably without utilizing opioids. Just because some people have an opioid addiction does not mean that everyone does. The war on opioids causes doctors and insurance companies to treat people who are in severe chronic pain as criminals or drug seekers. That generalization is not true and is detrimental to the people who need opioids to simply exist based on their severe level of pain.

The Restriction of opioids for people who have medical needs for them is cruel. It will cause many people to live in agony or unfortunately cause many people to seek out suicide as their only option to end the severe physical pain that they are suffering from.

The restriction and unwarrented criminalization of the people who genuinely need opioids is inhumane and detrimental to the health and well being of so many people in this country. Please allow doctors to decide the amount of opioids that are needed for their patients and stop applying so much pressure on doctors to refrain prescribe them to their patients. Doctors need more leeway not more restrictions when prescribing opioids to their patients. They are the people who know their patients best.

Just because some people have a problem with opioids does not mean that all people have a problem with opioids. Unfortunately with such an intense focus on people who have opiate addiction, the system does not allow for all of the people who genuinely need opioids and are not addicted to them. The people in the system also seem to indicate that they would rather have someone dead than living and addicted to opioids! Please show compassion and allow a range of options for prescribing larger amounts of opioids for people with chronic pain or acute pain who will greatly benefit from the ongoing use of opioids.

Thank you for your consideration,

Aliina Laine

From: Amy Monahan-Curtis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:40:58 PM

I have been a chronic pain patient since 1993 with cervical dystonia, a neurological disorder in the same family as Parkinson's that causes chronic pain and constant muscle spasms. I was disabled from this disorder in 2013. I was never prescribed opioid pain medication until 2008 as a patient under the care of a pain management physician (in conjunction with other therapies,) going against the myth that opioids were often and frequently prescribed as a first-line treatment.

I am one of the lucky chronic pain patients to still have pain medication treatment since the advent of the draconian 2016 CDC "guidelines." I still have been negatively affected. My pain management physician now only prescribes an extended release patch for me and a muscle relaxer. He cut an immediate release pain medication tablet that was used for extreme breakthrough pain, citing he could not write two opioid scripts for me. He explained the DEA would flag his prescribing rates per CDC "guidelines" and he needed to keep scripts as low as possible. The change in my medication had nothing to do with a change in my medical condition, diagnosis or prognosis. He even cut one muscle relaxer citing the same problem. This was two years after the CDC "guidelines." Due to the reductions in my medication, the increase in pain led me to the only solution I could think of to help alleviate pain and make up the gap for the medications my doctor discontinued, fearing the DEA following CDC "guidelines." I began to drink alcohol to help with physical pain. (Mind you I continued to also make use of botox injections for my muscles, PT exercises, massage, TENS unit, psychotherapy, meditation, heat, ice, etc. from a lengthy list of treatments attempted prior, during and after being prescribed opioids.) Drinking led to further health issues with my pancreas, and another option was taken away for pain control and more damage done to my health.

Also since the guidelines were implemented, a pharmacist, citing the MME "recommendation," and who knew nothing of my condition, medical history or medication history, refused to fill my valid pain medication script after holding it for 8 hours. She was simply "uncomfortable" with the dose. I went into withdrawal with no recourse.

I agonize before every appointment that this will be the time my doctor says he can no longer prescribe my remaining pain medication. It is a crucial part of my treatment and without it I will go from being 75 percent bedridden to 100 percent bedridden.

Going forward, it is necessary the guidelines are explicitly about the benefits and positive outcomes opioids can and do have for millions of chronic pain patients.

Opioid pain medication cannot just be advised for certain types of pain, (sickle cell, cancer, end of life,) which creates exclusionary care. An arbitrary 90 MME dosage fits no one, yet has now been legislated and made into policy that harms millions, forcing medication tapers for no therapeutic reason. Patients cannot be blamed for an addiction crisis through such guidelines when numbers do not bear out that chronic pain patients become addicts, nor are overdoses coming from prescription opioids.

Stakeholders in the chronic pain patient community, physicians and patients, need to be a strong part of the committee deciding these revisions, especially based on the direct harms from the 2016 guidelines - uncalled for medication tapers, removals, loss of physicians that will even offer pain care and patients dying by suicide. We are in a state of emergency and have been since the 2016 guidelines were enacted. Those guidelines have created another type of opioid crisis.

From: Amy Monahan-Curtis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 11:11:11 AM

I have been a chronic pain patient since 1993 with cervical dystonia, a neurological disorder in the same family as Parkinson's that causes chronic pain and constant muscle spasms. I was disabled from this disorder in 2013. I was never prescribed opioid pain medication until 2008 as a patient under the care of a pain management physician (in conjunction with other therapies,) going against the myth that opioids were often and frequently prescribed as a first-line treatment.

I am one of the lucky chronic pain patients to still have pain medication treatment since the advent of the draconian 2016 CDC "guidelines." I still have been negatively affected. My pain management physician now only prescribes an extended release patch for me and a muscle relaxer. He cut an immediate release pain medication tablet that was used for extreme breakthrough pain, citing he could not write two opioid scripts for me. He explained the DEA would flag his prescribing rates per CDC "guidelines" and he needed to keep scripts as low as possible. The change in my medication had nothing to do with a change in my medical condition, diagnosis or prognosis. He even cut one muscle relaxer citing the same problem. This was two years after the CDC "guidelines." Due to the reductions in my medication, the increase in pain led me to the only solution I could think of to help alleviate pain and make up the gap for the medications my doctor discontinued, fearing the DEA following CDC "guidelines." I began to drink alcohol to help with physical pain. (Mind you I continued to also make use of botox injections for my muscles, PT exercises, massage, TENS unit, psychotherapy, meditation, heat, ice, etc. from a lengthy list of treatments attempted prior, during and after being prescribed opioids.) Drinking led to further health issues with my pancreas, and another option was taken away for pain control and more damage done to my health. Simply continuing my opioid and muscle relaxer would have continued to be beneficial and in no way harmful to me.

Also since the guidelines were implemented, a pharmacist, citing the MME "recommendation," and who knew nothing of my condition, medical history or medication history, refused to fill my valid pain medication script after holding it for 8 hours until closing time. She was simply "uncomfortable" with the dose. I went into withdrawal with no recourse.

I agonize before every appointment that this will be the time my doctor says he can no longer prescribe my remaining pain medication. It is a crucial part of my treatment and without it I will go from being 60 percent bedridden to 100 percent bedridden.

Going forward, it is necessary the guidelines are explicit about the benefits and positive outcomes opioids can and do have for millions of chronic pain patients. Opioid pain medication cannot just be advised for certain types of pain, (sickle cell, cancer, end of life,) which creates exclusionary care. An arbitrary 90 MME dosage fits no one, yet has now been legislated and made into policy that harms millions, forcing medication tapers for no therapeutic reason. Patients cannot be blamed for an addiction crisis through such guidelines when numbers do not bear out that chronic pain patients become addicts, nor are overdoses coming from prescription opioids.

Stakeholders in the chronic pain patient community, physicians and patients, need to be a major part of the committee deciding these revisions, especially based on the direct harms from the 2016 guidelines - uncalled for medication tapers, removals, loss of physicians that will even offer pain care and most egregious, patients dying by suicide. We are in a state of emergency and have been since the 2016 guidelines were enacted. Those guidelines have created another type of opioid crisis that needs to be recognized and rectified immediately.

A.M. Curtis
Cincinnati, Ohio

From: Anna Phelps
To: NCIPCBSC (CDC); Anna Phelps
Subject: Draft Re-write of the 2016 CDC Opioid Guidelines - Feedback on #9
Date: Thursday, July 15, 2021 7:27:38 PM

My comment is in regards to guideline number 9. I strongly believe that any risk scores on the prescription monitoring software should be explicitly discouraged as part of the CDC revised guidelines. The prescription monitoring tools should only include what prescriptions for controlled substances a patient has picked up. This is important information for the prescriber to have and should be accurate.

In contrast, risk scores should be discouraged in the guidelines. There is far too much room for error in the predictive models generating a risk score. These models have been developed in isolation by each state with little to no transparency as to what goes into the score or the validity of the methodology. For example, some tools punish a patient by giving them a lower score for using multiple forms of payment across the year. This might be completely benign - what if they use their flex spending card in the beginning of the year and a debit card when their FSA card is out of money? In some states they will get a higher risk score. I think the scores should be illegal and that the guidelines should strongly discourage their use. Again factual information on filled prescriptions is fine and likely accurate. Modeled risk scores are not okay and have too much potential for patient harm. Furthermore, as discussed in the report below, the scores tend to exasperate existing disparities able discrimination.

The report below highlights a number of issues with PMDP risk scores. I strongly recommend each committee member read it.

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3768774

Anna Phelps
Health Economist

From: Anna Phelps
To: NCIPCBSC (CDC); Anna Phelps
Subject: Feedback on Opiod Workgroup Product - July 2021
Date: Friday, July 16, 2021 11:40:50 AM

First, I want to thank the current work group for recognizing many of the issues with the 2016 CDC guidelines. In my opinion, the 2016 Guidelines represent the biggest mistake that the CDC has made in my lifetime. I strongly believe that the CDC should revoke the guidelines and focus its efforts on the following two things:

- Undoing the significant harm caused by the guidelines (discussed below)
- Developing a strategy to address the real root cause of overdoses. We have a Heroin and illegal Fentanyl crisis as opposed to a prescription crisis.

How will the workgroup start to unravel the harm the CDC guidelines caused? I strongly believe this needs to be addressed. Harm includes, but is not limited, to the following:

- Thousands of doctors left pain management practice and deserted their patients throughout the US.
- CDC Guidelines used by DEA and State drug agencies as an excuse for raids on doctor offices
- Many US States legislated limits on dose and duration of opioid prescriptions for acute or chronic pain. These limits must be repealed.
- Some pharmacies, particularly national chains, refused to fill patients' valid opiod scripts.
- Insurers capped the number and doses of opiods they will cover causing some patients financial hardship. In some cases, insurance overreach goes even further. Blue Cross Blue Shield started paying surgeons a 35 bonus by drastically limiting opiods dispensed after certain surgeries.
- Thousands of hospitals and practices forcibly tapered legacy patients below minimum effective levels; patients often cut off without taper. Coerced tapering instead risks patient medical collapse.
- New chronic pain patients (the non-legacy patients) found themselves in significant pain with many doctors unwilling to initiate opiod therapy. There is currently no substitute for opiods.
- An alarming number of patients committed suicide after being involuntary tapered from opiods or cut off completely due to overwhelming pain.

If CDC and this workgroup insists on rewriting the 2016 CDC guidelines, then AMA House of Delegates Resolution 235 must become an explicit and central guiding principle in recommended practice. Separately, I will email edits to many of the guidelines in case editing is the only way corrections will be made.

From: Anna Phelps
To: NCIPCBSC (CDC)
Cc: Anna Phelps
Subject: Feedback on CDC guidelines
Date: Saturday, July 17, 2021 7:08:41 PM

I listened to the meeting held on July 16, 2021 and was shocked to hear that one of the authors of the updated guidelines, Dr Chou, had a significant financial conflict of interest.

I agree with comments made by Tamera from the P3Alliance.
"This is sufficient enough information that P3Alliance insists the process is corrupted, and the draft guideline ought be considered illegitimate & biased. Any further effort on this guideline draft should be abandoned."

Furthermore, Dr. Chou should not be allowed to vote on any matter relating to the guidelines.

Thank you,
Anna

Sent from my iPhone

From: Anna Phelps
To: NCIPCBSC (CDC); Anna Phelps
Subject: Public Comment to the July 16, 2021 meeting
Date: Monday, July 19, 2021 3:50:42 PM

Comments to the July 16, 2021 Meeting of The US CDC National Center for Injury Prevention and Control Board of Scientific Counselors

My Public comments relate to recommendation 4, recommendation 5, and recommendation 6. I strongly recommend that all references to dose thresholds and duration limits should be removed from the guidelines. I agree with the workgroup members that felt that specific opioid doses or durations would be misapplied as absolute cutoffs or thresholds for policies or practices. History has already proven this to be true based on the following examples:

- States passed laws that placed hard limits on prescription opioid dose and/or duration
- Insurers set policies limiting the dose/duration of opioids they will pay for
- Some doctors force tapered chronic pain patients below the MME threshold levels noted in the 2016 guidelines
- Many pharmacies have refused to fill prescriptions above a certain MME. There is a class action lawsuit underway against Walgreens, CVS, and Walmart.
- NCQA added a metric that penalizes providers for prescribing patients 90 MME or higher. These quality metrics can impact provider salaries, networks, and publicly available quality reports.

All references to dose thresholds and duration numbers MUST be removed from the guidelines. They are not well supported in any of the scientific literature and have clearly harmed patients. Furthermore, the CDC must find a way to get duration and dose limits removed from laws, quality metrics, pay for performance programs, insurance limits, and pharmacy policies.These limits were the direct result of the 2016 guidelines. The CDC owes it to the citizens of the United States to fix the damage they have done. Simply updating the flawed guidelines is not enough.

To be crystal clear, please remove the following dose thresholds and duration limits from the guidelines and do not replace them with other thresholds or limits. Instead, recommend that clinicians provide optimized care to each individual that balances the risks and benefits of opiod therapy for that patient's particular health care situation.

4 -If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully

reassess evidence of individual benefits and risks when considering increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to =90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day.

5-For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage.

6-One to three days or less will often be sufficient; more than seven days will rarely be needed.

Thank you,
Anna

From: Amy Rengo
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:46:33 PM

The way we treat one of our most vulnerable populations is an abomination. Doctors are abandoning their patients in their greatest hour of need because they're terrified of losing their license if they prescribe the prescription they need. The new guidelines are a very biased focus on the risks and harms of opioids and DOESN'T discuss the benefits of opioids for pain relief when used properly. These guidelines continue to set people up for a lifetime of misery because they are in so much pain they can't be productive. Most are in pain due to no fault of their own.

People in pain do not misuse opioids. People need opioids to keep them out of pain and that is the reason they take them. We're not selling our precious medications on the street corner. We are not getting high on our prescribed medication.

The arbitrary MME dose limits are not even based on science, because of this people will suffer. Please reconsider this portion, so they can actually help people with their pain. Then adding language that makes certain diseases more worthy of being treated for their pain is disgusting.

I suffer from idiopathic neuropathy stemming from my childhood trauma. I have to take Gabapentin, and it's been more times than not where the pharmacy would not want to fill the script my doctor wrote for me because of the dose. Suffering in terrible pain because someone somewhere decided that my dose was too high is hard to understand. During those times when I could not get my medication due to some arbitrary rules, I become suicidal. When Gabapentin became a schedule 5 drug my doctor's office insisted on drug testing me each quarter at my own expense ($1,000 a year) which of course was not covered by insurance. I was a patient with my doctor for over 10 years and never once had an issue with my prescription. I was made to feel like a criminal. This was the case in four other doctors' offices. I also have Chronic Fatigue Syndrome so spending $1,000 on something worthless for my healthcare is hard to do. Don't blame the doctors because they are all terrified of losing their license due to some rule regarding MME dose limitations.

I sure hope that the people responsible for writing these new guidelines need opioids for pain control. Lets see how they do with uncontrolled pain for the rest of their life.

From: Ashley Rodgers
To: NCIPCBSC (CDC); Lindley, Tonia (CDC/DDNID/NCIPC/OD); InjuryCenterEngage (CDC); Greenspan, Arlene (CDC/DDNID/NCIPC/OD)
Subject: CDC Guidlines and MME limits
Date: Tuesday, July 20, 2021 4:11:31 PM

Dear Sir or Madam:

As you know, millions of people in pain have been greatly negatively affected by the 2016 CDC Guidelines. Though supposedly not intended to be implemented as law, the Guidelines have been interpreted as such. Doctors are no longer free to prescribe pain medication as they see fit for their patients. The PDMPs along with the Guideines have destroyed the lives of millions.

I am writing not only as a pain patient but as an advocate for others whom cannot speak up for themselves. I have seen friends, famlly and our beloved Veterans crying out for help because of the damage that has been done to the healthcare system.

At this time, my pain is intense and I cannot even write a complete letter as I intended. This is life now, thanks to the destruction caused by the Guidelines. My doctor has admitted being afraid to treat me adequately, as that would make for a good "DEA target".

Please correct this now!!! WE ARE NOTHING SHORT OF DESPERATE!!!

Thank you,

-Ashley, chronic pain patient

Sent from Yahoo Mail on Android

From: Alchemy Saga
To: NCIPCBSC (CDC)
Subject: Comments on the latest Prescribing Guidelines
Date: Friday, July 23, 2021 4:43:59 PM

To Whom it may concern,

I am writing to make comments on the revisions to the CDC Opioid Guidelines and Pain Treeatment Guidelines.

I believe that the Guidelines have been influenced too heavily by individuals making recommendations for their own benefit or by abusing the power of their other positions to continue to implement. In particular I feel this way as the Guidelines are- contrary to the insistence of members of the work group- being enforced as law as lawmakers make laws based on the guidelines with no exceptions, and thus interfering unduly with medical practice.

In particular, the participation of:
Roger Chao, who did not disclose conflicts of interest until the most recent meetings, and who through his three positions has been able to effectively decide what studies to approve and what they mean.

Kolodny and Jane Balantyne who had conflicts of interest which they failed to disclose until recently and who's suggestions are still heavily incorporate into the guidelines.

Given all of these undeclared conflicts of interests, which have been present since the beginning and still influence the guidelines in their current forms, I believe they are unsuitable to implement on the general public, particularly as the board does not include any current pain patients from the general population. The fact that all approved studies that the Guidelines are based on consist solely of mild to moderate chronic pain, while deliberately excluding the reality of severe chronic pain is further reasoning to discard the guidelines.

I am a 26 year old with a genetic disorder that has led to severe daily pain, that I can expect to remain constant through my life. The causes of pain are those that cannot be treated through surgery. I do not think that it is right in either a moral or scientific sense that these guidelines are being implemented in a form that does not actually account for cases such as myself, but also does not allow accommodation as the Guidelines are enforced as law.

Nor does the groups insistence that the Guidelines are not enforced as law have any significance in face of the reality that not only are laws being written that limit opioid pain treatment, but insurance companies are enforcing caps on the amount of medication that can be prescribed based on the guidelines- particularly as insurance companies contributed to the severity of the opioid epidemic when it was actually fueled by prescription medication. Professing ignorance or innocence does not deny the reality that the Guidelines are being used as the basis of laws, which patients then suffer the consequences of- and as these laws and policies are based on the guidelines, those who write said guidelines are thus directly responsible for this suffering and deaths that occur.

Additionally, the failure of the guidelines to address that the 'fentanyl' that is currently fueling the epidemic is that of illicit origin- not fentanyl prescribed to pain patients- has increased deaths as people who use illegal, illicit street drugs are unaware of the risks they are taking.

The reality is that the Guidelines have been tainted by those who have sought to profit from what was at one time a prescription epidemic, but has long since become an epidemic fueled by illicit drugs. And yet the guideline and its writers would seek instead to punish those who received their medication through legal, medically monitored means, and who follow their doctors instructions. Also part of this reality is that the board would rather double down on their list of mistakes than admit that their guidelines did not reduce the opioid epidemic, but instead pushed legitimate pain patients into using street drugs or committing suicide, because they refused to relinquish their ableist insistence that the medication was the only reason that pain patients were not working and providing 'human capital' to the government and the corporations who pay the government to write laws that benefit them.

I request that the Guidelines be dismantled, and be admitted to have been based on flawed- if not outright fabricated- science, and the right of determining correct medical treatment of pain be returned to doctors. The board has proven itself incapable of drafting guidelines to accurately address the problem, without bias, and without causing undue harm to one demographic for the sake of another.

From: Adriane Sanchez
To: NCIPCBSC (CDC)
Subject: Meeting minutes July 16th
Date: Friday, July 23, 2021 12:55:48 AM

To whom it may concern,

This will be a long email with my comments from a chronic pain patient perspective. My medical history is deep & long.. as a breast cancer pt in remission (currently) who has associated neuropathy of the lower left leg & foot, chronic recurring shingles from an immune system gone awry, & post shingles neuralgia, psoriasis & psoriatic arthritis, sjogrens, liver & lung dis, spinal stenosis, & fibromyalgia too, I implore you to listen to US, the patients in these emails that we r sending you in hopes of effecting change. The ones especially who have been safely managed on LTOT with absolutely no ill effects, no addiction, no drug seeking behavior, no dr shopping, in fact my dr recently made an error on my script which I immediately reported to him & the pharmacy, (I'm extremely responsible) but, we r being cut off, force tapered made to undergo epidural spine inj, that we know don't work for more than a few days max, & pose a health risk, (I personally had my dural space punctured requiring an emergency blood patch in the emergency room) urine drug screens that can be negative (insinuating diversion) or positive insinuating street drug abuse, all of these things & especially SUICIDE DUE TO UN & UNDERTREATED PAIN is NOT acceptable to us personally or as a whole. Pain is different for every BODY. The current lid on MME is not productive, it isn't a 1 size fits all medication with a standard dose for all, (I can only take 1 opiate medicine, allergic to every single other)is not something we can simply just swallow 10 advil a day, or hold a yoga pose or breathe thru like labor pain & just suck it up & live with it! QOL IS EVERYTHING!! Without QOL we r vessels rotting & waiting to die. I've already been thru so many procedures including partial mastectomy, aggressive radiation, lymph node dissection, total hysterectomy & oopherectomy, abdominal lap, multiple liver bxs, breast bxs, had many types of treatment for pain including PT, EPIDURALS, TENS UNITS, BIOFEEDBACK, PSYCH THERAPY, SWIMMING, YOGA, GYM,, CHAIR YOGA, DEEP BREATHING & EVEN MMJ WHICH STILL DOESNT HELP THIS INTRACTABLE PAIN. my neuropathy is keeping me from EVEN getting up to go to the grocery store, I do use advil for breakthru but only in emergencies bcuz my esophageal GERD is so bad, but it doesn't HELP. if I get 2 hrs of calming effect it's a miracle. Alternative medicine is great if it's complimentary as with cancer tx for instance. It's meant to help with unwanted side fx, not intended for use w/o the actual TREATMENTS THAT KEEP US ALIVE, IE; CHEMO, ANTIHORMONALS ETC!!! EMPHASIS ON QOL!
Our drs r quitting or retiring as fast as the med schools can turn them out & the 1s they turn out r trained to go against opiatesnow after thousands of years of use! Our veterans have been cut off & r dying by suicide, our elders (my 90 yo old aunt) stable on 1 tramadol a day & 1 5mg Valium for years was abruptly cut off & ended up in the hospital with 200/100 BP! She nearly had a stroke. Her PCP cited she needed to go to a pain clinic for ONE TRAMADOL DAILY. She outright refused, being 90 doesnt mean she's stupid.. in fact she's so productive she surprises all of us, but one crushed sternum 5 yrs ago in car accident & she was happy now with 1 tramadol, why did this pcp suddenly stop her?? The orgs like PROP & Shatterproof & all the ones that are against opiate medication is bcuz in the beginning when pills were sometimes MAYBE overpresribed they fell into the wrong hands BY WAY OF IGNORANCE NOT TO ABUSE THEM. I STARTED with a pm dr during my cancer txs. He had no rxingmy meds, a low dose & worked his way up to still a doseunder 90 mme..the drugs work.. This is no longer the case, as u well know the rx meds have been so cut that some of us

r driving hours to find a dr to prescribe! This takes out of our lives & not bcuz we r ADDICTS, becuz we NEED TO TRY TO REDUCE OUR PAIN TO A LOW ROAR WHILE TRYING TO WORK, enjoy family & children, even my stage 4 mbc friends r having a hard time filling or even getting rx from oncologist! My oncologist will not rx pain meds unless our cancer is active. Sends us out to pm. Luckily I have a very caring ethical rheumatologist who thinks your guidelines are absurd.. less than 1% of ppl addict.. these can easily be weeded out & placed on adxn medication rather than leaving us all in the same boat, a boat we do not belong in with them. We r dependant yes, addicted no. Leave that up to qualified . THIS IS ABSURD & overkill & gives US ALL something to worry abt! This is not acceptable. Your information is skewed & WRONG, & little real scientific data to back up the claims. Every OD TODAY is from street drugs, pills presses ordered on line laced with carfentinil, polypharmacy, combos of cocaine, methamphetamine, hallucinogenics even. Pls dont buy into these lies that it ur grammas script, no!

PROP TWEETED that the overdoses from prescription opiates continues today rise & that is simply untrue,.misleading the public at large & truth be told, most drs want us all to go to rehab, do things we already tried 10 times b4 last resort of opiate pain meds. If u think I wanted to be in my early 50s, a 30 yr practicing yogi with incredible stamina despite my health issues, until I could no longer stand my pain & had to leave yoga, u r mistaken. We want to live normal lives. Being tortured with injections, alternatives like advil Tylenol which barely relieves a headache is wrong & unethical & since when is it the govts business what OUR DRS DECIDE IS BEST FOR US? IF ONLY THE CDC CARED ABT COVID AS MUCH AS THEIR ANTI OPIATE CRUSADE, maybe we'd get somewhere. It's time to do the right thing by the very human beings that trusted you!

U reading this KNOW that so much MISINFORMATION abt pain meds is out there,, make it right!! They, PROP should not even be permitted to weigh in. They r a group that has destroyed ppls lives, including mine with NO SCIENCE BACKED DATA, & THE HEADS OF THIS ORG, NAMELY KOLODNY HAVE only interest in addiction & interests in rehab centers, money, & power which drives this false narrative & less than any experienced staff treating chronic long term pain. They simply put, do not care abt our suffering. I'm sitting here past midnight EDT w/my leg & foot on fire. Do u have any idea how much I want to sleep? While it's easier to lay blame on drug cos like Purdue & the Sacklers, it's not the way to go. Now the other drug makers tho they admit no wrong doing in their marketing practices, will agree to pay out billions of dollars? Why do that to them? The "studies" r not science based. Addiction has been occurring for years decades & centuries. You taking our pain medication that gives us some semblance of life some QOL, some time with our families instead of being basically bedridden, have all but gone away with prescriptions at an all time low, how come overdose rates r 200+% higher today than in 2012 when pill mills were shut down & drs began stopping the #RXmeds? Why? U can't even find a dr to write an rx, much less find a pharmacist willing to fill it, so pls explain how the organizations r coming up with this data?? It's all LIES. WE R NOT DYING OF OD, the addicts r in the streets getting their hands in whatever is out there & they r dying, so treat addiction separately, not lump us all together like u have been. These gdlns do not work.. we need to go back & give pain pts their meds, while helping the addicted with theirs. Example I know if a girl lived near my son & would try & sell her suboxone! An addict, she didnt need that drug only, she needed intense therapy for the cause, not a script she wasn't even taking! Not me who has no mental illness background except depression now due to the fact I cannot move to b with my child! I have an 80myo husband with cancer & I csnt do anything anymore w/o pain relief! For 5 long years we have suffered died some of us buried, that one death is too many. I want to know why ppl with intractable pain are being shoved out the door leaving them in withdrawal, and why r drs putting LTOT patients on addiction medication like Suboxone, which was used off label as a narcotic analgesic when it does not work for pain. I've done enuff surveys to find that out, or that it makes them violently I'll & this is wrong. There's no one size fits all!! No one in the chronic pain community that I know, & I know hundreds if not thousands, have overdosed or gone drug seeking in the streets for fentanyl laced heroin or combos of polypharmacy!! Also, our access to anti anxiety medication has been stopped. I personally have PTSD & am on a benzodiazapine for same since 1985. 1 pill or 2 a day, & I have rid myself of panic attacks until the pandemic & being from Florida having survived Andrew, I need my medication but some drs today are not willing to write & some pharmacies r not willing to fill! I've been harassed at Walgreens by a floater pharmacist the night b4 a cat 5 hurricane Dorian was 50 miles off the Florida coast was abt to hit, she refused to fill me. I had to drive across town in inclement weather to an all night Walgreens scared out of my mind to beg the head pharmacist who immediately said to me "I don't understand why they wouldn't fill u, ur record is impeccable" she said to me & apologized & filled it. She felt badly & Walgreens corporate wanted me to report her but I've never been one to tattle, but she took the cake. She not only violated my HIPPA SHE EMBARRASSED ME in front of other elders citing she was uncomfortable filling the amt! 150 pills, 1 low dose pill, 5 times a day. W/O that same dose over many yrs, believe me when I say it works I would be in so much agony, does that not matter? What abt post op pain? I had no access in 2007 to opiate as I'm allergic & had to undergo many surgeries for my cancer without anything! Unfair, not right, inexcusable.

Here I am begging u to pls see it from our side. Put yourself in my feet, my broken body, help us. Stop this madness. We matter..pain pts r disabled & the ADA the AMA have all said we can be treated humanely so pls try.
I don't mean to ramble but pls, if u never did anything humane & for the greater good, pls get experts in science & ETHICAL CARING drs to sit & write new gdlns so that we can drive out of our homes, take a simple walk, get out of bed, leave the state for another like free Americans & expect to find & retain a dr in any state that will feel comfortable writing a simple script without dear the DEA will come in & shut them down & pharmacies the rights to dispense our medications. It's not for everyone, opiates, but for me it's been a lifesaver. I don't want to live in withdrawal at 65 with an immunocompromised body, exposed to any hospital especially during this pandemic that shows no sign of resolve any time soon. Pls give us our QOL our lived matter..pain matters. Put yourselves in our shoes for a moment & pls see our side.

I want so many things in this life I'll never have. I can't move from south Florida to the state my son is in bcuz no drs to continue care with! They meaning the drs & pharmacist want me to see my current rheumatologist here in Florida who agrees to still c me, write for me providing I can get a pharmacist to fill it in the state where I'd be living. I don't have the energy. This government has it so that I am trapped with my eighty-year-old husband instead of being with our son and his wife and new babies that are about to be born. I will not be able to drive back and forth to visit a doctor every 2 months, I can barely go to the grocery store to run errands as the pain in my leg & foot is severe. I have friends and colleagues from my former employer that drive in excess of 8 hours from one town to the next to see a doctor that will write for them and then come back and fill at a pharmacy near the town where where they live. This is outrageous and uncalled for, cruel and inhumane for those of us who cannot bear the pain that we are in on the lowest doses of medication we are forced to take same amount year in and year out, but some is better than NONE with the latter becoming more & more the trend!! And then there is the possibility of surgery. We have to go in and speak to surgeons & anesthesiologist about post-op care regarding pain, who are not willing to write post-op Scripts, if they do it's for a few days at a time and if you're already on medicine you're just out of luck. Imagine having you are both breasts removed or a hysterectomy and full radical oophorectomy with abdominal incisions and no way to manage that pain because no medicine was prescribed. Imagine that in your own mind and how you would feel if it was you or ur loved 1?. We are at a Crossroads in this country with regards to the 2016 guidelines, whoever was involved in writing contributing to them or are still involved and have decided that not much will change or if it does it will not benefit the pain patient rather the government or other orgs like PROP, SHATTERPROOF & THE OTHER ADDICTION ORGS. it's time to retract rescind and rewrite the new guidelines with the patient BEING THE ONLY IMPORTANT PERSON IN THE EQUATION, not the doctor not the hospital not the governments 3-letter agencies.

Get the DEA out of our drs offices. If a dr abuses his power, take that power from him, don't leave US W/O responsible ethical drs! If a pt abuses his or her mess, punish them not us as a whole.
Respectfully yours
A. Sanchez

From: Annie Shoger
To: NCIPCBSC (CDC)
Subject: July 16, 2016 BSC, NCIPC meeting .
Date: Friday, July 23, 2021 2:49:24 PM

To Whom it May Concern,

I was unable to make my comment during the meeting held on July 16, 2021. Below you will find my comments.

Hello my name is Annie Shoger. Thank you for giving me this opportunity to address you regarding such an important issue affecting so many Americans.

The CDC 2016 Guidelines for Prescribing Opioids for Chronic Pain is harming patients. These are folks who have chronic incurable diseases and/or chronic conditions that can not be fixed. In my opinion the CDC guidelines need to be suspended entirely and immediately. The last five years of my life have been totally intolerable and whether it's been intentional or not, the whole process and outcome has been very sketchy and ignored even when specific data comes to light when there has been proof of wrongdoing. For instance, it should be already known that the so-called opioid crisis has had NOTHING to do with the number of overdoses that have occurred in this country due to prescription opioids. The numbers of overdoses will continue to increase if the CDC guidelines are not suspended. We seem to not be learning anything from the last several years. The number of overdoses that are represented by the CDC DO NOT show the whole picture and this information has been proven and still not corrected. The actual number that is being presented represents mostly illicit fentanyl along with other drugs. The number of overdoses due to prescription pain medication only such as morphine, oxycodone etc. has been stable for quite some time. As reported by Dr. Josh Bloom of the American Council on Science and Health, "of particular significance is that prescription analgesic drugs remained a minor contributor (13%) to the total and the absolute number of deaths did not change between 2019-2020." Personally, I have never come across a Doctor who initially and/or persuasively prescribed an opioid. As a matter of fact, they did not prescribe it unless it was medically necessary and the last resort. Note that I have been a chronic pain patient for 26+ years and have seen many Doctors during this time. Additionally, I have tried an exorbitant number of alternative non opioid therapies before going to opioids as my plan for alleviating my pain. Opioids work at least for me. Also it should be noted that over the last 5 years my condition has deteriorated tremendously due to untreated pain. I now have severe osteoporosis causing 3 additional new compression fractures and 2 more herniated discs, severe osteoarthritis added to my existing diagnosis of multi level spondylolisthesis, bilateral pars defect, irritable bowel syndrome, stomach ulcers, migraines anterolisthesis, endometriosis, degenerative disc disease, and stenosis at L5-S1 Being in moderate to severe pain all the time affects the body in a very negative way. There is truth to "Pain Kills".

These 2016 CDC guidelines for prescribing opioids for pain have been tremendously misapplied. What is even worse is that it will continue to be misapplied unless the current 2016 CDC guidelines are repudiated immediately. Then the focus for reducing the number of overdoses should be to eliminate as much as possible the smuggling of illicit fentanyl into the country and to improve the services, programs and medication for addicts. Furthermore, having Dr. Chou on the committee to revise the guidelines is despicable as not only does he have a conflict of interest but he also continues to cherry pick data, over generalize his findings, has unacknowledged bias, and lastly fails public transparency. He should not be nor should he ever have been a co author of the guidelines. The relationship between a Doctor and their patient should not be overseen by any document written by government agencies such as the CDC, DEA, or DoJ. And, so long as there are morphine milligram equivalents (MMEs), the DEA will continue to wreak havoc on the Doctors and their patients. The CDC should never have been the place to oversee any medications. It is the Center for Disease Control not the FDA (Food and Drug Administration) which is where it should have originated from if it should have originated at all. However, when PROP (Physicians for Responsible Opioid Prescribing) went first to the FDA 2 years before they went to the CDC, the FDA would not accept their proposal in total i.e. They did not support the MME cap. Then when PROP eventually went to the CDC, the environment there was such that it allowed for acceptance of their proposal as the Director at the time was a former coworker of Dr. Kolodyn. This whole opioid crisis has never seemed to be about the well being of chronic pain patients. And, the concept of one size fits all can not nor should not be applied for medication to individuals. It just does not work.

I have added the below responses to the recommendations. This was not a part of my initial comments but I felt it was extremely important for me to respond.

Recommendation #1: Nonopioid therapies are preferred for common types of acute pain, Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to patients.
My response: As I mentioned, every pain management Doctor I encountered knew and implemented the above. As for my particular case, when I first went to the Doctor due to pain in my back, they suggested I see an OB-GYN Doctor to see if I had endometriosis. I did have it and had to have a hysterectomy. This was after they x-rayed and had a MRI of my back where they found that I had spondylolisthesis with pars defect and severe degenerative disc disease. Additionally, I have tried a multitude of nonopioid therapies. These include, but are not limited to, having several radio frequency ablations (RFA) performed after having a medial branch block, having multiple injections, years of massage and acupuncture, biofeedback sessions, having appointments with a physical therapist numerous times, trying a tens unit, seeing a psychologist, etc. The only relief I was able to find was with the RFA except I also needed to rely on pain medications specifically morphine IR and ER. Since the CDC guidelines were adopted, I am being forced tapered on my medications. Lastly, why does the stated recommendations use the word ONLY twice in the second sentence. The wording throughout the guidelines seems quite harsh and one concludes that opioids are very risky which is not proven. The only side effect I have had was constipation. And, as for respiratory depression, the research I have read mentions that it generally is not a problem unless the opioid is taken with multiple other drugs or when there has been an increase of one's opioid medication.

Recommendation #2: Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate.
My response: This recommendation is almost verbatim as recommendation #1. I would also point out that in my opinion pain management Doctors are already doing this. I believe they

know more than an addiction Doctor or the government.

Recommendation #3: When starting opioid therapy for acute, subacute or chronic pain, clinicians should prescribe immediate release opioids instead fr extended-release/long acting (ER/LA) opioids.
My response: I totally disagree with this recommendation. If I were only allowed immediate release opioids, it would be necessary for me to be on a very high milligram and be able to take it every 2 hours as opposed to every 4 hours. Otherwise my pain would not be controlled. Also for those who metabolize it quickly, they may need to be taking it even more frequently. The number of pills prescribed would be astronomically high. Each individual has different needs and what works for one does not necessarily work for another.

Recommendation #4: When opioids are started for opioid-naive patients with acute, subacute or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to > 50 morphine milligram equivalents (MME)/day and should avoid increasing dosage to > 90 MME/day or carefully justify a decision to titrate dosage to > 90 MME/day.
My response: MMEs should be totally eliminated from the 2016 CDC guidelines for prescribing opioids for chronic pain. There is no sound scientific data supporting these numbers. The only way there would be data reflecting these numbers is if the data is not a thorough scientific method used in the research. One can manipulate the numbers to their way of thinking if they want. There is also one'smetabolism. It makes a huge difference in the amount an individual needs in order to control their pain. This recommendation could definitely be misapplied for they may not know or understand dosage differences. It seems this recommendation and document as a whole does not address controlling an individual's pain whatsoever. Isn't the document's ultimate goal to address the well being of a person who suffers from pain. Another notation worth considering is that there is no standard for calculating MMEs.

Recommendation #5: For patients already receiving higher opioid dosages (e.g. >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosage or to taper and discontinue opioids.
My response: It seems that almost every recommendation addresses the harms. What about the benefits and why should it be every time that one should be tapered or discontinued. Oftentimes depending on the patient, they may actually need to increase their dosage especially if, for example, they decide to attend physical therapy sessions. This can cause an individual additional pain. Again, the MME should be eliminated from the guidelines.

Recommendation #6: When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed.
My response: The first sentence is fine except I believe the last part of it (severe enough to require opioids) is not necessary. This needs to be determined on an individual basis and depends on what is causing the acute pain. For instance, I would think that different surgeries would need different duration and milligrams again depending on the individual. There is way

too much tension and focus on the harms of opioids. There are great benefits for it too.

Recommendation #7: Clinicians should continue opioid therapy for subacute or chronic pain only if there is clinically meaningful improvements in pain and function that outweigh risks to patient safety. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
My response: In my opinion, the first sentence is not necessary. This has been repeatedly stated throughout the recommendations. Once is enough. Also, it seems unrealistic that the clinician should evaluate the patient after one week. If a patient is having trouble, I believe they are adult enough to call for an appointment after 1 week. Generally one would see their Doctor within a month for evaluation after their initial appointment. Again, this document is really not necessary at all. The problem with overdoses is with addicts who receive illicit fentanyl. Generally the folks who are suffering from pain are much older and their rate of addiction as reported by Jath Educational Consortium, LLC is 4/1000.

Recommendation #8: Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (>50 MME/day) or concurrent benzodiazepine use are present.
My Response: First sentence is redundant. In all the years when I was on a very high dose (much more than 90 MME), I never had any problem with my breathing. It seems forcing patients to have to get naloxone is just an unnecessary expense for pain patients. The medication is very expensive and insurance companies do not always pay for it. Generally, the folks that overdose are on multiple drugs, mostly illicit and they will do anything to get their drugs. Additionally, it is my understanding that Dr. Chou has collaborated with PROP whose President was Dr. Kolodyn who has a financial interest in the drug naloxone/narcan. Moreover, there should be no mention in the guidelines regarding MMEs.

Recommendation #9: Clinicians should review the patients history of controlled substance prescriptions using state prescription drug monitoring programs (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for acute or chronic pain and periodically during therapy for chronic pain, ranging from every prescription to every 3 months.
My response: I believe initially that the PDMP was a very good idea however it is being misused particularly by the DEA along with other misuses. A pain management doctor by and large prescribes multiple opioid prescriptions as many doctors will no longer prescribe opioids and the ones that do prescribe them have an exorbitant number of actual prescriptions as their patient base is high. This is then used against the Doctor. There is a problem in our country as there are fewer and fewer Doctors who will prescribe opioids. They are actually oftentimes closing their practice as they do not want to take on the hassle or the liability of being arrested by the DEA . This leaves pain patients unable to receive the medication that they need in order to have a somewhat decent quality of life. Without them, pain patients end up not being able to do daily functions that normal folks are able to do and they are often spending much of their time lying down and occasionally sitting or standing.

Recommendation #10: When prescribing opioids for chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
My response: This is a very difficult one. Too much emphasis is placed on the results which are not always accurate. Also, as a pain patient who is required to do a drug test, one feels as if they are on parole and considered a drug addict. It is quite degrading to have to pee in a cup. At the beginning of the introduction of the guidelines, I was having to do it every month. Currently, I do it at least twice a year. It can be very expensive too and oftentimes insurances will not cover (at least I have not had one that does and I have had Blue Cross Blue Shield and United Healthcare)

Recommendation #11: Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants.
My response: On what grounds is this being stated. Is there any research that has been done on it? I have been on both before and never had a problem. They can actually work well for a person suffering pain.

Recommendation #12: Clinicians should offer or arrange treatment with medication for patients with opioid use disorder.
My response: I believe this to be a good thing if it is used properly. It seems that opioid use disorder can be and has been inappropriately used e.g. by diagnosing someone with it when they do not have it.

In closing, I believe it is important that I bring your attention to one last point that has not been brought up and that is that many chronic pain patients are unable to make a comment as they are in so much pain it would be impossible for them to do so Consequently, they are not heard and you have no idea who they even are. Someday one of your loved ones and even yourself will find yourselves in a situation where you need pain medication but can not get any. I pray that does not happen to anyone of you but truly it is only the folks who live in chronic pain who know what it is like. You would find that you have only three choices; to try in hang on and keep living in intolerable pain, to find some opioid drugs on the black market or to end your life. That is why chronic pain patients are committing suicide at an alarming rate. It will get even worse unless the 2016 Guidelines for Prescribing Opioids for Chronic Pain are not suspended. Perhaps instead of it being referred to as the 2016 Guidelines for Prescribing Opioids for Chronic Pain, it should read, 2016 Law for Prescribing No Opioids for Everyone.

Thank you very much for carefully deciding on this life and death implementation of the 2016 Guidelines for Prescribing Opioids for Chronic Pain and its revision. You can count on if the MME of > 50 or 90 or whatever number is used is adopted, there will be more suicides. Haven't there been enough? One is too many in my book. In 2013, the United Nations General Assembly adopted a position that says under treated pain is paramount to cruel and inhumane treatment and tantamount to torture. Treating pain is the most basic of human rights and patients who are under treated might as well be tortured and then killed by ISIS.

Best regards,

Annie Shoger

anticipated

From: Angelita Torres
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:36:45 PM

Iam a 50 year old woman who has been diagnosed with end stage liver disease, chirrosis stage 4,liver cancer with palliative care, upper and lower scoliosis, spinal spondylosis, spinal stenosis, epilepsy, asthma etc. and after being on the same dosage of medication for 13 years I am being tapered off because of CDC guidelines. I was on 100mg and I am being tapered to 20 mg which is 90mme .I can't even get out of bed anymore, my quality of life has gone down and that scares me because since 2001 ive lost my mother, son,husband, sister, step,father, and many friends who have been tapered or refused medication for different diseases from m.s to cancer. I have 5 living adult children and 3 grandchildren who want me here and I am no fun to them being bed ridden. I would like my quality of life back. Its pretty sad I can move to a different town and go to a methadone clinic but I can't get the right amount of medication for my illnesses. Something needs to change soon. Thank you for reading this, I'm sorry I sound angry but damn it I am ,what has the world come to when an addict can get what they need from their doctors and us terminally ill people can't!!!

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Sent from myMail for Android

From: Ashley Walton
To: NCIPCBSC (CDC)
Subject: Submission of Comments: BSC/NCIPC's Opioid Workgroup Report
Date: Friday, July 23, 2021 2:22:15 PM
Attachments: 2021-7-23 ASA-CDCBSC-Opioid WkGrp Updt-Guide Commts.pdf

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Good afternoon,

I am writing on behalf of the American Society of Anesthesiologists (ASA) to submit comments on the BSC/NCIPC's Opioid Workgroup's report on the draft updated CDC Guideline for Prescribing Opioids, following last week's BSC meeting.

Thank you for the opportunity.

Sincerely,
Ashley Walton

Ashley Walton, J.D.
Associate Director, Congressional & Political Affairs
Pronouns: she/her/hers

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American Society of
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Submitted via email to ncipcbsc@cdc.gov

July 23, 2021

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control
Board of Scientific Counselors
(BSC/NCIPC)

Re: ASA Feedback on BSC/NCIPC's Opioid Workgroup Report on Draft Updated CDC Guideline for Prescribing Opioids

Dear Members of the BSC:

On behalf of the American Society of Anesthesiologists® (ASA) and our 54,000 members, I am writing to provide feedback on the Opioid Workgroup's report on the draft updated CDC Guideline ("updated Guideline") for Prescribing Opioids, which was presented at the July 16, 2021, meeting of the Board of Scientific Counselors. ASA thanks the workgroup for their thoughtful observations about the updated Guideline and careful consideration of whether any of the recommendations might be misapplied in future contexts.

While we understand that the updated Guideline in its entirety will be available for review and public comment in the future, when reviewing the Opioid Workgroup report, it is apparent that much of the generic language used in the first iteration of the 2016 Guideline seems to have resurfaced in this updated version. Several of the observations made by the workgroup are very concerning and ASA cautions the CDC against publishing the updated draft Guideline in its current form. We urge the BSC to take the recommendations of the Opioid Workgroup seriously and refine many of the recommendations.

General Feedback

ASA agrees with the workgroup's comment that the updated Guideline must carefully balance the risks and potential benefits of opioids. The report highlighted that in its current form, the updated Guideline focuses heavily on the risk or potential harms of opioids, with less attention on the potential benefits, or risk of not taking opioids or undertreating pain. This will likely result in the same misapplication that plagued the 2016 Guideline—legislation and payer policies that underappreciate the complexity of the clinician-patient relationship and importance of joint decision making. ASA agrees with the workgroup that there should be an explicit statement, early in the updated Guideline, that outlines its specific intent as a *clinical* guideline and not meant for payer or governmental policies.

The Opioid Workgroup report leads ASA to believe that combining acute pain, subacute pain, and all chronic pain in some recommendations makes the updated Guideline somewhat generic and non-specific. We advise that certain recommendations be further parsed out into specific categories of pain, with clearly defined terminology around each. The updated Guideline should also specify the audience for this guidance— it is primary care, not pain medicine physicians.

ASA also agrees with the workgroup's recommendation that close attention must be paid to racial/ethnic disparities and inequities in how pain is perceived, valued, and managed. We hope the updated Guideline gives adequate discussion of these important points. Additionally, ASA recommends that a key theme of the updated Guideline must be a patient-centered focus, with less emphasis on the conflict between public health and individual patient benefit. Further, there must be an acknowledgement about overall access to pain treatments and coverage concerns, as well as a clear emphasis on non-pharmacological pain treatments as an option for patients.

Last, the term ‘harm’ and ‘risk’ are used inconsistently and interchangeably throughout the recommendations. ASA advises that this be closely reviewed and accounted for in the updated Guideline. For example, the workgroup points out this specific problem for recommendation #7.

Recommendation #1

This is an instance where acute pain needs to be carefully defined and discussed in the updated Guideline. ASA suggests that examples/types of acute pain be given (e.g., trauma or major surgery, kidney stone or acute herniated disc).

Recommendation #4

ASA appreciates the workgroup’s comment that including prescribing thresholds in the document is complex. While this recommendation can be viewed as problematic on its own, with the proper explanation and supporting text, it is appropriate guidance for clinicians who do not treat pain patients as their primary practice. ASA suggests that specific care contexts be identified where a patient may require >90MME, even in an acute setting. For example, some hospitalized patients may require such increased dosing due to the acuity and severity of the cause of pain even in opioid naive patients. We also recommend that CDC identify which MME calculator they suggest clinicians consult in the Guideline, since there is variability among the different calculators.

Recommendation #5

This recommendation should closely mirror recommendation #4 by having a more balanced approach: one sentence about continuing opioids, and one sentence about tapering opioids in terms of risk/benefit analysis.

Recommendation #6

ASA agrees that the term ‘rarely’ needs to be removed from this recommendation. There is no data to support the extreme and non-evidence or consensus-based statement, “more than seven days will rarely be needed.”

Recommendation #8

While a few workgroup members expressed concern about the potential downstream effects of offering naloxone for patients of limited means, ASA believes the benefits of providing naloxone outweigh this concern; a strong stance should be taken on the important role naloxone can play in risk mitigation.

Recommendation #9

ASA appreciates the role prescription drug monitoring programs (PDMPs) play in patient care, but from the workgroup observations, it does seem that this recommendation should be re-done. It is not clear what role the PDMP should play in acute pain care scenarios.

Recommendation #10

ASA recommends that there must be a thorough explanation in the updated Guideline about how and why urine drug tests are used by clinicians, or this recommendation will be misinterpreted and even weaponized against patients. In addition, ASA shares the workgroup concerns about the potential financial implications of frequent urine drug testing for patients; many payers do not cover these costs, and this could perpetuate an adversarial relationship between patients and clinicians.

Thank you for the opportunity to comment on the Opioid Workgroup report. ASA looks forward to working with the CDC as the agency finalizes the updated Guideline. We hope the focus remains on both safe prescribing and high-quality patient care.

Sincerely,

Beverly Philip, MD, FACA, FASA
President
American Society of Anesthesiologists

From: Angela K. Willis
To: NCIPCBSC (CDC)
Subject: Fw: CDC meeting comments due by 7/23/21
Date: Wednesday, July 21, 2021 10:18:19 PM

I thought I sent this a few days ago but could not find it in my sent emails so am sending it now to make sure you have time to read it and check facts:

I would like to submit comments after reviewing the work group report & listening to the meeting 7/16/21. I apologize for the length, but it is all important to hear and while a few of these comments/concerns were heard from others during the public comment period, much of this was not and since I type almost as fast as I think, I'm including as much as possible. Also, there are so many more pain patients & families than what you have heard from because they are tired of fighting with no positives seen in a long time, so most of them have given up and hope that others will fight and/or speak up for them and others are actually afraid they will lose their doctor if they speak up (they state that because they now get such a small dosage, they can't risk getting cut even further or kicked out of the practice)! So please, I implore you to read what I have written (grab a bottle of water or cup of coffee & relax). You might even learn something new!

First, I thank you for trying to not just repeating the apparent agenda that the original 2016 guidelines were focused on due to authors who had a specific reason for this and I'm sorry to say that I don't believe their main concern was patient safety at all (I do feel there were not enough changes made that will help ALL pain patients and especially chronic pain patients). PROP's contribution (and Dr. Chou's), to those guidelines caused much patient harm & deaths which snowballed into the misapplication of the guidelines among insurance providers, lawmakers, pharmacies, law enforcement/DEA and much more. PROP has doubled down recently to ensure their propaganda continues to reach more and more people, by holding town hall meetings, webinars, etc. New non-profits have recently started, that focus on pure anti-opioid propaganda and a search of their board and supporting members, shows it's PROP members and many anti-opioid groups such as Shatterproof & Pharmed out. I doubt you are aware of the actions of Andrew Kolodny dating back to at least 2004 when he was paying doctors, hospitals, prisons & jails, $10,000 to switch OUD/addiction patients from methadone to Buprenorphine (Google this), and then, after he was instrumental in getting government funding for the Suboxone research and subsequent FDA approval, he was very involved in convincing doctors to switch patients with OUD/addiction, to this drug and continues this push. I won't tell you why I believe Dr. Kolodny has been fighting so hard or for so long against opioids but I'm sure you have a few ideas. **Also, I am concerned that Dr. Roger Chou was able to influence these new guidelines. He should have never been allowed to have any input into the revised guidelines due to extreme bias (he essentially represented the entire PROP group). During the public comment period, during the meeting, a member of PROP spoke.

The same propaganda we've been hearing for the past several years was repeated. One claim particularly frustrating (there are many though), is that the pro-opioid speakers are being paid by big pharma. This is just not true, and I believe the CDC knows this but just in case, I would like to bring this up. Dr. Kolodny has publicly accused Don't Punish Pain Rally Group of being paid mouth pieces for big pharma and we haven't received a dime from them, nor have ANY communications with them. Anytime someone speaks up pro-opioid on Twitter regarding an article comment, etc., the same claims are made, in an attempt to discredit these people (who aren't even a member of any group).

I'm sure you are aware of the risk of addition/OUD but since that member of PROP or maybe it was Dr. Gary Franklin, exaggerated this risk during her/his public comment, I would like to remind you that credible studies have shown over and over, that the risk for opioid-naive patients who receive opioids for acute/surgical pain, when properly screened & monitored, is extremely low. Chronic pain patients do develop dependence, but rarely addiction or OUD. Studies vary between 0.3-6%. Opioids do not "cause" addiction but those with addiction do abuse them (mainly mixed with illicit drugs), and millions of dollars has been spent in the addiction arena lately, but the OD rate has only skyrocketed, despite the massive decline in prescribing. Contrary to what someone said today during the comment period, claiming opioids have fueled this crisis and always have....well, prescription opioids have really only been around since approx. 1990. Illicit street drugs & poly drug abuse has always been the problem!

I would like to ask if the revised guidelines can recommend continued tele-visits with scheduled medication prescribers, which was occurring during the pandemic but was stopped as of 7/1/21 in Indiana, I guess by the governor? Pain doctors did require an in-office visit every 3rd month (varied among prescribers), for UDS unless they sent out the saliva swab test & watched the entire collection during the tele-visit. Pill counts were done every month in the same way, at least with my doctor. The pandemic is not over - not even close, and it is extremely difficult for most pain patients to drive (or get a ride), to see their prescriber every month or more, especially since so many patients now must drive long distances because they could no longer get a local doctor willing to prescribe. Those unlucky enough to have a doctor south of the I-65 closure in downtown Indianapolis, Indiana (but who live north of it), have a VERY difficult drive to/from their doctor! I won't even try to visit my elderly mother due to the nearly impossible interstate traffic now! If you know the area & the detour which also has construction, you'd understand why it's worse case scenario! I've been in a w/c for 22 years due to a spinal injury received during a procedure for attempting to halt new onset CRPS (aka "RSD") of both legs & lower back that I got as a complication of a knee surgery (it spread to the other leg & back within a few months after the spinal injury. I had all known diagnostic tests known for this disease plus, have traveled to see specialists in CRPS in Tampa, FL where I also received a series of sympathetic spinal blocks over 2 weeks (on my 2nd trip to FL). I also went to Mayo clinic in Rochester for possible help. I have had a massive amount of pain & edema in the legs/feet with severe & frequent muscle spasms in my legs, back & diaphragm and I have just about every external device & topical treatment made, plus a spinal cord stimulator, to attempt to lessen the pain & improve other symptoms enough to allow me to work less than part-time, because I love my job as a RN and found something I'm able to do safely & gets me out of my bed for a few hours twice/week. I am a determined to do whatever I can to help myself, but I am in bed 24/7 except for seeing 2 patients/week or to go to a doctors appt (the past 9-10 years, I have been able to use crutches a very short distance to get into a patient's house and to/from the bathroom at home because I can bear weight on my left leg). Over the past year or so, my healthy spine, has deteriorated rapidly & very unexpectedly due to osteoporosis and initially, I really didn't have much pain in my spine even though I was diagnosed with 2 compression fractures, moderate to moderate-severe spinal stenosis at all levels, DDD, multiple herniated & bulging discs all levels, severe arthritis of the spine, many bone spurs & bone spur complexes (cervical spine), and several other diagnoses from cervical to lumbar spine. Unfortunately, although I didn't think anything could top the RSDS pain, this has come close - especially when the radiculopathies developed in my C-spine and lumbar spine. Despite needing an increase in my pain medications (that is a battle I don't know I will win even with imaging showing all of the issues), I am currently just spending most of my days/nights on either large ice packs or heating pads. So, I am just one example of why continuing tele-visits would be very beneficial! After sitting up for 2-2 1/2 hrs, I just can't tolerate the pain, but my doctor is 3 1/2 hrs round trip plus the appt. time/waiting (I take a cooler with large ice packs plus a heat device that plugs into my van for the trip home). What choice do I have without the option of tele-visits now? I know of an elderly couple with the pain patient being bed-bound/totally immobile (wife refuses to put him in a nursing home), but he is too large for his wife who is much smaller, to transfer to a w/c and take to a doctors appt, and since he could not get into the pain doctor for a UDS, his opioids were cut off. There are other patients I'm familiar with who are also bed-bound, and in addition to intractable pain, they are not able to control their bowel & bladder, so going to an office visit is impossible so now they have lost their pain medications. The examples are endless and include terminal cancer patients refused adequate pain relief and families have contacted me to see what they can do. I really hope there is something the CDC can do to help Indiana with this tele-visit issue, at least?

Recommendation 1 and 2: Both of these focus on nonopioid treatments. While I appreciate the proposed changes to the guidelines, there is not enough mention about how opioids are necessary for some pain patients, including high dose opioids with high impact pain. The continued focus is all about alternative, non-opioid treatments but unfortunately, those on opioids have already tried these treatments prior to beginning opioids.

Recommendation 2: Please consider adding intractable pain to the current categories. Acute, subacute, and chronic pain isn't enough. Intractable chronic pain is severe daily pain that doesn't come and go, so just because it's "chronic pain", does not mean they should only be treated with non-opioid methods (which have already been trialed).

Recommendation 4: Regarding tapering, there should be a statement deterring forced tapering so that this recommendation isn't misapplied again like so many others. Also, careful word this, so no one can understand it to say that doctors are supposed to force taper their patients (or cut them off cold turkey)!

Recommendation 6: Opioid durations - Strict limits on the number of pills (i.e. for 1-3 days), is a big problem! The misapplication can be seen in the recommendations put out for how many pills surgery patients should receive (max amount), for xyz surgery. 10 pills for open heart surgery (5mg Lortab)! Double mastectomy was either 5 or 10 pills. There are other examples but the problem with this is that one size does not fit all, not in the surgery itself and not in the patient (many surgeries do not go as planned either, creating more pain). Granted, anti-inflammatories do help surgical pain, but many people can't take NSAIDS. Studies on IV Tylenol are poorly done and not accurate, so I hope you caught the errors in them and if not, have someone familiar with research studies show you what's wrong with them (someone who isn't an anti-opioid zealot). Many studies done by or reported by those against opioids, are poorly done. I've read them! The other disadvantage of these very strict limits for acute pain (which also applies to those with chronic pain), is due to something new being done by CVS pharmacies and probably other pharmacies. The pharmacist is no longer allowed to manually order scheduled medications! The computer orders them at the time the Rx is processed and CVS only orders what is needed for fill those Rx's. They receive shipments Mon-Fri only, so if the Rx is processed on a Friday, the earliest it will be received by the pharmacy is Monday. Someone who just had surgery can't wait 3-4 days or longer for their pain medication. It's the same for refills. CVS won't have the supply unless there was some left in the bottle they received. For chronic pain patients who aren't allowed to pick up their monthly Rx until the day of their last dose, it's even a bigger problem since even though the pharmacy knows which patient picks up their medications every month and how many pills they need, they will not be ordered until the Rx's are ran - so if the patient takes this medication at midnight (which is considered the next day - so the new Rx begins their month), they will be missing doses and many patients have taken these medications for years so they can't just skip several doses or several days! If their Rx's are due to be filled/picked up on a Thurs. and it takes more than 1 day for the new order to arrive, then it won't be received by the pharmacy until Monday at the earliest since they do not get deliveries on scheduled medications on the weekend (or holidays)! If it's processed on Friday, then the patient automatically has at least a 3 day wait to get their medications. A patient with acute pain that only needs a 3-5 day supply might be able to pay out of pocket but not a chronic pain patient who needs a 30 day supply. Oh, and when the Rx is finally processed, the pharmacy also finds out if a PA is required that month! This turns a 4-5 day delay into much longer since the MD must apply for the PA then wait for the insurance company (and if it's a medication change, most insurance companies are denying the initial request). If the patient can find another pharmacy that has the supply they need on-hand, they still need a PA plus they must wait until the MD sends a new E-prescription to the other pharmacy since they can no longer be transferred to another store, even if it's in the same pharmacy chain!! Any pharmacy who is now ordering this way, will not have enough medication for these patients, every single month (and again, the pharmacist can't order the medication ahead of time, knowing it will be needed on a certain day). Something needs to be done about this and it's only going to cause even more doctors to stop prescribing. I am getting ready to call CVS corporate to complain, as requested by the pharmacist but many pain patients are now talking about this & I've heard that Rite-Aid is doing the same thing. Also, when you specify how many pills or days' worth of pills that can be prescribed for acute pain, and if especially if it's only 1-3 days, they will have a problem getting the Rx filled much of the time, due to the weekends and refills will require a new Rx in addition to the problems with getting the actual supply into the pharmacy so it can be picked up by the patient! Of course, this is if the pharmacist will even fill the Rx, since so many people are being denied, even with a supply of 1-3 days! When the pharmacist refuses to fill it, the MD must send the Rx to another pharmacy (so the patient plays phone tag with the doctor's nurse and who knows how long it will take before the MD gets around to resending the Rx but I had this happen last month - before I switched to a pharmacy that delivers and only deals with scheduled medications, and I was without my medications for 5 days, after being on them for 22 years, so after being force tapered to such a low dose that I am barely able to get through each day, I had to cut my pills in half to avoid withdrawal until he resent my Rx and this was just prior to CVS switching to the new ordering process or it could have been even longer). It seems that every week, the hoops that pain patients and doctors must jump through, get worse and I don't know how much worse it can get!

I have a concern with the new "go-to" pain medications (after alternative treatments). I saw this coming due to PROP pushing Buprenorphine and Suboxone (and similar drugs). For approx. the past 12 months, new pain patients and even legacy chronic pain patients are being placed on these addiction drugs when there is no sign of addiction/OUD at all!! I'm sure you are aware of the side effects and efficacy of these drugs for pain, but did you know that for intractable pain, they do not provide enough relief? Some patients with more mild pain, say they are getting a fair amount of relief, but this isn't the case for those with severe and intractable pain. Plus, side effects are very common. In addition, they are also addictive for those prone to addiction and every person I've heard describe trying to get off them, said it was far worse than regular opioids (especially difficult with Suboxone). Also, when they have needed surgery, depending on which of these medications they are taking, they must wean off prior to surgery because the opioids given during and after surgery will not be effective! Again, doctors are so afraid of the DEA, they are willing to force taper and cut off patient's cold turkey or force them onto something that isn't effective and causes many side effects. When it comes to pain management, rarely is anything done in the best interest of the patient anymore and this is just wrong, not to mention inhumane! Lastly, patients with a history of having taken one of these drugs, is treated even more like an addict, even with no addiction present (and so many people now have access to our PDMP's, not just every doctor or nurse we see). Pain patients shouldn't be treated like or forced to live like, second-rate citizens just because they are unfortunate enough to have serious pain. We are doctors, nurses, police officers, judges, lawyers, teachers, and every other occupation. We are good people who want to continue working, not lying in bed 24/7. What can you do in the guidelines to discourage what has become routine use of addiction medications in place of other opioids? Patients shouldn't have to suffer even more because doctors are afraid of the DEA.

Comment regarding exclusions to the guidelines: Why is sickle-cell disease listed as an exclusion? I am a RN with 30 yrs experience in hospitals, long-term care, office nursing and more. Sickle cell disease produces episodes of severe pain, not continuous intractable pain. There are many diseases/disorders that produce intractable pain, such as CRPS, severe spine issues and so many more. I recently spent 3 years focused on the treatment and care of stage 4 cancer patients. The majority of these patients who were not going through chemo, had no pain until their final few days. Obviously, the type of cancer and location usually determines the severity of pain. My point is, there are many other diseases/conditions that cause far more severe pain and pain that doesn't just come & go, yet when only a select few are continuously mentioned in the guidelines, it will be misapplied and only those patients will have a chance at receiving adequate pain treatment (although many of these patients are having problems receiving adequate pain treatment).

I agree in the overutilization of category A, as it will lead to the continued misapplication of the guidelines. MD's who know their patients are the only people in a position to determine what is needed for them. The misapplication of these guidelines has caused a serious reduction in doctors who can/will prescribe, as many have retired or retired early, others have changed their field of practice and the few that are left are being forced to take their patient's off opioids due to fear of the DEA/medical boards/AG's. This leaves far too few doctors to care for pain patients and it's a well-known fact that when these patients need to find a new doctor, no one will take them if they have chronic pain! My pain doctor of 18 years moved across the country and although other doctors in that practice took over my "care", I was force tapered after 22 years on opioids plus I was forced to get a spinal cord stimulator even though I had one 21 years ago, but it had to be removed due to shocking me when it was turned on. Also, many pain patients can't even get a general practitioner to accept them as patients for their routine medications, like blood pressure meds! All doctors are very fearful of being arrested and the GP's fear their patient will need them to prescribe their pain medications at some point, so they won't even bother with these patients. Something must change!

RE: MME - Thank you for considering removing MME's from the main recommendations and moved, however, I still feel it will continue to be misapplied unless the CDC makes it very clear, the reason it is being included in the guidelines. I would also suggest that legacy patients be exempt from any reference to the MME "suggestion". Anti-opioid groups continue to call for the inclusion of MME in the guidelines but since the majority of opioid pain medications are being prescribed by pain specialists, they are uniquely qualified to determine what MME their patients require, not the CDC, not PROP members or any other anti-opioid group, with a financial interest in their own specialty, including those who sell medical devices such as spinal cord stimulators, etc. (despite the high risks being reported). Heart patients see a cardiologist, cancer patients see an oncologist, those with mental illness see a psychiatrist, etc., and pain management doctors specialize in pain treatments and opioid use (even general practitioners have a good knowledge of this but could consult with a pain specialist if they have a difficult pain patient). Yet PROP & other psychiatrists pushing Buprenorphine & Suboxone (and similar drugs), believe they should be recommending the guidelines on pain medications?? Surely you can see the issues with this, and it is why the 2016 guidelines created so much havoc, but I never expected the misapplication of those guidelines to the extent that has taken place. During public comments at the end of the meeting, I believe it was Dr. Greenspan (not positive), suggested clarifying Dr. Roger Chou's role in these new guidelines since the issue was raised several times during the public comments. I know a lot of people would like to hear about this and why did he recuse himself for the meeting but not long before this? I'm afraid his damage has been done to the guidelines - again.

Pain patients have been put into the same category as those with OUD/addiction, WITHOUT EITHER of these disorders. If the CDC revised the guidelines to reflect the truth, maybe the media would stop continually reporting false information! Just this week, AP News printed an article regarding the increase in OD rates for 2020 and outright blamed Rx Fentanyl and even said other illicit drugs are laced with this and it is responsible for the increased OD's, AND all of the OD's of the past! Many other media outlets reprinted the same story! I did write the AP reporter and hope he will make a correction but that doesn't change the fact, millions of people will have read the story and all of the other one's that used the same source. The CDC can help stop the stigma by coming out with the truth. **Despite what Dr. Franklin said in his comment, claiming Rx opioids were driving the OD epidemic, it's not true. Nor it is true that they always have! How can this be true when prior to Oxycodone and similar pain medications being developed, OD's were occurring at high rates - due to poly drug abuse, heroine, meth, and other illicit drugs! Illicit street drugs have always been the problem and now with illegally manufactured Fentanyl, OD's have skyrocketed. It's time to stop blaming Rx opioids, overprescribing and pain patients diverting their pain medications! Yes, there were pill mills that certainly shared in the responsibility, but they have been shut down.

One last concern I hope the CDC can help with, is the PDMP problem, especially when NarxCare is being utilized (please Google for articles on this problem and the impossible situation that has been created due to the misapplication of the guidelines). I won't go into a lot of detail & instead hope you will look into this because it's nearly impossible NOT to have a high Narx Score which indicates OUD according to their algorithms and patients are being dismissed by their doctors due to a high score & pharmacists are refusing to fill Rx's based on these scores and red flags. There are an unknown number of red flags, outside of our control. Some examples of red flags & actions that raise the score (learned about when the patient was told about it by their doctor/pharmacist which is rare), are: when we see more than one provider even when they are within the same medical office; using more than one pharmacy which is becoming pretty common, especially when the pharmacy doesn't have enough pills to fill the Rx so we are told which pharmacy does have the supply and the doctor sends new Rx's; traveling to a pharmacy or a doctor that's too far from the patients address; history of abuse/childhood abuse; history of mental illness including anxiety & depression; MME of 90 or more; co-prescribing with opioids and a benzo or certain muscle relaxers such as Soma; and the list is almost exhaustive. The patient cannot get their score, nor can they see their report to fix errors which are admitted being common.

Again, I am sorry for such a long email.   Many feel that if the CDC guidelines weren't as focused on OUD/addiction and instead split the focus at least half and half with real pain patients and the very real problems they face due to bias and stigma, it would certainly be a start in repairing the damage done by the misapplication of the original 2016 guidelines. Suspicion against pain patients shown by the CDC in these guidelines will be fuel for the fire that has been burning since 2016. We need your help to correct the problems the CDC created by allowing an anti-opioid group to essentially author the 2016 guidelines, resulting in too much to list in an email.
Thank you so much for your time and consideration!
Angela Willis RN and chronic pain patient

From: Angela K. Willis
To: NCIPCBSC (CDC)
Subject: Comments from BSC meeting (I was unable to comment during the meeting)
Date: Thursday, July 22, 2021 12:42:15 AM

My name is Angela Willis RN and I sent my BSC comments by email recently but left out some important information and it is crucial the CDC gets the revised guidelines right this time unless they will do the other right thing and just retract them (if anyone needs to put out guidelines, the FDA should be the agency to do it). The misapplication has greatly harmed millions of patients, hundreds of innocent doctors and even caused many suicides when patients with intractable pain were cut off by their doctors and could not find another doctor willing to prescribe. PLEASE, too many people are suffering who do not have OUD/addiction and it's not fair nor effective for pain patients to be treated like addicts. So many of these patients were able to care for their families and were working before having their opioids cut off or drastically reduced and now, they are on disability and a large % of them are homebound & are essentially absent from their families' lives. We understand there are other treatments for pain! Different types of pain respond to different treatments/medications, just like there are different severities in diseases/diagnoses causing pain (keep in mind, many people can't take NSAIDS or even couldn't tolerate long-term Tylenol, so opioids may be their only effective option). I truly don't know any doctor that doesn't first try other medications and treatments before prescribing opioids! Opioids are RARELY their first choice! If you had ever experienced really severe pain, like after a major surgery, maybe you could relate to this better. Well, chronic intractable pain patients don't have to tolerate their severe pain for just 4-5 days. It's every single day and all day/all night for years! Few can live like that, which is the reason for the increasing suicide numbers. It is inhumane and a violation of our rights, to dictate how we treat our pain and to force patients to lie in bed suffering.

As you know, state laws were even written, placing restrictions on opioids while quoting the guidelines, which were based on false information based on weak or no evidence. Insurance companies developed new policies based on the guidelines (misapplied them), and now will only cover a certain number of pills, even for legacy pain patients (for the little bit they will cover, they require a PA and they frequently refuse to approve imaging, PT, etc. and I have experienced this over and over for the past 2 years). This is just the tip of the iceberg of ways the guidelines were misapplied all due to false information the authors used when writing them. Are you aware that things are getting even worse for pain patients - not better? You're aware it has become difficult for pain patients to receive adequate pain relief in the ER or when admitted as an inpatient and during/after surgery, but at least for a while, they were allowing chronic pain patients (CPP's) to bring in their home pain medications to use, even if they wouldn't give an increased dosage (which IS needed after surgery or an accident, etc.), but recently I have heard report after report of people having serious spine reconstructions, knee and hip replacements, etc., who were not allowed to use ANY home pain medications and they were not allowed to have any type of opioid given during their hospital stay! I became a member of several pain groups a few years ago when things had gotten so bad, so I hear all of these horror stories - and I see this happen to my own patients (I am a home care nurse, mainly doing home infusions prn but just barely able to continue working and I am in bed 24/7 unless I have a patient)! I was lucky to see the information regarding this meeting, in one of those groups! Very few people even knew it was happening, so I'm guessing there are few public comments representing pain patients and most are probably from those against opioids, who have confused street drug addicts with pain patients and who believe what people like Dr. Chou, Dr. Franklin, Dr. Kolodny (and others), are trying to convince everyone of. So much of that information is just not true! Oh, and not even one of these pain groups I follow, are receiving any funding from or exchanging information with big pharma, which is what Dr. Kolodny tells everyone, however, these anti-opioid groups ARE receiving funding from big pharma (selling addiction drugs)! This is very easy to verify. If these guidelines are not just withdrawn, then they need DRASTIC revisions - much more than what I read in the work group report or heard during the meeting! Pain patients who no longer get relief from alternative methods, and who cannot get adequate pain medication, just cannot continue like this! The few doctors left who are willing to prescribe low doses, cannot continue jumping through DEA hoops and risking their practices, licenses, and lives. Many have already retired or changed specialties so there is a great shortage of pain management doctors. Many compassionate doctors have a very hard time watching their intractable pain patients suffer when they can't help them!! How about paying serious attention to the AMA's recommendations that were actually very good! Please read those again.

I feel Dr. Chou has greatly influenced the revisions and has provided much false information to the work group. Why do I believe this? First, we feel he is still working with PROP members, especially Dr. Kolodny (they worked together in the past and are friends), and we have read many articles put out by all PROP members and Dr. Chou over the past few years that contain flat out lies so this is the information he will be providing to the work group! I would hope that any "facts" he (or any other person who is so against opioids), present, would be checked using credible sources before being considered for the revisions, however, we are very fearful this will not be the case. Below, I am including some references just to get you looking in the right direction but it's far from complete! Since I have already submitted comments and there were many, I will keep this email much shorter. Please remember that a lot of this "crisis" is due to the incorrect OD rates put out by the CDC! Most of us know there are massive reporting errors for OD's (most are blamed on Rx opioids when it's illicit Fentanyl, poly-drug abuse, etc.), yet these same doctors continue to use those OD rates when trying to convince the public that Rx opioids are responsible for all of the deaths! I would like to see this addressed in the revisions. The media needs to know about these incorrect OD rates!! Some reporters are already aware of this and have written articles about it but mainstream media doesn't pick up their stories.

Dr. Chou works for OSHU and contracts to do the systematic reviews on opioids for AHRQ then he either presents this information or writes his own and presents it, for the CDC revisions, plus from what I heard during the meeting, he then has the authority to approve or deny what the work group decides to put in these revisions! You cannot let this type of bias seep into these revisions - not again! Please end it! Focus on addiction issues instead of how to ensure pain patients don't get opioids which is actually a great pain reliever that doesn't cause serious & life-threatening adverse effects like NSAIDS & acetaminophen does (some of the other common medications being Rx'd for pain also have bad side effects, for example, Cymbalta damages the liver and causes my liver enzymes to shoot up after only 1 week of taking it)! Let the patients' doctors decide when to begin opioids, when to end them and the dosage. If they are closely following their patients and following the DEA "rules" for how to avoid problems such as diversion (doing UDS, pill counts), etc., then they are watching for risk factors of OUD/addiction and can help suffering patients! A recommended MME should not be anywhere in the guidelines! I don't think I need to explain why (please research this if you don't know why since it should be obvious by now). Some patients need 2000MME or more! This is the minority of course, but it also doesn't mean the patient will always be on this dosage or will need to continue to increase the dose. At the beginning of my diagnosis of CRPS followed by a spinal injury where my L4 and L5 nerve root was destroyed and one of the spinal cord stimulator leads was misplaced into my spinal cord, I was on 2000 MME. It was the worse pain I have ever experienced, and it took a lot to get my pain under control, yet as that pain finally began subsiding, I tapered myself down slowly with the help of my doctor! I got down to around 600 MME but then was force tapered when my doctor moved! It is inhumane to expect intractable pain patients to manage on 90 MME or even 50 or less (some states are lower than 90), when 90 MME is the starting dose of extended-release opioid for those being switched from immediate release, especially when they were on opioids for years! All agencies should be focused on stopping the influx of illicit opioids and helping those with addiction. Cutting pain patients off their pain medications is NOT going to help a single addict or prevent a single OD due to illicit drugs!

Before I provide some links, I just want to address something brought up in the meeting regarding copying what Canada and Europe is doing (I believe Dr. Franklin made this suggestion but the facts he presented on this were not correct). Just be aware that PROP worked with Canada to write their guidelines - which they ended up abandoning due to so much patient harm! Then PROP began working with Europe, helping them write their guidelines (I'm not sure if they have published these yet). They were fed lies! So, these are not countries to copy. You must question everything (like a graph put out by one PROP member showing a huge increase in prescribing of Oxycontin between 1980-2006. What they don't tell anyone is that OxyContin wasn't even approved by the FDA until 1995 so it appears the increase was huge! This is just one example of the tactics being used by these groups that resulted in the massive failure of the 2016 CDC guidelines.

I just decided not to provide as many links as I had planned since my email is already so long, but the links I'm omitting were showing Dr. Chou's involvement in especially fairly new organizations and non-profits and how they and he benefitted financially in a very big way, including by receiving a large of amount of money from the opioid manufacture lawsuits (I believe the initial reason for all propaganda years ago by especially PROP but also Dr. Chou, was to prepare the public for these lawsuits - creating easy wins for these anti-opioid groups AND to eventually get all pain patients onto addiction medications which is DEFINITELY occurring now as I stated in my previous email). Putting pain patient's or forcing those on other opioids, onto Buprenorphine, Suboxone and Methadone is just wrong, but this is becoming very common practice in case you weren't aware of this!

Link #2 below was written by a pain patient and although it's not a "credible" reference, it provides many very interesting and true facts and she provided credible references! You really must see these. A one article was done by a media site I am not a subscriber of so I couldn't open it after the first time I viewed it, so I hope you're able to read it.

Thank you again for your time and consideration & I sincerely hope you have read this email and will read the following links for an introduction into how these anti-opioid groups have not been honest and are fighting so hard because they have their own agenda!! Please don't let millions of pain patients and innocent doctors down.

1) Totally false and misleading "facts" published by Dr. Kolodny (he and Dr. Chou are also on the boards of at least a few major anti-opioid groups such as Shatterproof & Pharmed Out):
https://legislature.vermont.gov/Documents/2016/WorkGroups/Senate%20Health%20and%20Welfare/Bills/S.201/W~Dr.%20Andrew%20Kolodny~The%20Prescription%20Opioid%20Crisis%20and%20the%20Heroin%20Crisis%20Presentation~1-28-2016.pdf
2) https://ramblingsoapbox.com/2018/06/26/an-open-letter-to-dr-andrew-kolodny/
3) https://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html

Addiction Treatment With a Dark Side

High hopes for buprenorphine, an effective treatment for opioid addiction, have been tempered by a messy reality: health complications and deaths, unscrupulous doctors and a reputation as a street drug.

www.nytimes.com

From: Angela K. Willis
To: NCIPCBSC (CDC)
Subject: Comments for BSC work group meeting: Important facts of law (CDC falls under) & science
Date: Friday, July 23, 2021 4:09:40 AM

You will find very interesting and important facts regarding not only the law as it relates to guideline revisions (or withdrawing them is even better), but also science-based facts. You must help stop the propaganda & lies brought to the CDC guidelines by the authors and those trying to ensure it continues in the revisions, like Dr. Chou, and the misapplication that has already occurred and must be stopped/reversed. It's up to you to do this and it won't be easy, but it starts by being truthful and very clear in what the revisions will say & depends on the use of credible references. Anything included in the revisions based on the propaganda and lies by people like Dr. Chou, Dr. Kolodny and Dr. Franklin (and others like them who have another agenda), is only going to add to the damage already done. Lawsuits have already started because of the harms caused and discrimination against chronic pain patients. Please use references with no ties to any anti-opioid organization or member, when looking at facts for topics such as addiction rates for opioid-naive patients when opioids are prescribed responsibly, surgeries being done while patients are only given IV Tylenol or NSAIDS during and after the surgery, and anything else that can potentially continue to harm all pain patients because every day there will be more and more people who must endure surgeries, including major surgeries (or have serious accidents/illnesses), without adequate pain relief, and chronic pain patients cannot continue to suffer any longer. They have had enough. Each one of you in the work group can become an acute or chronic pain patient at any time! Don't wait until that happens to finally understand what we have been telling you regarding what works for pain!

PLEASE consider the source when reviewing data on alternative treatments! So much of it is advertising. Listen to chronic pain patients who have been through all of these alternative treatments/medications and remember that not everyone can use these other medications or treatments. Whether it's due to the side effects of these medications or their conditions do not allow for treatments such as manipulations or even PT (unless all they will do are heat or ice treatments which can be done at home and I assure you, ARE being done at home). See my other comments emailed a few days ago for more information because I really want to keep this email short.

In addition to a large % of doctors who have stopped prescribing opioids (and they are needed in many situations & they are effective), because they either fear the DEA, they have received letters from their state medical board informing them they must adhere to the CDC guidelines or risk losing their licenses (I can provide an example of such letter if needed because they have been sent to doctors & hospitals in many states), or they have simply bought into the propaganda/or were taught this in medical school if they're recent graduates, there is a shortage of many opioids now due to the number of manufacturers who have been essentially forced to stop making them! There are critical shortages. This must stop and since the 2016 guidelines (well, the authors of them), is what started this, they are the only agency who can begin to stop it. I honestly don't know how all of the misapplications will ever get reversed though. Please read the below facts of law and science.

Thank you,
Angela Willis RN

https://www.academia.edu/35612995/Evidence-Based_Policymaking_Whats_Absent_from_the_Opioid_Crisis

Evidence-Based Policymaking: What's Absent from the Opioid Crisis

REVISED 1-14-2018. Evidence-based policymaking requires the collection and evaluation of evidence. Failed policymaking often results when known evidence is ignored. On the subject of opioids in pain care, that ignorance begins with what the

www.academia.edu

From: Lori Ravelli
To: NCIPCBSC (CDC)
Subject: An addition to my previous email....
Date: Thursday, July 22, 2021 10:57:57 PM

My previous email is posted below…
I feel the need to add some information that I did not state in my last email…
I relocated from California to Texas 4 years ago. In California I saw the same doctor without incident for almost 10 years. When I moved to Texas I could not find a doctor to treat me and prescribe the same medication I had been on for the last 10 years. The doctors in Texas saw my test reports and said they see exactly why I am in pain but none would take me on as a new patient nor write me a prescription for pain relief medication. Primary care doctors said I need pain management. I was told by several pain management doctors they would take me on of I would do lumbar spinal injections or a spinal stimulator device but not for medication. I even had doctors tell me if I do not get injections they refuse to have me as a patient at all. I saw in my first 2 years in Texas almost 25 different doctors in search of medical care for my documented chronic ailments. From pain management, orthopedic doctors, neurosurgeons, primary care…I was forced to doctor shop and still could not find adequate care. I was at my wits end, I reached out to my previous doctor in California and explained to home what I was going through. He told me he could care for me until I could find a doctor in Texas that would take me on as a patient. I had to fly back to California from Texas to see my doctor for every medication refill. It was the only way I could ease the pain I suffered from. The few (2 if I recall properly) doctors I saw in Texas that did offer to write a prescription cut down the dose so low it was not helping with pain relief and I was in constant agony. Most doctors blamed the CDC and the DEA and refused to write a prescription and mentioned the 90 mme. I was not even offered a prescription for 90 mme and my medication amounts were dropped with no tapering at all. I was in agony and decided my only option I had was to fly back to my previous

physician in order to be able live with a bit less pain due to the guidelines set by the CDC in 2016. I am so tired of life in agony and being treated like I am a drug seeker. I am just trying to be a productive member of society and with pain medication I am able to do so.

I am a 53 year old professional living in Galveston, Tx. I am begging to ask for a change in attitudes toward people in pain who need improved access to treatments. There are millions of people suffering from chronic pain, cancer and other debilitating ailments that cause severe pain and we are suffering and unable to receive proper medical treatment from our physicians. I am writing to you in hope that you can help with a matter that affects myself and a large number of your constituency.

I need help…I suffer and have suffered for years from severe chronic lower back and coccyx pain that is unbearable. Some of the issues I have been diagnosed with are chronic pain disorder, lumbar spondylosis with narrowing disc space at every level, there are also anterior and posterior osteophytes at all bubbles, hypertrophic set arthropathy at all levels, degenerative disc disease, lumbar nerve root disorder and along with scoliosis (I honestly do not know what all of this means but I know how bad it hurts). I also had a gastric procedure which limits the kinds of medications I am able to take(such as ibuprofen, muscle relaxers, naproxen and nsaids). Long lasting, slow release medications do not work for me because nothing lasts more then 3 hours in my system. I have had multiple appointments with neurosurgeons and other doctors to be told I have too much wrong with my back to have any surgical procedure. It cannot be emphasized enough and I've seen many, many highly-acclaimed surgeons, who are absolutely unanimous in what options I have. They've all said the same thing: Surgery is not an option for me and due to the nature of my conditions I should avoid any invasive procedures as they will make the pain worse. This includes spinal injections, radiofrequency ablation, spinal cord stimulators and pain pumps, to name a few. I have stacks of reports, cds and test results justifying my issues. I have had multiple injections with different medications and in multiple locations to drain my bank account, gain weight and still suffer in agony. Those injections have caused me permanent damage and now I have Adhesive Arachnoiditis. My only option is pain management thru medication and doing physical therapy at home. I can not sit down for any length of time, lying down hurts and I can only stand for so long without my legs giving out. In addition, these days I have shooting pain down my leg when I do sit. Sadly as much as a body needs rest...I can no longer rest comfortably. My quality of life is almost non existent due to the debilitating pain and without access to adequate pain relief I have contemplated if the daily struggle is actually worth it.

My pain has caused me to miss out on daily activities and has become extremely detrimental to my quality of life. I have missed family functions, and important events in my children’s and grandchildren’s lives. I have suffered with this debilitating affliction because I feel that I have been discriminated against by doctors and members of the medical community that have been hamstrung by legislation designed to combat the “opioid crisis”. This crisis made doctors fearful of prescribing medication that significantly improves their patient’s quality of life. There have been cases in which doctors are named in medical malpractice suits or even wrongful death suits based on the prescriptions they wrote for their patients. These outcomes have made even legitimate prescriptions seem like too much of a risk for some physicians. The lack of clear guidelines leads many doctors to become more conservative with pain medication than they need to be. This has caused patients that legitimately need these medications to have their medication dosages decreased or cut off completely. This in turn creates another problem that causes otherwise law abiding citizens to seek illicit drugs from the street and drug traffickers. Doctors have increasingly been tightening their standards for opioid prescriptions as the crisis worsens and more regulations are introduced at state and federal levels. These regulations are counterproductive and have caused many chronic pain sufferers to endure pain or become a criminal in the sight of the law. There are currently no nationwide federal laws regarding opioid prescription regulations. The Centers for Disease Control and Prevention (CDC) has released guidelines for prescribing opioids, but they are just that: guidelines. Enforceable laws about opioid prescriptions are down to individual states, and many of the laws enacted are incredibly restrictive. Refusal to prescribe pain medication leads to unnecessary suffering. It is becoming more commonplace for physicians to under prescribe medication for fear of litigation. I am not the only person caught in this circumstance. I am a member of several chronic pain groups on social media with membership in the thousands just in Texas alone. Chronic pain is something every physician should take seriously without fear of repercussions from the DEA or litigation so their patients can be treated humanely.

When people are not able to get their medication from the proper channels they will seek options from the street with hope of finding some relief. Pain relief is a human right and without relief people will take their lives. Living with debilitating pain you have little quality of life and no desire to wake up in the morning. I am suffering severely and sadly need medication to be a functioning adult. I know I will never be pain free but any relief is welcomed. Please, please for the love of God stop punishing the patients and the medical professionals trying to help them!

Lori R.

Sent from my iPad

From: cppadvocate2831
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:11:56 PM

This has to stop. Quality of life needs restored. We cannot continue to place blame! Addiction and dependence are NOT THE SAME!!!

I recognize addiction as a serious problem, but all too often, addicts are ashamed to admit and take personal accountability for their choices. It's easier to blame someone else (such as a doctor) for bad choices.

Opiates are life SAVING for millions who use them as directed. The side effects are often little to none.

Let's allow doctors to decide what's right for their patients. They have the medical degrees and the patients have the life experiences.

So-called experts with financial incentives should not have ever written up a "guide" to something that is not relevant to their scope of practice. Especially when it creates a cookie cutter, one size fits all approach to healthcare. WE ARE INDIVIDUALS!!!

Give us our lives back, please. This is AMERICA but it sure doesn't feel like it anymore.

Sad and disgusted,
Ashley

From: Billy Andrews
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:23:45 PM

Hi...I am a sixty-six year old retired tradesman.My life in construction work has not been kind to my body [I was retired with disability at age fifty-nine]. I won't bore you with the list of my injuries and ongoing pain...you've heard all that. The reason I'm sending this note is to add my voice to the [millions ?] of pain-sufferers that are NOT abusing their meds. Our Doctors are familiar with our conditions, and use prudence in prescribing the medications that work for us. There are people out here that suffer because of harsh guidelines imposed on us and our Doctors. Please, show some compassion.

William " Bill" Andrews

From: Bonnie Bell
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:42:26 PM

I Have servere fibromyalgia and sometimes the pain is so bad it feels as though every cell of my body is crying out . I had used low dose opoids for 20 yesra to helpme visit with family attend concerts baseball games etc . It helped me particitpate in in my own life . When my insurance company told me they would no longer pay for my medication I stopped . For one 2years , in the time without opoids my condition deterioted markedly . after being stable for 20 years it was socking to realize what a difference opoids made in my life . ai have sine then gone back to using opoids . I am hoping to regain my life

From: Barbara Bowes
To: NCIPCBSC (CDC)
Subject: CDC Guideline for Prescribing Opioids for Chronic Pain
Date: Friday, July 23, 2021 12:33:56 AM

This is a failure of epic proportions. Please immediately withdraw the MME Guideline and the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016.

2020 Drug Deaths Spiked 30%. And Pain Pills Had NOTHING To Do With It

Https://Www.acsh.org/News/2021/07/19/2020-Drug-Deaths-Spiked-30-And-Pain-Pills-Had-Nothing-Do-It-15669

From: Becky Brandt
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 11:33:54 AM

To whom it may concern,
As an RN, Intractable pain patient for 15 years and a patient advocate, I NEED YOU TO UNDERSTAND that these current pain guidelines are atrocious and leave a HUIGE population of law-abiding patients to suffer. Many in this huge group of long term pain sufferers have absolutely no other pain relief options. These patients are NOT HIGH RISK because they've proven year after year that they can use their medications/opioids etc AS PRESCRIBED BY THEIR DOCTOR! Long term patients often need larger, higher doses than normal because they are tolerant to these meds, unlike someone who walks into the ER with an emergent issue and has never taken opioids.

Your facts are skewed, these guidelines HAVE NOT improved illegal opioid problems & overdose, and you're making decisions under a BROAD umbrella, leaving intractable pain patients to suffer horribly for ABSOLUTELY NO GOOD REASON!

I'm available to join your work group as an RN, PATIENT ADVOCATE, adding a voice for all patients who are not present at your table . We just want transparency and a seat where decisions are being made on our behalf for treatment of our pain. Patients are dying because their pain is uncontrolled, In fact we lost a good friend to suicide 2 weeks ago. Picture your daughter or mother writhing in pain because they have no pain medication whatsoever. Would that be acceptable in your family?
Doctors and patients need to make these decisions, not someone who has absolutely no idea who I am or what I need.

Please Contact me for questions and to add me to your panel for future engagements. We need to talk!
Thank you,
Sincerely,
Rebecca A Brandt RN
Cofounder Central Pain Nerve Center
bbhomebody@msn.com

From: Bram Cast
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:41:24 PM

I certainly don't see much difference in the 2016 guidelines and the 2021.
This is sincerely outrageous. Severe pain patients are committing suicide. The same pain patients that were functioning well years ago on prescribed opioid medication . Never abusing said medication. Only having some relief from agonizing pain.
Maybe it would take the people writing these cruel guidelines to contract severe chronic pain in one form or another to understand the seriousness of this.
Sincerely;
J. Bram Cast.
Get Outlook for Android

From: Bram Cast
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:55:23 PM

I certainly don't see much difference in the 2016 guidelines and the 2021.
This is sincerely outrageous. Severe pain patients are committing suicide. The same pain patients that were functioning well years ago on prescribed opioid medication . Never abusing said medication. Only having some relief from agonizing pain.
Maybe it would take the people writing these cruel guidelines to contract severe chronic pain in one form or another to understand the seriousness of this.
Sincerely;
J. Bram Cast.
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Get Outlook for Android

From: Barbara Domer-Hostetler
To: NCIPCBSC (CDC)
Subject: Opioid guidelines
Date: Monday, July 19, 2021 2:08:42 PM

I am 67, widowed and living alone, and permanently disabled with Ehlers-Danlos Syndrome (EDS) and ME/CFS, and additionally have fibromyalgia, hyperadrenergic POTS, gastroparesis, DDD, spinal stenosis, osteoarthritis, and Celiac Disease. In 2016, I was kicked out of pain management after 15+ years, due to a false positive on a tox screen. Since I was not notified until 3 weeks later, a retest would have been redundant. It took me 3 1/2 years and 8 doctors before I found one who would even CONSIDER treating me. My pain treatment used to be at 120 MME. I am now limited to 30 MME.

EDS has no treatment or cure and is degenerative. I will only continue getting worse, and my pain is increasing steadily.

I am told that my inflammatory markers are dangerously high, likely due to under-treatment of my pain. There is a history of heart disease in my family, with my father suffering 3 heart attacks in his 60s, and my older sister suffering one in her 50s. My pain management team knows this but still they refuse to increase my medication.

I am not suicidal, but most days I wish I was dead. My husband died in 2012, and I now considered him the lucky one. This is because of you, the CDC.

You wrote guidelines in 2016 based on incorrect information, led by a group headed up by a man who has no experience treating pain. This group, led by Kolodny, was rightfully turned away by the FDA, yet your organization decided to listen to them. Because of your guidelines, states throughout the country wrote laws pertaining to the treatment of pain, and doctors are now constrained by those laws, as well as the the threat of the DEA, who your guidelines unleashed, with virtually no oversight.

I always thought the CDC was the premier medical organization in the United States. I can see now that you happily invite in unqualified “professionals” to influence guidelines pertaining to something the have absolutely no experience in treating. Yet you ignored chronic intractable pain patients, as well as the doctors who treat us. You relied on incorrect figures to write your damaging guidelines. You are aware of it, yet you refuse to rescind those guidelines. You are responsible for numerous suicides by chronic intractable pain patients who simply could no longer live with their pain. Those of us who are still fighting this are tired of being treated worse than addicts. We only want to be functional again, as well as having some quality of life again as well.

We just wonder why you persist in advancing guidelines that are so harmful to so many? How do you live with yourselves, knowing that you are ultimately responsible for numerous suicides? If you’re receiving some kind of profit from all of this, I sure hope the money is good. Enjoy it, but just pray that you or a loved one never end up in chronic intractable pain.

I, personally, could never imagine anything justifying driving someone to suicide.

Barbara Domer-Hostetler
Mechanicsville, VA

Barbara Domer-Hostetler (iPhone)

From: Brandi Kaplun
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:36:13 AM

My name is Brandi Kaplun, I am a long time chronic pain patient. At only 27 I have had three back surgeries. As you can imagine that has taken a toll on my body.

Because of my age, it’s becoming harder to be prescribed the medication I need to be able to get up and be active. Without my medication I live life at a pain level 8.

Thankfully, as of now, I still am prescribed the pain medication I need but if guidelines are changed I may not “qualify”.

Pain is pain and should be treated as such. People should not be turned away and told to live in pain just because someone is young, or looks a certain way, or you don’t consider their pain a problem. Our pain is real and we should be able to get the medication we need.

From: Brenda Lindner
To: NCIPCBSC (CDC)
Subject: 2016 Opioid Guidelines Revision - my experience
Date: Tuesday, July 20, 2021 2:10:35 PM

I had shoulder surgery a few weeks ago to reattach three of my four rotator cuff tendons because they tore after a fall. After surgery the surgeon gave me no pain meds, but told me to take ibuprofen.

My pain was so bad I wasn't able to sleep at all for several days. It was the worst pain I've ever felt in my life. I was in regular contact with my surgeon and after several days he finally gave me a weak prescription for hydrocodone which only helped some but did allow me to get some sleep. I wish I never would have had the surgery and would have rather had my arm rot off. I won't be having any more surgeries if my pain won't be controlled after the surgery. I also suffered bad stomach problems from taking so much ibuprofen.

Please change your policies so that people can have their pain adequately treated.

Sincerely,

Sue Shoberg
Duluth, Minnesota

From: Barbara Marino
To: NCIPCBSC (CDC)
Subject: Reduction of harm from opioids
Date: Friday, July 16, 2021 3:18:29 PM
Attachments: open letter.1250.7.14.21.docx

Portugal had a severe opioid crisis in 2000. They were losing 7000 citizens per million to drug overdose deaths.So they decided to take a medical approach and DECRIMINALIZED ALL DRUGS. Within 5 years their ODD rate dropped to fewer than 3 per million and their prison population dropped to around 20% incarcerated on drug charges. Even more importantly, their chief drug officer is a physician and all people with substance use disorder are offered MAT. This has reduced their new HIV cases by over 90%.

We would do well to follow their example. The Drug Policy Reform Act has been introduced by The Drug Policy Alliance and will decriminalize all drugs and start treating substance use disorder as a medical condition. MAT is the only effective treatment.

Patients are all unique. Stop issuing irrelevant guidelines and leave dosing to physicians. Stop arresting those of us willing to treat the millions of people needing long term opiates to function and release everyone who was incarcerated on non violent drug charges.

Thank you

Barbara Marino MD

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The War on Opiates: The War on The American People

2021 marks the 50th anniversary of the Controlled Substances Act (CSA) and the start of our government's war on opiates. When this war began in 1971, annual drug overdose deaths (ODD) numbered under 7000 and have escalated to 10 times higher as of last year.

Over 90,000 ODD are likely to occur this year, 1000 HCP will be indicted and 1.6 million US citizens will be arrested. on drug charges. Our courts and prosecutors have transformed the CSA into a weapon against the medical community, against patients needing long term opioids and against American citizens.

The belief that prescription opiates are the main cause of ODD is a lie. Prescription opiates are the third most common drug found in ODD but are commonly found with lethal drugs. Synthetic illicit opioids are the most common class of drugs detected since 2015. The number of drug related deaths skyrocketed over the past 6 years as more lethal variants of fentanyl cross our open borders. Opiate prescribing peaked in 2012 and has decreased by 42% as of 2020 yet ODD continue to climb. Prescription opioids are clearly not the cause of rising ODD.

The DOJ/DEA regulates the legal opioid market. If prescription opioids were fueling this crisis, the government would be liable in the increase of ODD. This highlights the malicious "success" of the weaponization of the CSA. This abuse has led to reduced numbers of privately owned pharmacies, reduced number of opioid prescribers and increased difficulty of continuing on opioids for 8-10 million citizens who need them as well as keeping our prisons full with valuable innocent members of our society.

Over 400,000 healthcare professionals, 8-10 million patients harmed by opioid policies and millions of people wrongfully incarcerated on drug charges are standing together against the guidelines set forth by the CDC. These guidelines have weaponized the CSA which is leading to a loss of compassion in healthcare, abandonment of our patients and prosecution of the medical community and US Citizens. It has brought us under a tyrannical reign with nearly 45% of people incarcerated in federal prisons convicted on non-violent drug related charges brought by the DOJ/DEA which devastates our communities.

This **war on drugs has failed from targeting the wrong enemy.**

And who is the wrong enemy? Our courts, media and the DOJ/DEA all wrongfully believe that the enemy is the medical community, 8-10 million US citizens who rely on safe and effective opioid pain medication and the millions of people who use illicit drugs. 3000 people per day are being forced off their long-term pain regimens non consensually and without medical justification. The war on drugs is no longer a war on drugs but a war on the medical community and on 8-10 million US citizens

The fact that the DOJ/DEA supports the extremist agenda proposed by PROP, whose goal is to eliminate opiate pain medicine treatment completely is particularly concerning for the approximately 6000 HCP who legally and with good conscience write for long term opiate therapy for the 8-10 million US citizens who need them to function. Dr Andrew Kolodny, founder of PROP, helped create the CDC Guidelines, and said of our 4000-year usage of opiates: *these are not medicines (opioids) these are lethal weapons that should be removed from the market. 2019.* Yet 8-10 million US citizens are taking them safely without being addicted or suffering harm, unlike long term use of alcohol or acetaminophen

We believe the Drug Policy Reform Act is the best way to end the abuse of the CSA and end the war on The American People for the following reasons:

1. **DPRA includes regulation of Drug Rehab Centers:** The US has an unregulated drug rehabilitation industry where Medication Assisted Therapy (MAT) is not universally offered. MAT is the only effective treatment for substance use disorder and leads to improved functioning and significant reduction of relapses and ODD.
2. **DPRA decriminalizes MAT:** The DEA is targeting MAT by wrongfully arresting physicians who prescribe them as well as pharmacists who fill them. This has removed regulation from the medical community, and placed it into the hands of law enforcement. We are the only country with a dedicated federal drug police and separate prescribing licenses for narcotics housed under the same authority which is **a violation of separation of powers and of due process.**
3. **DPRA reassigns the regulatory function of the DEA to HHS as the medical regulatory body:** Patient harm would disappear if the regulatory function of the DEA were separated from the law enforcement function.
4. **DPRA decriminalizes all drugs and ends entrapment of HCP using 21 USC § 841, the trafficking law of selling drugs for personal gain.** This law has been wrongfully applied to HCP who care for some of the 8-10 million citizens whose pain is treated with opioids. The DEA uses this law to falsely portray physicians as practicing medicine contrary to non-existent federal practice standards. The practice of medicine is regulated by the states with no federal standards needed. Each state has a Medical Board entrusted with this task.
5. **DPRA decriminalizes all drugs and would help end the current culture of "opioid-phobia".** Opioid-phobia is how the DEA has a 95-98% conviction rate in prosecution of HCP and seems to also determine sentencing. Dr. Steven Henson missed detecting criminals in his practice as most physicians will, and he had a single drug overdose death of a person he had never met but had taken (stolen or bought) medication written by Dr. Henson for a legitimate patient. Clearly the overdose was outside of Dr. Henson's ability to influence to either

deter or to cause. At sentencing, the Federal Judge pointed a finger at him and said “you are evil” and sentenced this innocent man to life in prison.

6. **DPRA Releases all prisoners incarcerated on drug charges: I**t is in the best interest of society to release nearly all physicians, pharmacists, midlevel practitioners and clinic owners currently incarcerated on drug charges and the people incarcerated on drug possession charges and it is our prayer that restitution be given to all. Expunging the records of all and restoring them into our medical and general communities is the necessary next step.

Portugal ended their war on drugs 30 years after the US started theirs. Portugal now spends 90% of funds on treatment of substance use disorder and 10% on criminal prosecution. They are treating addiction as a medical condition rather than as a crime and that is reflected in the fact that their top drug official is a physician while ours is a law enforcement officer. Their success with decriminalization of drugs is irrefutable. Fewer than 3 ODD per million people, fewer than 21% of incarcerated people for drug crimes, 90% reduction of new HIV cases (104.2/million to 4.2/million) The Portuguese people are happier, fewer of them are using drugs and those who do are receiving effective therapy. America would benefit from their approach.

But for right now, 8-10 million US citizens are unable to stabilize their pain, 1.6 million are in prison and 400,000 HCP are under threat of being destroyed all because of abuse of the CSA.

It is past time to end the war and begin the healing. This only happens with community involvement.

Write to your representatives and senators and insist that they support and pass the Drug Policy Reform Act sponsored by the Drug Policy Alliance and Representatives Cori Bush and Bonnie Watson Coleman

From: betty miliano
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:32:55 PM

Hello. My name is Betty, I am 62 years old. In Jan. of 2003 I was walking to work when a car going too fast slid on the ice and hit me. A moment later the driver of that car drove away, leaving me broken and bleeding in a snowbank. In the ER I was given x-rays on my foot and shoulder and sent home. At the time that was what hurt..The next day, of course, everything hurt, especially my my back and right foot. Over the next few months my lower back got worse instead of better.. The were a large number of physical therapy appointments, exams by a neurologist, and orthopedic doctor and ultimately they gave up and sent me to pain management..The pain specialist was surprised that no MRI had been done and ordered one. This showed that a tiny piece of bone had chipped off my backbone and puctured my spinal column. This allowed the caustic spinal fluid to microscopically leak out when I made certain movements damaging everything in it's path..muscles, ligaments, tendons, nerves, bone. They were able, to dislodge the chip and plug/patch the tiny hole. This was done 11 months after the accident..Quite a bit of damage had been done. It wasn't something that could be corrected. In addition, my foot and ankle developed strange symptoms that wasn't diagnosed until 2019 as Complex Regional Pain Syndrome..This disorder is at the top of the most painful conditions known to humanity.. More painful than childbirth or amputation.. It is terrible.. Over the next two years I changed primarily care doctors a few time. A couple retired. I has many shots in my back...corti- steroids, nerve blocks, etc. Any relief from pain was short lived. I had been resistant to narcotic pain medication, but after trying everything mentioned above plus massage, yoga, acupuncture and more, there just were no more options. It was almost miraculous.. I was able to use a cane instead of two Canadian crutches. I began to sleep better and joined an aqua therapy class. It took several years to find the right combination of medications but settled on time release morphine, and shorter acting oxycodone. I had been doing well enough to walk a little every day.. To participate in aqua therapy and a stretching program that really helped. I had some pieces of my life back. And then 2016 happened and I was forced to taper to 100 morphine equivalent milligrams..from 245 mme..The first step down was a name brand narcotic medication (Opana) as my regular medication didn't come in the dosage my doctor wanted me to have. I evidently didn't have the ability to metabolize this particular medication... My pain level went through the roof and I was immediately thrown into withdrawal. My doctor was out of town and his replacement was unable to prescribe something different as I had a 'pain contract' with my doctor stating I couldn't get any from another doctor. I wound up in the ER in a hypertensive crisis..Unable to eat, sleep, get dressed or use the bathroom by myself.. It was the 5 days of my life.. When my doctor returned, I was so far into withdrawal that we decided to put me at the 100mme right then instead of having to 'taper' again. And now it is 5 years later..I haven't regained the pieces of my life that the higher dosage of medication allowed..I barely sleep.. I can't do my own grocery shopping, I can't do much in the way of housework. I can barely participate in life at all..I have a beautiful 2 year old granddaughter and I'm missing out on being "Grammy".. My life has shrunk to this recliner 80% of the time..I have become something I never wanted to be, a burden on my adult children.. Maine (grudgingly and almost secretly) added an exemption for people with " unremitting, unrelenting, chronic pain such as neurological "...and I am at 120mme per day..less than half of what I require. My doctor knows that I was doing so much better with the higher dose. He looks at me pity and wants to help me, but it's like there is a DEA agent in the examination room with us..He is afraid to endanger his license... and I don't blame him for that.. And I don't want to blame you people... I know there is a problem with these medications, but it isn't people like me who are putting meds on the streets... You see, we need them..I have never, in any way, diverted a single pill..You can look at the overdose rates and see that taking away medication from chronic pain patients hasn't fixed the problem.because we didn't cause it.. We may be responsible for our own overdoses..Some have been intentional, to escape the pain by suicide.. others have been driven to the streets in desperation trying to supplement the meager dosages we are allowed... Some have found that what looks like our regular meds are actually made from counterfeit, illicit fentanyl.. And some have died because of it...But on the really bad days,(there aren't many good ones) when the pain is so bad that it hurts to just breathe, these can be seen as viable options.. Most of us don't want to die..and we all know that we will never be pain free..But, there has to some quality of life here It doesn't seem like too much to ask for wanting the weighing the decisions between risk and benefit to be between myself and my doctor. The DEA and, with all due respect, legislators should not be practicing medicine and don't belong in the examination room. I just want some pieces of my life back..the ability to occasionally go out to lunch with friends..to clean up after myself.. to maybe dance with an old boyfriend at a high school reunion.. go for a walk with a beloved grandchild..Can you put yourself into my shoes for a moment.? Is this too much to ask..? Thank you for your time and attention.

.

Betty A. Miliano
8 Waterville Rd.
Belfast, Maine 04915

Sent from Yahoo Mail on Android

From: Beverly Minich
To: NCIPCBSC (CDC)
Subject: MME and 2016 CDC Guideline
Date: Wednesday, July 21, 2021 12:42:58 PM

I'm a long time high impact chronic pain patient. My journey began in 2003 with a rotator cuff repair, from which scar tissue causes pain. That wasn't the problem, it was in my Cervical spine. After two cervical surgeries, my neck hurts more than before the three surgeries. My lumbar spine is a mess and I'm sure he'll say surgery, but I don't want yet another failed surgery, especially since I can't turn my head (because of hardware in my neck) to care for it. My husband is now gone every day, until late evening. He can't stand seeing me crying and shaking in pain, knowing he can't do anything for me. I'm also mostly housebound because my pain WILL rear its ugly head when my small amount of meds is gone for the day. I can't get any higher MME, because of the guideline and because of the ruthless DEA threats of losing medical licenses.

I was on 152 mme (according to one chart) and doing great, now on 104 and not good at all! I had my limits and heeded them when I did too much. I didn't use the handicap parking spots most of the time because I could walk!! I exercised 4-5 times a week at the Y and have a recumbent in my basement; I can no longer do either. I WANT to take care of myself and be able to walk our dogs, play with my grandson and just enjoy my life, not exist in this state of torture. The mme has no scientific backing, as we all metabolize different meds differently. It should be totally gone and each patient should get what we need to LIVE. What happened to patient centered CARE?? It's gone. It's now "be aware of the DEA" with good reason, Doctors ARE afraid to prescribe our medications and won't. We're stuck in a world WE didn't create. We DON'T use the illicit drugs that ARE the problem.

The entire guideline should be gone, along with getting the DEA out of the medical practice and on the border to catch the tons of illicit fentanyl coming in the country! How do they know a doctor is "over prescribing" when they don't have a clue about our conditions or how to treat them? The PDMP should never have been made public; we have zero autonomy. HIPPA-crits. They're why I lost my wonderful, caring doctor of 13+ years. I'm at a DRILL MILL now, the ONLY place that would take me, and was forced to have RFA's in my neck (the pain is from hardware in my neck) and now ESI's in my messed up lumbar spine, all against my will but to remain compliant. Several months ago, I was going to have my fourth neck surgery until I asked the neurosurgeon about pain management post-op. He said "I'm not going to lose my license!!" So no surgery. It's not possible to heal properly without pain control!! I couldn't have had either my knee or hip replacement without ethical pain management. Now, I hear that surgeons get extra money for NOT prescribing pain meds after surgery! Do you know how crazy that is?? The DEA runs the medical system in Ohio. I worked my butt off for almost three decades, 6-7 days a week in a factory, only to lose my LIFE when my bones and joints decided they would degenerate, among other things. I've had one hip and one knee replacement and need the others but not without proper pain management! VERY painful surgeries.

Do you know how hard it is to be a part of the family and be able to be a wife, mother and grandmother with constant pain and always crying because I see no hope? I'm lucky to still have my husband but he's getting tired too. He's got to do everything around the house. I'm not able to cook a meal or run the vacuum, let alone be a wife. My daughter has all but forgotten me, because she can't stand seeing me in such pain that my body will shake on its own and I WILL cry in pain during her visit. She says it's too depressing to see me, the way I am now. I've missed so many family events because I can't travel far and we're not invited to do things now because they know I can't. Do you know what a lonely "life" this is? I can understand why so many choose SuicideDue2Pain. I've thought about it more than once, because waiting until the end of 2022 is so far away, I can't imagine how bad I'll be in another 18 months. I just know that I can't go on like this. The mme has to sunset IMMEDIATELY, and the DOJ/FDA has to call off the DEA. They don't have years of medical training and experience in treating complex conditions like most chronic intractable pain patients have. I never had high blood pressure until I lost my doctor to the overzealous DEA. They have no idea about prescribing (or "over-prescribing" which is a myth) pain meds. Co-prescribing is not a problem for most of us, especially when we've had pain meds and a benzo for many years. Especially now, anxiety is part of being a chronic intractable pain patient. If something would happen to me from taking both, let ME make that decision!! I'm a 59 year old woman, I'd taken my "high dosages" of pain meds for almost 18 years, on and off at first, before and after surgery, until my pain became chronic.

I don’t know how Roger Chou is able to have anything to do with the treatment of the disabled with non-stop pain, when he has so much blood on his hands from the 2016 guideline. Anyone that had anything to do with them should NOT be included in this process. They’re responsible for so much death and endless suffering. They’re responsible for every suicide, every lost year of our “lives.” The mme has to “sunset,” as does the guideline. PROP has much to do with the original death guideline and has no right to force us on their Suboxone!! That will red flag us forever. I’m getting 2 20mg ER OxyContin and it went from $42 to $128 month! Between that, other scripts and vitamins I take daily, I don’t have much left over for bills and groceries (IF I could go grocery shopping).

Please have mercy on us and end the death sentence of tens of millions of disabled Americans. I worked in a factory for almost 30 years, only to be thrown away like trash when I need the MEDICATIONS I supposedly paid for all those years. Believe me, I’d MUCH rather still be working and making good money but it’s not an option. I appreciate you taking the time to listen to us and take our utter misery in to consideration. When a country decides the disabled aren’t worth cheap pain meds for ADL and Quality of Life, stop taking money from the working class to waste and not give us cheap pain meds for us to have a reason to get out of bed in the morning. Right now it’s iffy. A day is 24 hours long and I don’t have anything for when my legs start throbbing at night. The ER OxyContin doesn’t last close to 12 hours. I thought the patients had the right to determine our pain care, but as long as anti opioid zealots are included, we have no chance. This was not supposed to be for legacy patients that had been doing well on the same dosages for many years and decades but it has destroyed many lives. We’ve tried every alternative, most aren’t covered by insurance and cause more pain, but give doctors extra money NOT TO GIVE OPIOIDS AFTER SURGERY! Talk about a conflict of interest! Roger Chou could care less about us! He’s part of PROP, who wrote the death guideline for what turned out to include legacy patients that WERE steady at our dosages but have lost all faith in the medical system WE were forced to pay for, all of our working lives. I don’t know of one CPP/IPP that says the guideline is good. You are responsible for countless deaths and mere existences, NO SELF WORTH. This could be any of you at any time. Congress shouldn’t be involved with our doctor’s appointments without medical licenses, nor should THEY decide how much is enough for some procedures. PLEASE LET US LIVE. That’s all we want. Please make them stop forcing the many expensive alternative procedures, just to be compliant! We are ADULTS and I’d rather have the option for the recommendations of Drill Mills, NOT be forced. Must we suffer until we’re at the end of the our rope when we can’t handle it anymore and finally end it? Please get rid of the useless guideline (from PROP) and completely restore our LIVES. Do we deserve this torture? I’m 59 and jealous of 80 year olds that can out do what I USED TO DO. Nobody WANTS to have anything to do with chronic incurable chronic pain, especially when doing so well for so many years, only to have everything taken away because of something beyond our control, that we have nothing to do with. The illicit fentanyl and other drugs coming in over the wide open border IS the problem and you know it. Punishing the disabled for what the DEA DOESN’T do is evil. I don’t even know what illicit fentanyl looks like or how to get it. I DON’T want it, but I DO want my LIFE back.
Thank you for your time.

Bev Minich
167 W. Broadway St.
Plymouth, OH 44865
567-224-3404

From:	Beverly Minich
To:	NCIPCBSC (CDC)
Subject:	Mme Limits
Date:	Friday, July 23, 2021 3:42:27 PM

My 58 year old wife and entire family has been devastated by the withholding of lifesaving pain medications that she'd taken responsibly for almost two decades. She can't do anything that she wants or needs to do, always in pain, since her long time PM Doctor was arrested for doing his JOB and CARING for her and other "complex" patients. He's been convicted, so until you get the DEA out of Pain Management, she and millions of disabled Americans will never have a life worth living. YOU ARE RESPONSIBLE FOR THE INHUMANE TREATMENT OF THE DISABLED. The DEA is arresting Doctors for caring for their patients while having no medical licenses or years of med school for giving her and others a Quality of Life they can no longer have. ADL are impossible, as she sits in her recliner and cries for the life she's lost twice. This is NOT what she paid for, all of her adult life. This is pure torture for all of us, as we see her go from disabled but 80+% functional to a shell of the woman I married.

She worked in a factory for 28 years and now that she needs the benefits the government took her money to have, there's no doctor available to give her what she needs for a decent life. The DEA has made it clear that they WILL arrest them and take away their livelihoods. What country is this? China? Iran? N. Korea?

She's often depressed about her inability to do what she could just two years ago, WITH her pain medications. Her Doctor treated the guideline as it was stated, NOT for pain management specialists treating "complex" patients of many years. She's done everything she was told to do and now the DEA and CDC have destroyed her life (and her entire family's) with their greed and unchecked power. They're not supposed to be an agency that goes after MEDICAL DOCTORS while allowing illicit fentanyl to flow throughout the country, the REAL killer drug. How much do they know about caring for people with incurable chronic intractable pain, that WAS very well managed? Her Doctor was 82 when the DEA indicted him, stealing his well earned assets and caring for her and hundreds of patients over a very long career! How much do they know about prescribing legitimate prescriptions for serious chronic pain? Until the DEA/DOJ is reined in, there will never be pain CARE in this country. How can you throw away millions of disabled Americans by fake numbers and efforts to force ADDICTION MEDICATIONS on chronically ill patients, who aren't addicted, that will be forever in their records? She always kept her meds locked up because we had a young daughter when her horrific journey began. She still does, with the small, ineffective "mme" she's lucky enough to get. She's FORCED to have invasive procedures against her will, to be able to go to the only Doctor in Ohio that would take her. That sounds like malpractice to me! Forcing legacy patients to do dangerous invasive procedures that are unlikely to be effective for her conditions, that she's already done many times, is pure lunacy. What happens when/if it goes terribly wrong? Who's going to take care of her?

There should NEVER have been any anti opioid zealots (PROP) and addiction specialists writing a guideline for intractable chronic pain! This conflict of interest has killed countless innocent people via suicide, heart attack, stroke and just giving up. I'm afraid my wife is in the latter stage, as another summer passes her by and she's progressively gotten worse. Would YOU want to be in constant uncontrolled pain? I doubt it. It breaks my heart to see her crying all the time, rocking back and forth, when she just needs pain MEDICATION to be able to LIVE again. It scares me, that we could lose her due to this nonsensical made up mme crap. As she gets older and loses hope, I'm afraid of just that. She's missing out on her only grandson growing up and going fun places. The summer fairs are here, but she can't enjoy them. Soon, she won't be able to walk at all. Is that okay? She loves gardening but that's also a thing of the past.

Everyone that had anything to do with the original guideline is guilty of torture and murder, for every suicide and lost YEARS of LIFE. Humanity has used these medications for centuries, FOR PAIN, but now we must have arbitrary limits that have no basis in science? Where did these numbers come from? Who decided now 50mme is sufficient? 90mme was bad enough, but to cut that in half, with no official conversion chart, is unconscionable. Do you people have any compassion at all for your fellow Americans? It appears not to be the case. Nobody chooses to need these valuable medications or to be disabled, but it happens. Everyone is one accident or diagnosis away from a "life" not worth living. Will YOUR family member ever suffer, like tens of millions of Americans have and are? Is this what America is now? Care for addicts by giving them taxpayer funded "safe injection sites" and "free" clean needles while doing nothing for intractable pain patients? It's a very sad time for America. This is what dictatorships do to their Citizens!! The American Holocaust is here. The CDC is killing disabled Americans.

I hope that everyone involved will see the horrific damage the mme limits have done, let alone the DEA making even surgeons not able to give proper medications after major surgeries! Can you imagine having a weight bearing joint replacement and then given IV TYLENOL for pain? How is PT possible with no pain medications? Narcotics are safe and effective when used properly but acetaminophen is NOT safe long term. My wife has had a knee and hip replacement and needs the others done but she refuses because she knows the pain that comes with these surgeries and has suffered enough. Let chronic intractable pain patients have what they NEED, to allow them to do some of what YOU take for granted. Who voted for the CDC to manage chronic pain?? Why were they written in secret, by people NOT qualified to treat the illnesses that took away lives?

The entire thing needs to go away and restore proper pain management. We USED TO be a country that bragged about “world class healthcare” but now we don’t take care of our own Citizens and let them suffer while allowing millions of illegal aliens in the country and giving them “free” everything. Get rid of the flawed CDC guideline and everything that came with it. LET DOCTORS BE DOCTORS!! The FBI has harassed her primary care physician multiple times! WHY?? Take away the limits on legitimate pain MEDICATIONS and send the DEA after illicit drugs, NOT OUR DOCTORS!!

What a cruel bunch of people you are. To let this go on for five years, and then to make them wait until the end of NEXT YEAR is malpractice itself. If we had a real Justice Dept. this would never happen. Why should we pay taxes, only for the government to take our lives? You better get this fixed and before the end of next year! How much more suffering is necessary for you to make this right?

John Minich
Plymouth, OH

From: Bill Murphy
To: NCIPCBSC (CDC)
Cc: Bill Murphy
Subject: CDC Opioid Work Group Comment
Date: Saturday, July 17, 2021 1:22:10 AM

To whom it may concern,

I participated in the CDC Opioid Work Group Review meeting today. I was registered to comment but did not get the opportunity to do so. My name is Bill Murphy. I’m a Patient Advocate in the state of New Hampshire. I was a member of the small team who authored a bill that is now state law in New Hampshire which provides support to those who suffer with chronic illness and resulting pain as well as the physicians who treat them. The law gives the physician the right to treat patients as they deem medically necessary, even when that treatment includes the prescribing of opioid analgesics, without the need to adhere to predetermined MME language.

My comments follow:

First, let there be no misunderstanding about this; were the updated CDC guidelines to include specific morphine milligram equivalent (MME) language, there would absolutely be misapplication of the guideline language. We need look no further than the many states who used the 2016 upper MME thresholds within the CDC Guidelines as a basis for defining language within bills that are now state law. These state laws dispel any and all notion that the CDC language was to be used as a “guideline” as they now set legal limits for opioid prescribing. Let’s not kid ourselves, we all know these same states would revise these laws and implement the updated 50 MME language as the new stated legal limit. Other states that have been considering such bills would quickly act and follow suit. If the CDC pushes forward with the draft as written the damage already acknowledged by the misapplication of the 2016 CDC Guidelines will be forgotten as trivial compared to what will come. Please let us not underestimate the political motivations of state level elected officials to pursue legislative changes that they recognize to be currently popular with their voting base. Unfortunately, our elected officials know only the priorities of the loudest of their constituencies.

We must also recognize the damage done by the 2016 CDC Guidelines in terms of loss of life due to suicide among those who suffer with chronic illness and resulting pain. Those who suffer with debilitating painful disease and injury already face challenges most will never understand even with appropriate pain management. These patients have no expectations of a life without pain, only a hope for an improved quality of life and some ability to participate in activities of daily living. The current guidelines have already resulted in the loss of treatment for hundreds of thousands and a steadily growing rate of suicide due to pain. It should be made clear to all that any stipulation of more limited care, that being a 50 MME threshold, will drive further loss of care and a growth in loss of life that will quickly rival that of drug overdose deaths. By implementing even more severe limits in a physicians ability to make use of a proven and safe tool designed for the treatment of pain, we are creating our next crisis.

Many today have spoken of a desire for a more multimodal approach to treating pain; I agree. I personally make use of four different non-medicinal therapies for managing my pain. It is important to note that for many, opioid therapy is key in enabling a patients ability to participate in other, alternative treatments.

Several have insisted here today that the origins of opioid use disorder (OUD) are most often traced to the use of prescription opioids. What they have failed to explain is that, in the majority of these cases, the use of prescription opioids was not legal use, in that, the opioids were not prescribed to those persons. Time and time again it has been very well documented that the misuse of opioid pain medication is largely the result of those who take from the prescription of a family member or friend, or buy Rx opioids off the street. It is disingenuous for anyone to insist that majority of misuse is the behavior of those to whom the opioid pain medication has been prescribed.

It is often not a mistake to make a mistake, but it is certainly a mistake to knowingly repeat the same mistake. If as a society we are truly interested in doing our best for those most unfortunate among us, let us not yet again make use of MME thresholds knowing they will be misapplied.

Kind regards,

Bill Murphy
Patient Advocate ~ New Hampshire
Manchester, NH
(603) 620-9424

From: Brian Wescott
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Thursday, July 22, 2021 9:21:46 PM

Dear CDC Opioid Prescribing Workgroup,

Please rescind the Opioid Prescribing Guideline and stop interfering in the doctor-patient relationship.

I suffer from Intractable Pain (secondary to hypermobile Ehler's-Danlos Syndrome and adhesive arachnoiditis) that leaves me one bad pain flare from a bullet.

I have remained stable, for years, on a multi-modal pain management regimen including opioid analgesia, but a recent change in my insurance means that I likely soon will lose the opioid analgesia based on the deeply flawed 2016 Guideline. The 90MME limit is arbitrary and was meant only for new patients with acute pain, not for stable, established patients with chronic pain. Far too many like me are being abandoned and left to 1) die a miserable death or, at best, 2) be condemned to miserable disability and be unable to work at all.

Please tear up the 2016 Guideline and rewrite it to protect the ability of doctors to prescribe what their patients with chronic pain pain need to remain stable and, whenever possible, able to work and contribute. Addicts have many options for their affliction. Chronic pain patients have no other options. Please don't abandon us yet again.

Brian Pagaq Wescott, PhD

Sent from my iPad

From: Karen Polizzi
To: NCIPCBSC (CDC)
Subject: Guidelines
Date: Friday, July 23, 2021 10:51:18 AM

Good morning,

I have a rare chronic disease, chronic pancreatitis, that is very poorly understood by most medical professionals. Chronic pancreatitis is classified as one of the most painful and difficult to treat conditions known to man. Consequently, even under the best circumstances, even decent care is very hard to find for most sufferers. With the introduction of the CDC guidelines, somewhat decent medical care has been replaced by dismissive cruelty. Medical professionals are afraid and are being trained to practice without empathy. They are breaking their oaths, causing irreparable harm to patients who are already suffering unimaginable pain. Even if the guidelines were not intended to create suspicious, hostile, and abusive medical environments for patients, they have!

We need the CDC to stop acting as if it has no control over how the guidelines are interpreted. The CDC created the problem and now needs to help fix it. Pain patients can't fight for themselves. They are struggling just to make it through the day. They are busy scrambling for hope and fighting thoughts of suicide. Although opiates can undoubtedly cause serious problems, they are currently necessary to get many chronic pain patients through the day, to get patients to their next doctor's appointment, their next surgery....

My disease is going to progress. My pain is going to get worse. I NEED to believe that the medical profession will help me. That I won't be left writhing on the floor in the ER while being called an addict...I won't be escorted out of a hospital for asking for a patient advocate. I won't be told that I can't have medication to treat my pain because the CDC put out guidelines justifying the insane and unethical behavior of the DEA.

Doctors and pain patients need your help. You can do something. Upset mothers of deceased addicts and anti-opioid lobbyists and doctors with conflicting interests should not drive your decision making around pain care. Put the power securely back in the doctor's hands. Let them treat their patients without fearing for their own lives. Addiction should be treated by addiction professionals and should not prevent chronic pain sufferers from getting the help they need. In a society where discrimination is now supposed to be taboo, pain patients have been targeted, neglected and abused.

Thank you for your time and consideration,
Boykin Polizzi

From: Brian Rabinovitz
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Thursday, July 22, 2021 5:50:28 PM

I write to urge you to remove the 90 MME prescribing limit original put forth in the 2016 CDC guidelines. I am both a neuroscience professor who has taught classes on addiction and the husband of a woman who suffers with chronic pain. My wife has found the use of opioids essential in order to allow her to regain function and begin work as a counselor and help others dealing with chronic pain. She is a model patient who takes her medications as prescribed. Yet, she lives in fear of those medications being taken away and being condemned to unending pain. That fear leads to a stress response with cortisol release, which ironically only increases her pain. We need a humane system where people suffering from chronic pain have access to the best tools to mitigate the pain.

The 90 MME limit does not apply for all cases and what is appropriate for an average person with a broken leg is not appropriate for someone with a complex disease that generates immense pain and has no cure. While I recognize that the original intent of the 90 MME limit was to reduce addiction, the impact has spiraled out of control and is directly harming chronic pain patients. I have spoken to pain management doctors who have said that they do not prescribe opioids against their better judgment out of fear of the FDA. At one point my wife tried to relocate to attend a good graduate school and could not find a doctor who would continue her treatment. One doctor told her that he believed her dose was appropriate for her condition but he would not prescribe and wished her luck in finding a doctor who would. Unless you have been in this situation you cannot imagine how terrifying it is.

You must make distinctions between prescribing practices for primary care doctors and pain management doctors. You must not take a one-size-fits-all approach. You must eliminate the 90 MME limit. There are people suffering with chronic pain who are being cut off from the one medication that helps them and committing suicide… although I think murder would be a more appropriate term if it is known beforehand that cutting them off will lead to their suicide. We must have compassionate care. We must understand addiction and realize that it isn’t from the drug itself, but the way the drug interacts with reward systems in the brain (specifically dopamine in the mesolimbic pathway) and we must factor baseline activity in that pathway prior to drug administration. Pain management doctors must be allowed to use their best judgment without fear of the FDA looking over their shoulders. There is such a thing a legitimate opioid use for pain and removing that option is cruel to those who suffer.

Sincerely,
Brian Rabinovitz, PhD

From:	Bailey Rose
To:	NCIPCBSC (CDC)
Subject:	Opioid guidelines
Date:	Friday, July 23, 2021 5:58:55 AM

I have Chiari malformation and have been on opioids for my entire adult life. I earned a B.S. degree, M.S. degree and teaching certificate and was a great high school math and science teacher for 19 years until 2017 when my pcp sent me to pain management and my insurance co stopped allowing the modest dose of opioids I was on that allowed me to teach, raise my daughter with cerebral palsy alone and travel during my time off. Seven months and a 25% reduction in daily mme later, I developed high blood pressure so high I was hospitalized, tachycardia, tinnitus and severe dizziness. My neck pain from the chiari also came roaring back. I was forced to stop working and am now home on ssdi, having to retire from my beloved teaching career.

I exercise everyday, eat a clean diet, do mindfulness, breathing and CBT therapy. I don't smoke or drink. I have a list of over 50 different meds and alternative therapies I've tried over the past 40 years. Opioid pain meds help my pain and give me a quality of life that nothing else does. If it weren't for the opioids, I wouldn't be able to get out of bed at all to exercise or cook.

I found out today I have breast cancer. Know what scares me more than dying? I'm scared my pain won't be adequately treated. This is a reasonable fear given the countless stories I have read from cancer patients that are not given proper pain treatment. We live in America in 2021. I worked for 40 years of my life, mostly in service jobs like teaching. I taught at-risk students in low income neighborhoods despite having a masters degree in science. I could have continued my career as a scientist, making a good living. Instead, I chose to earn 35,000 a year to be a teacher because what I did mattered. It mattered to me, my community and my country, yet in return, my country let me down. My government said they knew more about what meds I needed than my doctors. Now that I have cancer, will I receive the adequate care I deserve or will I spend my days praying for death to escape untreated pain?

I deserve proper pain management. I've been a model patient for my entire life (and a model citizen) only taking my meds as directed. Please, please make it crystal clear in your updated guidelines that patients like me, who have painful conditions and cancer, who have been compliant patients for many years, deserve to have adequate opioids to manage their pain if their doctors believe the benefits outweigh the risks as in my case.

I should be concentrating on getting better and staying alive, not scared out of my mind about un treated pain. You have the power to undo the damage that was done to millions from the 2016 guidelines. Will you help us or continue to cause us harm?

Thank you for your time

From: Bill Runge
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:46:41 PM

TO WHOM IT MAY CONCERN;
I am an intractable pain patient and have suffered with chronic pain for over twenty-five years. My pain was initially managed by an orthopedic surgeon who soon realized managing my pain was over his head; he wisely referred me to a pain management specialist. My pain management physician was also certified as a neurosurgeon, thus his credentials were impeccable. He explained to me how opiates were one of the oldest drugs known to man and that with careful, managed care I could indeed take large amounts of opioids that my level of pain required, quite safely. He gave me precautions to follow and had me keep a journal of my pain and its cycles throughout each day, as well as how much medication I was taking ***to manage my pain.*** I had a very positive and healthy therapeutic relationship with my physician until he was killed in a plane crash. By ***treating me as a patient who needed opiates*** to live a more normal life, I was able to indeed do just that-**LEAD A NORMAL LIFE!** It was a healthy, trusting Dr.-patient relationship; I took the medication as prescribed and ***he, my Dr. managed how much opioids I took!*** I was under the care of a different Dr. in the same therapeutic manner as before when your 2016 OPIOID PRESCRIBING GUIDELINES were issued. My Dr. who treated his patients with compassion as well as skill, continued to base his treatment of his patients using guidelines that were individualized to the patient's need for pain management. This wise, caring physician had his entire practice, his medical license, ***his personal life***, under attack by the state medical board, the DEA, and ***pharmacists!***

Herein lies the problem with the current and proposed guidelines: **they do not take in consideration that ALL patients are DIFFERENT.** Individuals have different tolerances for medication, different metabolisms, differing liver and kidney clearances, different genetics, and ***VERY DIFFERENT TYPES AND LEVELS OF PAIN!!!*** The CDC's guidelines reduce pain patient therapy to "cook-book medicine recommending (*demanding)* the same types and quantities of opiates for all patients of a certain criteria. Psychiatrists do not treat all psychotics or all depressed patients with the same class and amount of anti-psychotics or anti-depressants do they??? Do oncologists treat their cancer patients all in the same way? Pain is an entirely subjective type of malady. By listing guidelines ***based on no scientific evidence*** for ***all*** pain patients, the CDC is basically stating that we can be treated according to your flawed formulary (MMEs), without allowing the treating physician to treat who and what he/she sees.

There are millions of Americans suffering from chronic pain. Their pain, their very lives have been adversely affected, and very many (thousands and counting) have committed suicide, due directly to your agency's guidelines. Of course you may counter ***that they are just guidelines***, however the DEA, state governments, and other law enforcement agencies treat your guidelines as ***the letter of the law!*** How many of us must continue to suffer, to be pushed to suicide, and have our entire lives destroyed because of your faulty science (MMEs). Why do you take the false expert advice of family-practice physicians, when the expert advise of the AMA, pain management physicians, anesthesiologists, and other experts have tried to weigh in with their recommendations and warnings are being ***completely ignored???*** Why haven't you created a true panel of experts in pharmacology, pain management, and anesthesia who deal directly with pain patients daily and who are truly experts??? The entire lack of scientific basis, practical experience, and true experts demonstrates a willingness by the CDC to simply change the wording of the 2016 guidelines around a bit.

I ask the CDC to consider my concerns in this issue not only for myself, but for millions of Americans-both patients and dedicated, caring physicians. The insanity, lack of reason, and the absence of sound and expert science of your new guidelines will simply repeat the tragedy it ignited five years ago. Please listen to the real experts and pain patients and produce guidelines that are realistic and founded on sound logic and science. Thank-you,

Sincerely,

William Runge
Eagle River, Ak.

Sent from Outlook

From: Beth Seickel
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:45:24 PM

As a RN who is now disabled from work injury causing Complex Regional Pain Syndrome (CRPS), formally known as Reflex Sympathetic Dystrophy (RSD), which is rated 42/50 on Mc Gill Pain Scale; higher than childbirth, amputation, cancer.

Honestly, if I didn't have CRPS, I could never wrap my head around the pure physical torture this disease wreaks havoc on my body for past 14 years. CRPS started in left leg/foot but over the years has spread full body including internal organs. Most of my treatments are NOT covered which is huge financial burden on my family.

However, of the plethora of medications I am on, only 1 is an opioid, prescribed and regulated by my doctor. There are days I absolutely can't care for myself without it. I'm one of the lucky ones.

As a RN I have had patients who were drug addicts. Yes, for them opioids and illegal drugs should be removed.

But please know there are many living with CRPS who will choose suicide if opioids are not available. CRPS patients , like myself, are NoT drug seeking, we are utilizing in addition to other medications and treatments. To deny access to those who utilize safely is medical torture.

There should be room for ALL including nurse Beth Seickel, the CRPS patient. I will not survive the constant burning, electrical currents, stabbing, ice and hot pain, temperature/skin changes running through my body, as CRPS causes our brain to become centrally sensitized from a malfunctioning central nervous system causing a "constant pain loop", never recognizing the injury has been resolved. Truly wouldn't wish this on anyone.

PLEASE hear patients, like nurse Beth, who are responsible opioid patients under continued doctor supervision.

Sincerely
Elizabeth Seickel RN, BSN
"Aka" nurse Beth, CRPS volunteer, RSDSA.

From: Brenda Shoberg
To: NCIPCBSC (CDC)
Subject: OWG Report Comments
Date: Tuesday, July 20, 2021 1:12:48 PM

Hi, I'm a chronic pain patient and have been since 2008. I've had six spine surgeries plus 13 other surgeries including decompression of multiple severely compressed nerves in my left leg due to double crush syndrome, endometriosis attached to several nerves, Grave's Disease, bone spurs in my shoulder and ankle, plus more. I am no stranger to pain. I don't drink alcohol, don't smoke, I take my medications as prescribed, and have never given away or sold any of my medications.

I want to tell you about how the 2016 CDC Opioid Prescribing Guidelines have affected me. In December 2017 I received a letter from my pharmacy insurance company, CVS Caremark, which stated that as of January 1, 2018 they were overwriting my doctor's prescription for my opioid pain medications to bring me down to a "safe dose". I was never consulted as part of this process. My pain isn't nearly as well controlled on this lower dose, and I live in fear every time I have to renew my prescription that I'm going to be tapered or have my dose lowered again. I'm the guardian, conservator and caretaker for my husband who suffers from a terminal illness and I'm also fearful that if my dose is tapered again or cut off that I won't be able to care for him.

Since the 2016 CDC Opioid Prescribing Guidelines were released, other than my pain management doctor I've found that doctors I go to no longer have sympathy or compassion for me as a chronic pain patient. It was a very noticeable change in the attitudes of doctors. Since this time I've been asked by various doctors if I thought I was an addict, was notified that the dose I was on was enough to kill a horse, was told that they would likely have to send me to detox, had a surgeon in a recovery room after surgery loudly tell the nurse I didn't need to be prescribed any pain meds because I was "already on pain meds, a LOT of them". This is no way to treat chronic pain patients!

I no longer feel like I can discuss my pain with any of my doctors other than my pain management doctor. There have been several times I probably should have gone to the ER or been in the hospital due to the severity of my pain, but I know that in the ER's and hospitals today we are treated like we're seeking pain medications and not like patients so we just stay home and suffer.

The two hospital/clinic systems in my area no longer allow any of their doctors to prescribe opioids for chronic pain patients on a monthly basis and call it hospital policy. This is so wrong and inhumane! Patients in droves are trying to get in with my pain management doctor but he's not able to take the inflow.

As far as what you can do to help, please remove the 90 MME ceiling from the guidelines, and make it abundantly clear in the guidelines that they are not to be used to make laws, craft insurance coverage, or prosecute doctors/pharmacists/patients. Please make it clear that opioid pain management therapy has clear benefits for many people including chronic pain patients.

Thank you for listening, and I appreciate your efforts to help bring compassion back into the doctors' offices.

Sincerely,

Brenda Shoberg
Duluth, Minnesota

From: Becky Vaughan
To: NCIPCBSC (CDC)
Subject: CDC guidelines
Date: Tuesday, July 20, 2021 11:27:00 AM

The CDC guidelines need to be withdrawn , not rewritten. Because of those guidelines and the way states reacted, my husband’s doctor refused to continue the medication he had been stable on for 15 years. No pain doctor within driving distance would accept him as a patient because they were only wanting new patients where injections worked. We were forced to sell our house and move 1000 miles away where we had been seasonal residents for several years and were established with a pain doctor. This pain doctor reduced my husband’s dose to the CDC guidelines, and of course his pain was not as well controlled. Insurance companies are also unwilling to allow scripts above this guideline. This is not even what the CDC is supposed to oversee. This should never have been allowed.

Becky Vaughan

From: brent wennerlind
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:42:58 PM

To whom it may concern at the CDC,

I am writing today on the behalf of the updated draft on the opioid guidelines. I have read both versions of the guidelines and not much has changed except how it is worded. It looks as if they were copied and pasted and changed only a few words! I do not have chronic pain, but my family members do! I can not begin to tell you how heart breaking it is to see your loved ones in so much pain they can't think, can't barely move, and to where they can not even hide it any more and they are violently shaking! Imagine being a prisoner in your own body, and then imagine there is only one thing that lightens the pain, doesn't take it away, but makes it so you can move your body just to get out of bed! Now imagine being looked at like a criminal, an addict when you go to the doctor, some where you should go for help and to feel safe! And your scoffed at and treated like garbage, all for something you have no control over. You have tried all the therapies and all recommendations given in your 20 plus years of pain. Nothing works, except a drug that's produced in a factory with quality ingredients and quality controlled! I am an ex-drug addict! I say ex because I no longer will hold that title. I have been clean for over 15 years. I will tell you, I never once blamed anyone else for my actions! They were my choices and mine alone! Addiction is everywhere! Sugar, caffeine you name it. Are we as humans now going to start regulating how much sugar and coffee we can put in are body in a day! Addicts will find any way to get what they want and will substitute anything in its place! The only ones affected by these so called guidelines are the doctors and the actual patients needing opioid pain medication! Doctors have been threatened to lose their license, raided and held by gunpoint because the DEA and state legislators have weaponized the 2016 CDC guidelines! Pharmacies are being threatened! Patients are being abandoned and disregarded! Patients are in so much pain they would rather DIE! I never understood suicide! I couldn't imagine anything being so bad that you want to take your own precious life before your time is up (and trust me I have been through a lot). Until I have seen my loved ones go through so much pain and agony, while being treated like garbage! What kind of life is that? That is no quality of life, and not one person on this earth should have to go through it! I urge you, let these people live what life they have left! not in agony! Let the doctors be doctors and actually do their job without the fear of losing their lively hood and even their freedom! These guidelines have hurt and even killed so many! I truly believe the CDC guidelines should be retracted!

Sincerely,
A very concerned and worried loved one, EX-drug addict
Brent Wennerlind

From: Bob Williams
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 3:21:14 PM

CDC,

My daughter is chronically ill with EDS and other factors. We agree with the comments below and urge you to make improvements to the paid care in our country. Thank you, Bob Williams.

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

We hope that in drafting the final Guideline, the CDC takes these views into consideration.

From: Brian Zbikowski
To: NCIPCBSC (CDC)
Subject: CDC guidelines has caused me great harm.
Date: Monday, July 19, 2021 4:34:03 PM

A neurologist told me my back can not be operated on in 2012.
He said I can benifit from pain medicine, I'll need for rest of my life.
2012- 2015 was getting caught up on 35 years of no medical insurance.(Kept working hurt till I couldn't.
2015- minus 20mme so 60 to 40.
2017- minus Xanax (was getting backlogged shots tests,teeth removal. and blood draws)
I still haven't got A Covid shot.
Medicaid doctor will not give me A Xanax to save my life from Delta covid.
(They want me to try A 5th non habit forming anxiety med that don't work.)
2018- minus 10 pills so 110 A month instead of 120.
Medicaid max dose ???
I worked 35 years industrial (union electric,plumber and should not even be on SSI, should be SDD.
I was getting healthy doing everything medicaid doctor wanted me to do except concilling .
Im not mental.
I'm not abusing my meds.
2019- October 2019 Norco 10-325s became very weak and formula changed.
My feet swelled,gained 45 pounds and worse chest pain.(Was quiting cigs 2017 and Xanax was helping me for I've smoked since 1973 and became addicted to in 1960s
Grew up in Pittsburgh,PA.
Everything smoked and breathed alot if toxic industrial dust.(Have COPD,have Spinalstenosis/ with nerve pain.
Stage 5 periodontal diese.
Changing my meds has destroyed my one chance at qaulty of life.
I'm now just crawling around to survive another day and suffer underdosed now with meds that are no stronger than A Aleve,which I had to quit using after 12 years of taking.
I may need over 90 mme in future for my body is tore up bad.
I didn't need harmed more and that's exactly what has happened...

From: Bobby Zeigler
To: NCIPCBSC (CDC)
Subject: CDC Guidelines
Date: Monday, July 19, 2021 12:55:39 PM

Hello,
I am a 44yo disabled male who has arthritis and am talking 212 pills a week in order just to use my walker to move around the house. The pain pills that I do get help reduce some pain and allow some quality of life. I am pleading with you for help.. I am an American citizen in pain crying everyday struggling and suffering, please help me….

From: Brittney W
To: NCIPCBSC (CDC)
Subject: Regarding MME
Date: Wednesday, July 21, 2021 1:06:46 AM

CDC,

During this process of updating your 2016 CDC Prescribing Guidelines, I want to urge you to get rid of the MME aspect. Putting limitations on Prescribing doesn't make any sense since no one person is the same in pain levels, disabilities, the way someone's body matablozises medications, ect. Since these guidelines have been written, I have had friends and family that are suffering needlessly because of the 2016 Guidelines MME! You're preventing a doctor from doing what they view is best in their own professional opinion. You guys aren't in the exam room with each patient as all of this has been unraveling, seeing many of us suffer. Please stop this madness. We want a quality of life to be productive members of society. These guidelines make us the complete opposite. What kind of care is this? Is this the care you'd want for yourselves or your mothers, brothers, friends when the time comes? Because surely, it does come for almost all of us at some point in our lives. Pain doesn't discriminate. Thank you for your time.

Brittney

From: P Hillman
To: NCIPCBSC (CDC); Lindley, Tonia (CDC/DDNID/NCIPC/OD)
Subject: BSC Meeting Public comment July 16, 2021
Date: Thursday, July 22, 2021 10:59:27 PM

I'm a patient living with severe chronic illness. I advocate for pain patients to have reasonable access to pain medication and I have no conflicts of interest. It's clear to me that the goal of the guideline as stated by Debora Dowell:

(The) "overall goal is safe and effective pain care to maximize the benefits and minimize the risks of opioids in pain management in general." Also to, "maximize benefits and minimize risk of guidelines itself."

is simply lip service. The actions of the authors speak louder than their words at this meeting. The authors are intelligent enough to use words like "patient centered" yet produced guidelines which are anything but patient-centered. There is no mention of the impact of undertreated pain or the benefits that opioids can provide. If "safe effective pain treatment" is the goal, they have failed massively. You cannot ignore that there will ALWAYS be a subsection of patients who have failed all else and will require opioids, many at levels higher than 90 MME, to be able to do activities of daily living and have some quality of life. You simply cannot have a guideline with arbitrary MME limits and expect the Guideline to be patient-centered. It is virtually impossible due to pharmacogenetics, which make MME indisputably inaccurate dosing guides that these authors refuse to accept, and the propensity for policy makers and lawmakers to imbed the Guidelines into law and hard edits. Anyone who does not see that the use of MME is a fatal flaw in the guidelines is living in fantasy land and has no interest in patients having an accurate dosage that will reduce harm.

It would be one thing if pain patients were the majority of the people dying by overdose but that has never been the case and these others know it. This is a crisis proven to be mostly made up of non-medical drug users.

According to Dr. Walenski, 594,000 overdose deaths out of 841,000 between 1999 and now DID NOT involve Rx opioids. 72% of ODs in 2019 alone DID NOT involve Rx opioids yet the authors continue to pursue a guideline that is solely focused on Rx drugs with the fantasy that following this guideline will make a difference in the number of OD deaths. This result could only happen if prescribed drugs are responsible for the OD deaths. CDC's own data dispels that myth with no reasonable contradiction possible. This guideline was so poorly written that, by the authors own admission, it has been widely misapplied to the detriment of pain patients. But, it's not only pain patients that have been abandoned and left to suffer without their life-saving medication. Those with SUD in any form have been largely ignored because of the political obsession with Rx opioids and the money and power that can be gained by that false narrative. This narrative has literally killed thousands and harmed millions.

I applaud the OWG's efforts to instill ethics, evidence based treatment, and logic into the Guideline in an effort to protect patients from further harm by CDC's Guidelines but unfortunately, it's clear that the authors of the Guidelines and even some in the OWG have no intention of making the

Guideline patient-centered. Instead they prefer to continue to implement the same harmful policy that is killing people. It is unconscionable to continue something that has killed thousands and tortured millions. History will not view these actions favorably. Which side of history do you want to be on?

Most of the opioids litigation is done now. Drop the false narrative and stop drug prohibition before you kill us all...or is that the goal?

Roger Chou and Deborah Dowell should not be allowed to author the Guidelines. Dr. Chou has clear conflicts of interest with his ties to the authorship of the original Guideline, his ties to PROP, his history of making anti-opioid biased statements/policy, his financial gain for biased opioid reviews, his connection with AHRQ, and his connection with the BSC. Dr. Dowell was an original CDC Guideline author, appears to have ties to PROP, clearly has an anti-opioid bias, is unable to acknowledge inappropriate scientific dosing principles such as MME, and appears unable to accept major scientific principles that are crucial to patient safety and the understanding opioid metabolism and uptake. Such immense COIs should not be tolerated and put patients in grave danger.

UDT should only be used under certain circumstances. It is extremely expensive and often not covered by insurance. It is subject to false positives and negatives and can lead to patient abandonment and mistreatment. Even patients who have SUD deserve to have their pain treated. UDTs violates 4th amendment rights and should only be used in certain circumstances as determined by the physician. We know from CDC's data that pain patients are almost never involved in overdose deaths so why stigmatize them and drain their financial resources unnecessarily? Such tests are likely to damage the patient/provider relationship.

In conclusion, save a life. Repeal and DO NOT replace the fatally flawed CDC Opioid Guidelines.

Sincerely,
Peggy Hillman

Sent from Mail for Windows 10

From: Carol Adams
To: NCIPCBSC (CDC)
Subject: Opioid Workgroup comment
Date: Friday, July 23, 2021 4:55:24 PM

To whom it may concern,

This is my written response to the Opioid Workgroup’s written recommendations to the new CDC Opioid Guidelines for Chronic Pain. Though I do wonder what happened to the original draft that was titled Appropriate Opioid Prescribing Guidelines for Primary Care Physicians. Those guidelines states they were for the opioid naive patient. That chronic pain patients should be managed by Pain Management Physicians. If there is someone in the CDC that can answer that question, I would appreciate the knowledge.

As to recommendation #1. As to the word “preferred”, preferred by who? People that have never had a serious injury, operation or disease or illness that causes pain? Doctors that have not trained in recognizing and treating pain, or doctors that decided to treat patients with Substance Use Disorder or, Opioid Use Disorder? The logical choice is to do away with this entire recommendation because it makes no sense to a logical person. I have no complaints about other non-medication measures to treat acute pain. i.e, a fracture that gets braces will help ease pain due to it causing immobility which then reduces pain from the mechanical issue.
Several years ago studies were done on the effectiveness of opioids post surgical. It was found that patients were able to move better and earlier after surgery than without opioid pain therapy. This decreased the chances of side effects due to anasthesia and immobility. Like pneumonia, blood clots, and bowel blockages. For patients with joint replacements they were more readily able to participate in the physical therapy, than if they weren’t medicated. Ice, compression, intermittent pneumatic compression devices, and incentive spirometers are devices that are utilized in an effort to control swelling and reduce the risks of the stated side effects of surgery.
Most instances of acute pain can be, or as painful as post surgical pain. By not providing patients that are most likely to be sent home from a visit to the ED or their family physician, by not providing them with appropriate FDA approved opioid pain medication they will most likely do whatever it is that will ease their pain. They will stay immobile, take too much over the counter pain medication, use alcohol to dull the pain, possibly mixing otc’s with it. Some may ask a neighbor or friend, family member if they have anything for pain. They could also try to get illicit substances in an effort to relieve their agony. I conclude that doctor prescribed FDA approved medications would be the most prudent choice to have the benefit of pain relief and mechanical function for a patient, and therefore the safest choice.

As to recommendation #2 Treatment goals should be discussed with patients. In order to do this clinicians are going to require more than 15 minutes in an exam room. Insurance disbursement to clinicians for their clients needs to reflect the added time for appropriate time and patient education in the clinical setting, Chronic Pain Patients are told to never expect to be totally out of pain. We are started on the lowest dosages of medications, with the caveat if there is no improvement of pain, that dosages may be adjusted accordingly. This is a rare occurrence. When a patient asks for some type of intervention to help their pain, be it an increase in opioid medication dosage, or an adjunct therapy or treatment, they are often looked at skeptically and belittled, or degraded by medical professionals. Pain is so subjective. We don’t live in someone else’s body, and therefore have no right to disbelieve their accounting of it. Again, if a chronic intractable pain patient can not find adequate pain relief, they will add in otc's at higher than reccomended dosages, or turn to other substances, be it alcohol or illicit substances. They may decide that the pain is so unbearable and don't see a future life of any quality for themselves or their loved ones, so will take their own life in some manner. They may become so enraged at the nontreatment and trivialization of their pain, they may commit a violent act upon the practitioner and anyone in the vicinity at the time. Their body will give out at some point due the stresses the pain puts on the vascular and nervous systems of the body. Be it high blood pressure causing a stroke, or a heart attack.

Recommendation #3: I agree that the lowest dosage required by a particular patient's needs. Patient bodily size, metabolism, genetic makeup needs to be taken into account when determining dosages. And patients need to feel like they are in a safe space when in the exam room when discussing with their physician, be it primary care or pain specialist, that they will be listened to and that their feelings will be validated. That they won't be derided or their pain be trivialized. As to abuse deterrent factors, there needs to be more study on the effect of narcan use in the body long term. There needs to be more study on the other ingredients being used at present on their effect from long term use. Many pain patients I have personally spoken to that are prescribed medication with abuse deterrent properties state that it is not as effective as the same opioid medication without the deterrent. There needs to be more study of how the abuse deterrent may be interfering with the patient's body's ability to absorb the medication. For efficaciousness. Again, this is a patient safety issue. There is also a stigma that needs to be overcome, as most chronic pain patients have never abused their opioid pain therapies, ans therefore feel they are being prejudged.

As to recommendation #4: Again clinicians need to be able to take the many different factors of the individual human body needs into consideration when making prescribing choices. It is done for other medications such as Lanoxin, Thyroid hormone replacement, and insulin for examples. What clinician would tell an insulin dependent diabetic with blood glucose levels consistently high that they can't have an increased dosage of insulin? Just because pain is subjective doesn't mean it doesn't require the same clinician response of care than a disease that can be tracked objectively.

Unfortunately I have run out of time to go through the rest of the recommendations. As a final statement, clinicians in the area of pain management should be the ones consulted when writing any guidelines for opioid pain therapy. The focus of the guidelines should be on getting the best pain control using opioid pain therapy in conjunction with what any individual patient is comfortable with.

My body, my choice. I deserve to be heard, and my opinion and needs validated. The doctor patient relationship is a sacred one and should not be interfered with by outside entities.

sincerely,

Carol Adams

From: Carrie Barrack
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 6:56:49 AM

Hello,
I am sending in comments regarding your new prescribing guidelines as I see they don’t seem to vary from the 2016 existing guidelines. I beg of you to research better on who this is really hurting by limiting necessary pain control to valid, honest citizens. I for one am sick and tired (many days literally) of paying the price for so many who misuse, abuse any type of opiates. I am tired of being treated disrespectfully and having my pain doubted and ignored. I have chronic migraines and have for over 20 years. I have a reaction to all triptans I’ve tried and even the new migraine injections caused a reaction. I’m on or tried any preventative medication out, I’ve had 45-50 Botox shots in my head and neck every 3 months for over 5 years until that too didn’t work.I used to receive much better pain control. I received another stronger pain med for the most severe pain days and never mistook, abused, gave away or sold any of my medications. I was treated with much more respect and not like a druggy looking to score. Nor have I EVER ended up trying to obtain it or any other stronger opiates illegally. We should not have to suffer and have less quality of life because of the actions of others. Start talking to more pain and especially chronic pain patients and really listen and ease up on these Drs who, most I believe are just wanting to help their patients. People die daily and suffer alcohol addiction and there are still liquor stores on every other corner. These drugs are all over the streets and these guidelines are really ruining innocent people’s lives.
What ever happened to people being responsible for their own actions and what they put into their body??
Maybe time and money should be spent educating the public of the dangers of buying street drugs or abusing their legal meds. (For whoever has been living under a rock and isn’t aware of what can happen).
Stop making the innocent PATIENTS pay for the abuse of others!
Carrie Barrack

Sent from Yahoo Mail for iPhone

From: Casey Bendig
To: NCIPCBSC (CDC)
Subject: CDC Opioid Prescribing Guideline Revision
Date: Thursday, July 22, 2021 11:33:11 AM

The CDC opioid guidelines MUST be rescinded. Any new guidelines must remove the arbitrary 'MME' limits. They are NOT backed by science and have caused an unprecedented crisis in the United States as patients on stable regimens that were doing well were suddenly given massive cuts in their medications or dropped completely by physicians. This has resulted in numerous deaths, as well as devastating health consequences in myriad patients such as strokes. Countless doctors have left practice altogether in response, as they no longer could treat patients ethically and could not live with the fear mongering from the CDC and DEA. It hasn't even just had devastating consequences for chronic patients who can no longer find care and who have been left to suffer and die, but also for acute and end of life care. Patients are being denied pain control after major surgeries, are being denied pain control in the emergency room, and are being denied pain care ON THEIR DEATH BEDS because of the ridiculous and arbitrary CDC guidelines.

The damage that has been done is massive and there is no way that I could cover all of it in this short e-mail comment. But I assure you that everything I have said above is the absolute truth, and I would testify to it in a court of law. If you allow these guidelines to go forward, especially with the arbitrary 'MME' limits, then each one of you becomes culpable in the in the absolutely disastrous ramifications these guidelines have wrought on healthcare at large, and the incredible damage they have caused to the most vulnerable members of our society. It is absolutely unconscionable to allow these guidelines to continue wreaking havoc on our healthcare system, they will only continue to cause harm to innocent patients, and have had ZERO impact on rates of addiction or overdoses, as prescription drugs were never the issue in the first place! Rates of opiate prescription had already been declining for years before these guidelines, and it has been illegal drugs like heroin and illicit fentanyl that were the culprit since the beginning. This is why rates of overdoses have DOUBLED since instituting these guidelines; they have only harmed legitimate patients and had zero effect on those abusing opiates. The statistics and studies that back this up are easily accessed and have been available for quite some time, so there is no excuse for any of this to have taken place. To allow this to continue would be ethically and morally repugnant.

You MUST rescind the 2016 CDC guidelines in full. Any new guidelines MUST leave decisions about 'MME' between the doctor and patient, as any arbitrary 'MME' limit is unscientific and will only continue to harm vulnerable patients. It could be any one of you or your most precious loved ones being left to suffer unimaginable pain, even while dying. Remember that.

Sent from my iPad

From: Becky Brandt
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 11:33:54 AM

To whom it may concern,
As an RN, Intractable pain patient for 15 years and a patient advocate, I NEED YOU TO UNDERSTAND that these current pain guidelines are atrocious and leave a HUIGE population of law-abiding patients to suffer. Many in this huge group of long term pain sufferers have absolutely no other pain relief options. These patients are NOT HIGH RISK because they've proven year after year that they can use their medications/opioids etc AS PRESCRIBED BY THEIR DOCTOR! Long term patients often need larger, higher doses than normal because they are tolerant to these meds, unlike someone who walks into the ER with an emergent issue and has never taken opioids.
Your facts are skewed, these guidelines HAVE NOT improved illegal opioid problems & overdose, and you're making decisions under a BROAD umbrella, leaving intractable pain patients to suffer horribly for ABSOLUTELY NO GOOD REASON!
I'm available to join your work group as an RN, PATIENT ADVOCATE, adding a voice for all patients who are not present at your table . We just want transparency and a seat where decisions are being made on our behalf for treatment of our pain. Patients are dying because their pain is uncontrolled, In fact we lost a good friend to suicide 2 weeks ago. Picture your daughter or mother writhing in pain because they have no pain medication whatsoever. Would that be acceptable in your family?
Doctors and patients need to make these decisions, not someone who has absolutely no idea who I am or what I need.

Please Contact me for questions and to add me to your panel for future engagements. We need to talk!
Thank you,
Sincerely,
Rebecca A Brandt RN
Cofounder Central Pain Nerve Center
bbhomebody@msn.com

From: Cheri Buchanan
To: NCIPCBSC (CDC)
Subject: Access to necessary pain medication
Date: Thursday, July 22, 2021 7:36:25 PM

To those concerned:

As a chronic pain patient, I am writing to urge you consider allowing pain management doctors more leeway in prescribing life changing pain medications that are needed to live as normal a life as possible.
At 35, after several years of unrelenting pain my doctor thought my pain was caused by ovarian cysts so I had a total hysterectomy. After 9 months the pain had not deceased and I was finally correctly diagnosed with Adult Onset of Idiopathic Scoliosis.
Prior to getting my Intrathecal Drug Delivery System which delivers small doses of Dilaudid directly into my spine, my life was nothing but pain and misery. I tried every other modality out there some of which were spinal stimulators (2 different ones), acupuncture, nerve ablation, physical therapy, TENS device to finally disc fusions without getting any relief. Even though I found relief through the use of prescribed opioids, I wasn’t getting the relief I needed. The pain pump saved my life.
I beg you to consider what state you will leave millions of people in if you continue to hog tie pain management doctors.
In regards to the opioid crisis, perhaps you need to look at how other countries have successfully helped get people off the drugs they no longer require and return them to a productive life.

https://www.northcarolinahealthnews.org/lessons-from-abroad-how-europeans-have-tackled-opioid-addiction-and-what-the-u-s-could-learn-from-them/

Thank you for listening and feel free to contact me with any questions.

Regards,
Cheryl Buchanan

Sent from my iPhone

From: cindy caron
To: NCIPCBSC (CDC)
Subject: guidelies
Date: Thursday, July 22, 2021 10:27:43 PM

To Whom....
After listening ti the WorkShop recording, I became quite angry as, itis very obvious that the first guidelines were issued with conflicts of interests, erroneous information, and , of course, the authorship violations. Directly after the issuance, over 300 physicians fom the AMA publicly disagreed. I'm sure you are aware of our wonderful advocate, Dr. Red Lawhern, highly esteemed by the chronic pain community. I suggest, before the final draft, you take a hard look at the Facts. The guidelines were built on false premisses and, of this by now, I'm sure you are aware. There has been data manipulation, the one sided reporting, referring to the "opioid epidemic" and including those from the chronic pain community, to make it appear that legitimate pain patients are addicts. The outrageous profits of rehabilitation facilities, many being run without even having a physician on staff. This has become a thriving industry and the new phrase OUD, has become a weapon directed at people who are suffering. Modalities, such as injections an easily referenced treatment that has not been approved by the FDA! I have been to "doctors" who have insisted on a plan of 8 injections in a year- a very dangerous protocol, considering by general medical assessment the very most annually would be 3 injections.
It is quite obvious, to anyone taking the time to investigate a bit that the original guidelines were put out with a certain amount of subterfuge.
Moreover, the new modalities, the pain pump, for instance, has resulted in many patients being traumatized after finding that either through a faulty mechanism, improper placement, and/or too many infections for anyone to seriously consider wanting this.
Since it's inception, the drug laws were specifically designed to adversely affect people of color, those in our society who are on the verge of poverty, and the disenfranchised which, not by lack of design, conveneintly enriches the prison system.
Then there are the grandstanders, those in the political eye, wanting the public to believe that, what?, chronic pain does not exist? I wish no harm, but if any of these anti opioid zealots were diagnosed with a disease that required medication - which without, would condemn them to the rest of their lives in severe pain, I think they would surely change their stance. There are so many things wrong with the original guidelines, I honestly wonder- was anyone thinking about doing no harm and actually listening to people in pain? As a chronic pain patient who has been mistreated, disrespected, and lost the ability to function in any meaningful way, I'm letting you know, we are out here and it's past time that this failed policy be done away with. Oh, and when did it become acceptable for the DEA and FDA to concern themselves with the confidential relationship that exists between physician and patient? It is reprehensible !!!
I want to believe that those in the decision making process are humble and compassionate enough to recognize, acknowledge, and ameliorate this terrible wrong that has resulted in so many suicides, and too many good people living each day in agonizing pain. As you can imagine, I could go on but I'm sure you want my rant to

end- just as I want my pain, well, not to end, but at least be adequately addressed and have my dosage enough so that I could have some mobility. I'm a good senior, I got my vaccine, I want to believe that government agencies be benevolent to their citizens who worked all their life
hoping for a peaceful end. Until these guidelines are addressed with unbiased, science based information, and the pleas of the most vulnerable in our society, I, and all of the chronic pain community, will not have that deserved peaceful end. We will die in a bed or recliner with sores on our body and unwashed hair. Hopefully some of us will have a window from which we can see some light, for the darkness that has overcome our very existence, has been caused by the cruelty and negligence of a society we once believed was merciful. I thank you for your time. I pray for celerity in your decision.
One of the forgotten.

From: cindy caron
To: NCIPCBSC (CDC)
Subject: Guidelines
Date: Wednesday, July 21, 2021 6:48:40 PM

Triple Border

Yes, through the years I have commented, signed petitions and called my reps.. All to no avail. I have suffered immeasurably since the 2016 Guidelines. I am a legacy patient living in 24/7 pain ever since my medication dosage was cut by over half. I am old, alone, and so very compromised by my lack of mobility. My cervical and lumbar regions are riddled with DDD, scoliosis , spondylosis , arthritis, herniated discs. My condition is inoperable. There is no doctor patient communication in my case. I live in fear each time I go to his office that he will lower my dosage even more. I've been disabled since 1998 and have tried any and all modalities- many putting me in financial straights. I beg you to listen to chronic pain patients. Without a change in these guidelines, as well as the medical professionals, who are implementing them

as law, so many of us will not survive. Honestly, I don't know how much longer I can continue with this ever present pain. I beg you, HELP!!!

Cindy Carson

Triple Border

Yahoo Mail Stationery

From: Cindy carson
To: NCIPCBSC (CDC)
Subject: CDC Worshop & Guidelines
Date: Wednesday, July 21, 2021 9:03:14 PM

First, I would like to thank you for reviewing the 2016/18 guidelines and inviting chronic pain patients to contribute to this process.

I am an elderly gentleman who has been disabled since the 90's. I have been adversely effected by the 2016 guidelines. I won't go into all of my conditions, suffice it to say, I have severe chronic pain which was well managed until the guidelines of 2016. I, at that point, was thrust into a nightmare of having problems finding a physician to treat my pain, feeling dismissed by the doctors that I did find, and frankly, disrespected by these so called "professionals". I had a difficult time understanding how my chronic pain, which I have lived with for quite some time, was being viewed and prescribed differently. For many years my primary care physician had taken care of me and I was on an adequate dosage of pain medication that allowed me to enjoy life in a limited but satisfying way for a man with my medical difficulties.

Sadly, my doctor passed and, upon finding a new doctor, I was made aware that to be prescribed my pain medication I would have to have another doctor specializing in pain management.

Then, I soon realized that I would no longer have access to the dosage of medication that

had worked for me for years.

Without my consent, I was tapered down to a dosage more than half of what I had been receiving. It didn't take long for me to figure out that this situation was untenable and each time I expressed my difficulty to my doctor, it was met with a shrug and a "well, that's how it is now, so you should get used to it". Well, I didn't get used to it and I watched myself go from being a generally happy and mobile individual to someone who felt that my body had become an extremely uncomfortable prison. My attitude changed from agreeable to cantankerous.

My mobility became so restricted that I no longer was able to ambulate. My time was spent, for the most part, in my recliner and I could no longer manage my slow brief walks that gave me pleasure. Upon awakening, in the past, I felt eager to begin my day. Now, when I open my eyes, after a mostly sleepless night, my spirit sinks to know that I am still here in this world that holds only infirmary and pain. I have fear that this is the way the rest of my days will be.

I understand that there is a problem with youth, always wanting to try new things and that the world has changed with the cartels and illegal drug trade. I feel so sorry for those families who have lost loved ones to that "opioid epidemic" that I hear constantly from the media. I, however do not fall into that

category and have always been informed and responsible with my prescribed medications. It seems that I am lumped into the same group as addicts and /or the indiscretion of youth. This is wrong, medically, ethically, and, to me, basic human rights and dignity.

I ask that, in your review, you take into consideration that there are people, who, of no failing of their own, find themselves in the position of having no quality of life due to abandonment by the medical community. Surely, this is not what was intended, and yet, this is exactly what has happened.

I beseech you to look at the statistics. I ask you to realize that these guidelines are erroneous. This has become a political football, a propaganda filled agenda, and a violation of the most basic of human rights. End this nonsense and restore medication to those who are suffering.

Thank You,
Mr. Brian Bines

From: Cassie Everett
To: NCIPCBSC (CDC)
Subject: Opioid Prescribing Guideline
Date: Thursday, July 22, 2021 9:54:57 PM

To whom it may concern,

I am writing this letter on behalf of my husband and my brother in law who both have a life worth living because of the effects of opioids on chronic pain. Both suffer from totally different uncurable disease one is a quadriplegic that was injured over 10 years ago from a devastating car accident, and the other who suffers from chronic Lyme disease-causing major joint pain from damaged nerves. Chronic pain is something that those of us blessed not to have to suffer from may never truly understand. To fight a battle in life to ensure that your loved ones have minimal suffering and can try to have a life worth living is something I never thought I would face. If you have never watched your loved one in excruciating pain you may not fully understand why I am so concerned with this issue. We are blessed in this day in age to have the gift of technology to be able to manufacture a safe and effective medicine that allows people in chronic pain to somewhat enjoy life as you and I do. What a blessing it is that our loved ones can receive medicine that allows them to function somewhat normally on a day-to-day basis.

I never thought the day would come that we would persecute the chronically ill in the name of drug addicts. I never thought the day would come that we would charge a doctor for upholding the oath to their patients to do everything that they can to help them live a normal life.

I have spent a lot of time researching the facts and figures and did present them to our prior district attorney showing that because of botched statistics that label illegal drugs as opioids and lump them all in one category we hurt our most vulnerable in society.

How can the best nation with the best health care turn their back on our ill. How did we end up with botched statics? When I confronted them on these statics that I got to the bottom of and was able to prove that this opioid "epidemic" was nothing but a lie to sue the drug companies I was shut down.   I have the stats, I have the numbers and I can show at least in Oklahoma that this was a lie. I beg whoever will listen for the good of our society to understand punishing the sick and injured is not what should happen. We have safe drugs on the market to ease the pain that allows millions of people to live a life that you and I do. Please do not take this away from them. Please do not punish the doctors who are simply trying to full fill their oath.

If I can be of any further assistance I have no problem with someone contacting me. Your time is greatly appreciated to fully review this matter and ensure that we can provide a life worth living to those who suffer from pain.

Yours truly,
Cassie Everett
405-880-5965
everett.cassie@gmail.com

From: Cfremouw
To: NCIPCBSC (CDC)
Subject: Opioid proposed revisions
Date: Thursday, July 22, 2021 11:09:12 PM

Greetings
I’ve read through the proposed guidelines and I am deeply concerned about #4 that recommends immediate relaease as opposed to extended release medications
In 1992 I was diagnosed with Fibromyalgia. This along with Endometriosis, Arthritis and advanced degenerative discs I am a patient who lives with chronic pain. I am an opioid user for many years. The last 5 years I’ve been prescribed Nucynta or Xtemza with are extended formulas. They have changed my life and helped me to be a functioning person who lives with chronic pain. These so not make me feel drugged nor have any effect on my cognitive skills
Another concern is the requirement for pharmacists to use red caps on all opioid based prescriptions. I am extremely uncomfortable that someone in the store will see this and I feel vulnerable simply picking up my prescriptions.

As a patient who wants to live a life and function with daily activities please do not impede the availability for extended release formulas

Respectfully
Candice Fremouw
602-993-9566

From: carolgib2014
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 1:32:31 PM

In February of 2011, I became so incapacitated from back disc problems and spondylolesthesis that I had to crawl everyplace. I had to push my breakfast across the floor. The only treatment that has been effective is an opioid. Since then, I have tried physical therapy, psychological therapy, water aerobics, etc. All help, but nothing gives me as much pain management as opioids.

Your 2016 guidelines meant for PCP's were also interpreted as suggestions by pain management physicians. Many doctors cut opioid prescriptions or took them away all together. The DEA took your guidelines as reasons to pursue physicians whom they thought weren't following these guidelines. Some physicians were engaging in illegal sales. The state lists of controlled substance usage is a great mechanism to prevent patients from doctor shopping.

Prescription opioids, when taken as directed and supervised by a pain management specialist (anesthesiologist) can reduce chronic pain such that one can have a decent quality of life. I have been able to travel again--even solo, play tournament bridge, do some housework, exercise, etc. I don't take my opioid to get a high. I am a rule follower, I take them exactly as prescribed. Though not completely pain free, I am definitely not lying in bed or wheelchair-bound as many patients have been forced to do.

No pain meds following major surgeries is just morally wrong. I follow Claudia Merandi's Don't Punish Pain Rally group on Facebook. It would help if you, the committee, would read the posts written by people who have become bedridden or wheelchair bound by their dearth of pain meds.

You know you are punishing chronic pain patients with these guidelines. I know the argument is that kids get hooked by stealing opiods from Grandma's purse.

Please don't punish us chronic pain patients. You are driving people to

get street drugs where they unknowingly
get fentanyl-laced oxycodone which causes many to OD.

The real problem is the illegal fentanyl pouring across our borders by drug mules and in shipping containers from abroad.
Recently, an arrest was made at our southern border. Enough fentanyl was confiscated to kill the entire state of Florida. Illicit fentanyl is the OD problem--not prescriptions opioids.

I would think the CDC would be better served to have a billboard campaign telling prescription opioid users
to LOCK UP YOUR PAIN MEDS. Georgia had billboards everywhere saying just that when we were there in 2018.
I thought it was a great suggestion. Rather than punishing us chronic pain sufferers, put a positive emphasis on
what people can do to keep kids out of "Grandma's purse'. A national campaign to lock up your pain meds, both on
billboards and Public Service Announcements would be a meaningful step. We who are chronic pain sufferers
shouldn't be punished for what others wrongly do.

Thank you,
Carol Gibboney

From: Christine Hawkins
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 1:45:17 AM

I want to know why I cannot have pain medications. You let the drs shoot us in the back. Last week 3 injections hit the nerves. One into my pelvic ,leg ,and back.The shots don't work .I've had 2 back surgeries. Now the drs want to do a spinal cord stimulator. Who is suffering here. Certainly not the drs. I know it takes 7 months for these disk to heal why not give me pain meds to ease the pain. No you want me on the floor begging in pain like a dog. They don't know if the Stimulator will even work and they're gonna have to put me on steroids which I'm really extremely sensitive to.it's should be the patients choice people with terrible disabling pain. You drs went from prescribing 150 30 mgs of oxycodone to 17 yr olds who surely would of healed on their own with physical therapy . Instead they died from
Overdose after not having any documented pain problems. You gave these drs permission to run hell all over town. Now the people who truly need them cannot get them. And drs have reverted to snake oil treatment. Oh now they want to do IVs with vitamin infusions. People don't metabolize vitamins and they have to be in a broken down form for them to even work any only way you can tell by doing a genetic test which cost Medicare another thousand dollars apiece it's got to stop you're ruining peoples lives I'm 63 years old they want to do a rod I could heal on my own but I need help you have the medicine I need yeah you deny me constantly over and over again

From: Christine Hawkins
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 1:54:50 AM

Drugs have been around every since before Freud pain medication has its purposes we know the consequences of getting off of it that's the price you have to pay so you get on Suboxone subutex what's the big deal why make me suffer every day every day I can't stand for over 10 minutes.I don't want your sympathy I want action here I just went through a year of pure hell with this pandemic and losing my husband now I'm getting ready to live again and I can't because Of the pain I have my jobs everything I had and this is what they gave me back.I'm not a child. I'm an adult. I'm responsible take less than Drs percribe. I'm on Xanax why because it's useless to get up and try to do something with bend my waiste. 10 min then the anger .1 hr up. Couple of minutes fighting back the pain to walk the dogs. Who can live like this. Could you. Could your mom or dad? I have records going back 12 yrs. these pain clinics are a joke who are these anesthesiologist what special training that they get it's not empathy that's for sure and they do everything but prescribe you medication because if they do pick up prescribe you medication they don't make any money first thing they do is set you up for injection read you want one or not then they want to do a stimulator on you they don't give a damn about me

From: Christine Hawkins
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 7:39:04 AM

Christine Hawkins, have sugffered with Degenerative disc disease for 12 years I'm blowing the same disc six or seven times sometimes to L4 L5 S one at the same time at least be incapacitated for six months unless is so bad I had surgery which I have had two surgeries and six sets of three injections now my back went out again my dr decides to give me three injections at once.I am taking burpernorphine for pain that's it it works with sciatica but it does not work for three herniated disc. Now they want to do a spinal stimulator I'm gonna let somebody go in there after doing two surgeries and thread this into my back from L2to S1. And if this fails to help with pain what are you just let us suffer? Pain medication is for people who have pain. Nobody ask Drs and their pharmacy to open up pain clinics a block apart from each other all the way down the coast of Florida. I don't deserve this abuse. Oh the new one is Vitamin infusions. This is crap. Some people do mot Metabolize vitamins and they have to take them and they're broken down form so what good is this therapy oh and then you have ketamine infusions $3500 please cash would that work long-term no. People are trippin on this stuff. You will allow this but deny pain medication to people who really are struggling with just living with pain. I didn't ask for this. I like me and I don't like the fuzzy feeling. However. I will trade temporary for relief of this pain. I pray for you or anyone whom you live with or related to never help ave to feel the pain I do on a daily bases.you don't want to live because it's too painful. I'm sure if there is a medication out there people can abuse they will. Paregoric was given to children for diarrhea long until it's given to adults with diarrhea both of those had an opioid. There's a ton of other medication's out there that had opioid is one of their ingredients to help with different problems.I still do not understand why we have these pain management doctors that do nothing but take your money and make us feel like we're a bunch of drug attic's because were begging for pain medication for relief I'll never understand that specially those of us I don't even like the medication but it helps and help you function how to do the things you have to do

From: Constance Incrocci
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:10:19 PM

To whom it may concern:

I am a 65 year old woman with many issues, including MS.
I suffer from chronic pain which had a devastating impact on my life.
Before 2016, when I was able to get a proper dosage of pain medication. I was able to live a fairly normal life.
ALL of that changed when in March 2016 where my doctor said he can no longer treat me because he didn't want to lose his medical license.
I was left to suffer.

I now have a new doctor who constantly tells me that he's afraid to prescribe the dosage I need because HE TOO is afraid to lose his license.

I suffer EVERY SINGLE DAY in vane!
Why are you punishing me for deeds of people I don't even know!

I have NEVER abused drugs of any kind. I have never smoked a cigarette and I don't drink alcohol.
Chronic pain patients have had their lives derailed.
What can I do? Can you help me get a doctor who can prescribe adequate medication that's not afraid to lose their license?
Pain isn't only physical, it affects your mood in such a negative way.
Being in constant pain is really difficult, especially when you know that tomorrow isn't going to be any better.

I feel like I don't matter now that I'm old I and useless. Every night I pray that I won't wake up. No I don't believe in taking my life, but sometimes I wish I could.
There's absolutely nothing I can do, it's out of my control.
I know this letter doesn't mean anything and probably won't even get read. But if someone does read it- can you please help me find a doctor or help my current doctor treat me (he's from China and feels that that will go against him.

Thank you,
Constance Incrocci

From: MR. Christopher Jennings
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:24:37 PM

Hello my fellow American's I'm glad that we could connect and continue to forge the future of Cannabis, I truly believe that we have a bright future ahead of us we must continue to research this amazing plant for it's medical benefits plus undiscovered compounds that my be found in the near future.
Sincerely your Mr. Christopher Daniel Jennings.

From: Cynthia Johnson
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:31:57 PM

I am not a doctor or a lawyer. I have read the new CDC Guidelines for prescribing Opioids for pain. Some of it I understand some I don't. All I can tell you is my story and how these guidelines have affected me. I started suffering with chronic pain back in 2009. I had bad skiing accident which caused damage to my lower spine and it got so bad I had to seek medical treatment. I saw several doctors and finally found a good one who started treating me with physical therapy, massage, pain medication which actually allowed me to continue staying active and fit. Having a strong body was a big part of keeping my pain level down. When all else failed I went for injections. All of this worked for me very well for almost 10 years. I never had any bad side effects from taking a low dose of pain medication I have never taken more than prescribed. I don't do illegal drugs, I don't do pot and a very occasionally consume alcohol. At this point I would like to state that I am an educated person. I am an accountant and I have owned my own business for over 20 years.

Eventually the doctor that had treated me for many years retired. I started seeing another doctor. Thanks to the new guidelines I had 1 mishap in over 10 years I was taken off of the pain medication. The doctor that was seeing treated me horribly like I was a drug abuser and addict and he even exaggerated things on my records to make me look bad. I went to see my primary care physician and she actually yelled at me that SHE DOES NOT PRESCRIBE PAIN MEDICATION, NOBODY DOES ANYMORE and THERE'S AN EPIDEMIC OUT THERE AND PEOPLE ARE DYING! I didn't even ask her for pain meds. She just assumed that was the reason I had gone to see her! I was so upset after how I had been treated that I ended up going to a therapist. Something is wrong here. If you can't go to your doctor for help and you get yelled at for no reason. That's just crazy. My brain cannot comprehend this! It WRONG on so many levels I just don't understand this attitude that healthcare professionals have. They don't care about people anymore. There's no empathy, no caring for patients with chronic pain. All they care about is themselves. These guidelines have changed healthcare professionals. They are so scared to even think about prescribing pain medication because they are worried that they are going to lose their licenses or get in trouble This is causing people with pain to suffer. I am one of those people It has to change. I've tried to find another pain doctor but have had my referrals denied with no explanation as to why. I have been dealing not only with my pain, but now I am very depressed and I am starting to have other health issues like high blood pressure.

The last thing I would like to comment on is that I believe it was wrong for doctors to OVER prescribe pain meds. That was extreme but now NO doctor will prescribe pain medication and that is the other side of the extreme. That is not right either. There has to be something in the middle.

Thank you for reading

From: Kollas, Chad D. MD
To: NCIPCBSC (CDC)
Cc: Kollas, Chad D. MD
Subject: Written Comments for the CDC's Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) meeting on July 16, 2021
Date: Monday, July 19, 2021 1:16:44 PM
Attachments: image002.png
Written Comments (CDK) to the CDC BSC-NCIPC OWG Meeting for July 16 2021.pdf
PROP's Disproportionate Influence on U.S. Opioid Policy - The Harms of Intended Consequences.pdf
Importance: High

Dear Representative of the CDC BSC-NCIPC Opioid Work Group:

I have submitted my written comments for the CDC's Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) meeting on July 16, 2021, below and as a PDF attachment to this e-mail. Thank you in advance for your review of them and their inclusion within the minutes for the Meeting.

Sincerely,

Chad D. Kollas, MD, FACP, FCLM, FAAHPM

Medical Director, Palliative & Supportive Care
Assistant Professor, University of Florida College of Medicine
Clinical Assistant Professor, Florida State University College of Medicine

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About the Author:

My name is **Chad D. Kollas**, M.D., and I currently serve as the Medical Director of Palliative and Supportive Care at Orlando Health Cancer Institute in Orlando, FL. My written comments regarding the Center for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors Meeting (hereafter CDC BSC-NCIPC Meeting) on Friday, July 16, 2021, represent my own views.

I disclose the following potential competing interests:

I serve as the Secretary of the Board of Directors of the American Academy of Hospice and Palliative Medicine (AAHPM). I also serve as the AAHPM Delegate to the American Medical Association (AMA) House of Delegates, and I am the Chair of the AMA Pain & Palliative Medicine

Specialty Section Council and is a member of the AMA Opioid Task Force. I have provided testimony at a 2004 Congressional Hearing on OxyContin, and I have served as a medical expert witness in cases involving professional opinions regarding the standard of care in internal medicine and hospice & palliative medicine. I have received educational research grants from the AMA Education & Research Foundation, Geisinger Clinic and M. D. Anderson Cancer Center Orlando. I serve as the editor for the Advocacy section of AAHPM Quarterly, and I am a member of the Editorial Advisory Board and conduct reviews for the Journal of Pain & Symptom Management. I have also served as a reviewer for the Journal of Palliative Medicine, Annals of Internal Medicine, Journal of General Internal Medicine, Journal of Graduate Medical Education, and the Educational Clearinghouse for Internal Medicine.

Regarding the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain (Hereafter the Original CDC Pain Guidelines):

I have written a comprehensive article about my views on the Original CDC Pain Guidelines, which can be found at https://www.pallimed.org/2021/05/props-disproportionate-influence-on-us.html. I have attached a PDF copy of this article to this e-mail for inclusion in the written comments for the CDC BSC-NCIPC Meeting. For these written comments, I will summarize my main points as follows:

1. The advocacy group, Physicians for Responsible Opioid Prescribing (PROP) enjoyed a disproportionate amount of influence in the creation of the Original CDC Pain Guidelines, much more so than any other stakeholder involved in the writing or review process.
2. The creation of the Original CDC Pain Guidelines seems influenced, at least in part, by PROP's rejection of a Food and Drug Administration (FDA) Decision to reject the concept of an arbitrary threshold based on maximum morphine equivalents (MME), which lacked a firm scientific basis. Despite concerns raised by several stakeholders about potential harms from including this concept in the Original CDC Pain Guidelines, it was included within them. Additionally, many health policy analysts have argued that the FDA was the appropriate venue for Pain Guidelines, not the CDC.
3. In a short period of time, the Original CDC Pain Guidelines were misapplied by health insurers, pharmacies and state governments in a way that encouraged blunt reductions in opioid prescribing that led to harms to patients suffering from chronic pain, including suicides in patients who were forced to participate in involuntary opioid tapers. Ultimately, the CDC and the FDA issued Announcements that opposed involuntary tapers, but this was only after intense pressure from several stakeholders, including the AMA, AAHPM and many other.
4. Several articles, including those authored by CDC scientists, have called into question the method by which the CDC has calculated overdose deaths caused by opioids over the last decade. In particular, CDC methodology gross overestimated deaths caused by prescription opioid medications. These figures were touted by PROP and other anti-opioid groups in ways that encouraged misapplication of the Original CDC Pain Guidelines.
5. A pattern of undeclared conflicts of interest on the part of PROP members became

apparent in the aftermath of the release of the Original CDC Pain Guidelines. This raised concerns about the Original Guidelines' integrity, especially considering the relationship between PROP and Guideline co-author, Dr. Roger Chou. I would note that Dr. Chou declared no conflicts of interest, which should have included "conflicts that might have a direct and predictable effect on the recommendations," as reported within the Original CDC Pain Guidelines.

Regarding the Revised CDC Guideline for Prescribing Opioids for Chronic Pain (Hereafter the Revised CDC Pain Guidelines):

During the Roll Call for the July 16, 2021, CDC BSC-NCIPC Meeting, Dr. Chou stated the following: *"I'm present. Uh… I do have a conflict. I receive funding to conduct reviews on opioids, and I'll be recusing myself after the director's, uh… update."* (See https://www.youtube.com/watch?v=wb4ysxY0sUo at 0:46). This disclosure raises serious questions about the creation process of the Revised CDC Pain Guidelines:

1. Does this disclosure call into question the integrity of the Original CDC Pain Guidelines? Did Dr. Chou fail to disclose a material conflict that "that might have a direct and predictable effect on the recommendations?"
2. Does this disclosure adversely affect the integrity of the Revised CDC Pain Guidelines? Should not have Dr. Chou made this disclosure *before* Dr. Chou he began his work as a co-author of the Revised CDC Pain Guidelines?
3. From what has Dr. Chou recused himself? Has he only recused himself from the proceeding of the CDC NCIPC/BSC Meeting? Or does this mark a recusal from his involvement in the Revised CDC Pain Guidelines moving forward?

Immediate Recommendations:

Based on the concerns and issues raised above, I would make the following recommendations to the Centers for Disease Control and Prevention:

1. The CDC should immediately rescind the harmful and misapplied portions of its Original Pain Guidelines:
    a. The CDC should **rescind arbitrary opioid dosing thresholds** used by health insurers, state or federal governments and pharmacies
    b. The CDC should announce its profound commitment to **individualized care** for patients with chronic pain.
2. The CDC should consider indefinitely postponing its release of the Revised CDC Pain Guidelines pending an internal investigation of the issues raised in this written comment.
3. If the CDC is unwilling or unable to do commit to such an investigation, I would encourage other stakeholders to join me in a call for a Congressional or Department of Justice Investigation into the conflicts of interest described in these written comments.

Sincerely,

Chad D. Kollas, MD

About the Author:

My name is **Chad D. Kollas**, M.D., and I currently serve as the Medical Director of Palliative and Supportive Care at Orlando Health Cancer Institute in Orlando, FL. My written comments regarding the Center for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors Meeting (hereafter CDC BSC-NCIPC Meeting) on Friday, July 16, 2021, represent my own views.

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2) The creation of the Original CDC Pain Guidelines seems influenced, at least in part, by PROP's rejection of a Food and Drug Administration (FDA) Decision to reject the concept of an arbitrary threshold based on maximum morphine equivalents (MME), which lacked a firm scientific basis. Despite concerns raised by several stakeholders about potential harms from including this concept in the Original CDC Pain Guidelines, it was included within them. Additionally, many health policy analysts have argued that the FDA was the appropriate venue for Pain Guidelines, not the CDC.
3) In a short period of time, the Original CDC Pain Guidelines were misapplied by health insurers, pharmacies and state governments in a way that encouraged blunt reductions in opioid prescribing that led to harms to patients suffering from chronic pain, including suicides in patients who were forced to participate in involuntary opioid tapers. Ultimately, the CDC and the FDA issued Announcements that opposed involuntary tapers, but this was only after intense pressure from several stakeholders, including the AMA, AAHPM and many other.
4) Several articles, including those authored by CDC scientists, have called into question the method by which the CDC has calculated overdose deaths caused by opioids over the last decade. In particular, CDC methodology gross overestimated deaths caused by prescription opioid medications. These figures were touted by PROP and other anti-opioid groups in ways that encouraged misapplication of the Original CDC Pain Guidelines.
5) A pattern of undeclared conflicts of interest on the part of PROP members became apparent in the aftermath of the release of the Original CDC Pain Guidelines. This raised concerns about the Original Guidelines' integrity, especially considering the relationship between PROP and Guideline co-author, Dr. Roger Chou. I would note that Dr. Chou declared no conflicts of interest, which should have included "conflicts that might have a direct and predictable effect on the recommendations," as reported within the Original CDC Pain Guidelines.

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Sincerely,

Chad D. Kollas, MD

PROP’s Disproportionate Influence on U.S. Opioid Policy: The Harms of Intended Consequences

pallimed.org/2021/05/props-disproportionate-influence-on-us.html

by Chad Kollas, MD (@ChadDKollas)

Introduction

A recent study by the Centers for Disease Control (CDC) has captured the attention of the palliative care and chronic pain communities (1). Published on February 12, 2021, in Morbidity and Mortality Weekly Report (MMWR), it observed that the “age-adjusted overdose death rates involving synthetic opioids, psychostimulants, cocaine, heroin, and prescription opioids during 2013–2019” have increased a whopping 1,040% (1). Several critics have attributed this increase in overdose mortality to failed federal opioid policy, particularly the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain and their misapplication (2-4). This criticism has generated recent flurry of activity on social media by the anti-opioid advocacy group (5), Physicians for Responsible Opioid Prescribing (PROP). This commentary will explore how PROP’s flawed policy approach over the last decade has reduced legitimate access to opioid medications and contributed to harms from increases in overdose deaths in the United States (US).

PROP Appears on the Opioid Policy Scene

In 2011, a group of internists, including Michael Van Korff, Andrew Kolodny and Roger Chou, co-authored an article that modern palliative care physicians would recognize as a “warning shot (6)” in the world of opioid policy (7). They announced the creation of Physicians for Responsible Opioid Prescribing (PROP), a “nonprofit organization with no pharmaceutical industry funding or ties,” that would “identify practical approaches to more cautious opioid prescribing in community practice (7).” They declared that “Guidelines for long-term opioid therapy should not be developed by the field of pain medicine alone. Rather, experts from general medicine, addiction medicine, and pain medicine should jointly reconsider how to increase the margin of safety (7).”

PROP Petition to the FDA on Opioid Labeling

The Petition is Filed
In its first effort to influence national opioid policy, in July 2012, PROP submitted a Petition to the Food and Drug Administration (FDA) calling for a change in labeling of opioid analgesics (8). Signatories to the Petition included PROP President, Andrew Kolodny, PROP Vice-president, Michael Van Korff, and PROP Board Members, Jane Ballantyne, Roger Chou, Stephen Gelfand, and Gary Franklin, among other medical specialists, including American Society of Addiction Medicine (ASAM) President, Stu Gitlow (8). In its petition, PROP requested that the FDA to make three main changes to the labeling process for opioid analgesics:

1) Strike the term “moderate” from the indication for non-cancer pain (the only clinical indication for using an opioid analgesic would be for severe cancer pain).
2) Add a maximum daily dose of opioid analgesia, equivalent to 100 milligrams of oral morphine, for treatment of all non-cancer pain.
3) Add a maximum duration of 90-days for continuous (daily) opioid analgesia use for non-cancer pain, after which opioid analgesia would be discontinued (8).

The FDA acknowledged receipt of the PROP Petition on July 26, 2012 (9), and it simultaneously received a letter of support for its petition on the same date, led by Congress member, Representative Mary Bono Mack from California (10).

The Backlash to the PROP Petition Begins

This unity within the supporters of the petitioning group was short-lived. A representative from within the palliative care community alerted PROP FDA Petition signatory and American Society for Addiction Medicine (ASAM) President, Stu Gitlow, about substantial concerns from the pain management and palliative medicine communities about the potential reduced access to opioid therapy for many patients. In response to concerns that the PROP Petition might have a chilling effect on medically-legitimate opioid prescribing, ASAM released a statement by Gitlow clarifying its position that “the relabeling proposals [were] not intended, in any way, to limit a chronic pain patient’s access to clinically appropriate opioid pain therapy or to impinge upon a pain specialist’s ability to make individual decisions regarding the most effective therapy for their legitimate pain patient (11).”

Several prominent pain management experts echoed important concerns about over-restricting patients’ medically legitimate access to opioid analgesics. Bob Twillman, a pain psychologist and Director of Policy and Advocacy for the American Academy of Pain Management (AAPM), pointed out that “the 90-day limit on use of opioid for [non-cancer pain was] arbitrarily chosen (12).” Because PROP’s Petition had criticized the use of long-term opioid therapy by citing a lack of evidence for opioids’ long-term effectiveness, Twillman also pointed out that “when considering opioid analgesics, FDA has used the standard of a 12-week trial of the medication[;] it has not required longer studies (12).” Similarly, co-chair the New York State Palliative Care Education and Training Council and palliative medicine physician, Russell Portenoy, wrote that in light of “the stunning disconnect between the label changes demanded in the petition and the ‘scientific basis’ presented to justify them, I am concerned that all of the signatories possess an incomplete understanding of opioid pharmacology and pain medicine, and as a result, may pursue regulatory changes that are not in the best interest of public health (13).”

Other PROP critics included several medical professional organizations, like the American Society of Anesthesiologists (ASA), who challenged the clarity of a definition of cancer pain, asking rhetorically, “Who will decide whether the persistent pain, for example, of nerve damage incurred during an otherwise curative course of chemo- and radiation therapy is or is not cancer-related? (14).” Likewise, the American Academy of Pain Medicine (AAPM) stated “we have serious concerns about the petition and believe the rationale for the requested changes is seriously flawed, potentially harmful to patients with debilitating pain conditions for whom opioid therapy is indicated, and without substantive scientific foundation (15).”

The American Pain Society (APS) cited similar concerns about the Petition’s “insufficient scientific evidence base to support [its] recommendations. Further, we are concerned that implementation of these labeling changes which would dictate indications, dosing and duration of opioid treatment will not accomplish the intended goals, but instead have unintended negative consequences for patients including but not limited to untreated pain and loss of access to individualized care (16).”

FDA Response to the PROP Petition

On September 10, 2013, the FDA provided its response to the PROP Petition to change opioid labeling, which was granted in part and denied in part (17, 18). The FDA agreed with PROP that “more data are needed about the safety of long-term use of opioids,” and, to this end, they required “all new drug application (NDA) sponsors of ER/LA opioids to conduct postapproval studies and clinical trials… to assess certain known serious risks of ER/LA opioid use: misuse, abuse, hyperalgesia, addiction overdose and death (17).” Additionally, based on stakeholder input, the FDA determined that “safety labeling changes to the labeling of ER/LA opioid analgesics [were] needed to more effectively communicate to prescribers the serious risks associated with [those] drugs, and to more clearly describe the population in whom these drugs should be used be used in light of these serious risks – thus encouraging better prescribing, monitoring and patient counseling practices involving these drugs (17).” This included a new box warning to disclose risks from ER/LA opioid analgesics and the addition of the phrase, “indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time (17).”

Despite calling for these changes, the FDA disagreed with the most important requests from the PROP Petition. It rejected PROP’s separation of non-cancer pain from cancer pain, noting “a patient without cancer, like a patient with cancer, may suffer from chronic pain, and PROP has not provided scientific support for why labeling should recommend different treatment for such patients (17).” The FDA also rejected PROP’s call for a 100 mg/day maximum morphine equivalent (MME) daily dose limitation, noting “the scientific literature does not support establishing a maximum recommended dose of 100 mg MED (17).” Furthermore, the FDA noted that creating a maximum dose of 100 mg MED “could imply a superior opioid safety profile under that set threshold, when there is no data to support that conclusion (17).” Finally, the FDA determined that PROP’s request to limit the maximum duration of treatment with opioid analgesia to 90 days was “not supportable” based on the evidence presented in the Petition (17).

PROP’s Influences the CDC Guidelines

A New Federal Regulatory Target

Although the FDA had rejected the most important changes which PROP had requested, based on a lack of scientific evidence, PROP publicly framed its FDA Opioid Labeling Petition as successful, then repeated its calls for a 100 mg/day MME (19). PROP had also explored other avenues to influence opioid policy and reduce opioid prescribing, reaching out for example to the Federation of State Medical Board (FSMB) to encourage it to make changes in its Revised Model Policy on the Appropriate Use of Opioid Analgesics in the Treatment of Pain (20).

Ultimately, PROP identified a more accommodating regulatory agency than the FDA, the Centers for Disease Control and Prevention (CDC), which revealed via engagement webinars on September 16 and 17, 2015, that it had been drafting its own Opioid Prescribing Guidelines (21).

Another PROP Backlash

In the days following these engagement webinars, critics expressed concerns about a lack of transparency in the drafting of the Opioid Prescribing Guidelines, because CDC had failed “to disclose what outside advisors it consulted with during the drafting of its controversial opioid prescribing guidelines for physicians (22).” Additional concerns involved an unusually short, 48-hour period for stakeholders to submit comments about the CDC Pain Guidelines upon their originally planned release in September 2015 (23). Moreover, revelations that at least five PROP Board Members - including PROP President Jane Ballantyne, PROP Vice-President Gary Franklin, PROP Founder Andrew Kolodny, PROP Board Member David Tauben and PROP Board Member David Juurlink – had served on the panels that helped develop the CDC Guidelines, stirred deeper concerns (23, 24). Jane Ballantyne MD, who had succeeded Andrew Kolodny as PROP President, served as the sole clinician from the pain management community to be included in the CDC Core Expert Group (25).

Medical professional organizations joined in criticism of the CDC for a lack of transparency in its policy review process and the scarcity of pain management experts represented in the Core Expert Group (26). The American Medical Association (AMA) wrote that the “review process used to date by CDC, especially the public engagement webinars, [had] generated concern about lack of transparency (26),” and that the “process may have been better served by constructing a more balanced panel that included clinicians from various medical specialty and practice settings (26).” The Patient Quality of Life Coalition (PQLC), an advocacy group that included the American Academy of Hospice and Palliative Medicine (AAHPM), AAPM, the Center to Advance Palliative Care (CAPC), and the Hospice & Palliative Nurses association (HPNA), among others, wrote that “the Guideline in its current form is focused on curbing inappropriate [opioid] use, but seems devoid of empathy for patients who need legally-prescribed opioid medications for relief from serious and long-lasting pain that compromises their quality of life and independence (27).”

Following this outcry for transparency and expanded clinical representation regarding content, the CDC announced a second, 30-day open-comment period on its proposed 2016 Pain Guidelines, effective December 14, 2015 (28, 29). This delayed the roll out of the CDC Pain Guidelines past its originally anticipated implementation in January 2016, and prompted PROP founder, Andrew Kolodny to complain, “Opening a docket will tack months on to the process [and also] increases the likelihood that the guideline may never be released. This is an enormous win for the opioid lobby (30)." Interestingly, Kolodny co-authored a subsequent article examining the role of pharma funding and support of the CDC Pain Guidelines, and found that “of the 158 organizations that commented on the CDC’s draft guidelines, approximately 80% supported them either with or without recommendations, including many that received funding from opioid manufacturers (31).”

The CDC Guidelines are Published, Despite Ongoing Concerns

Notwithstanding PROP-founder Kolodny’s fears that the guidelines “may never be released (30),” the CDC Pain Guidelines were published via MMWR on March 18, 2016 (4). While most pain experts generally felt that the Pain Guidelines would be useful for those prescribing opioids in primary care settings, many expressed concerns that the Guidelines could be misapplied and affect a much broader group of patients than intended. For example, AMA board chair-elect, Patrice Harris, said that while the AMA shared the goal of reducing harm from opioid abuse, it remained concerned “about the evidence base informing some of the recommendations, conflicts with existing state laws and product labeling, and possible unintended consequences” including insurance coverage limitations for non-pharmacotherapeutic options for chronic pain (30). Similarly, Bob Twillman, executive director of the AAPM, said the CDC guidance “leaves much to be desired,” particularly regarding the limitations on dose, duration of treatment and arbitrary dosing threshold (32, 32). “Our concern is that, based on experience when states have implemented similar guidelines, some clinicians will interpret these ‘soft limits’ and thresholds as absolute ceiling doses, and that people with pain will suffer needlessly as a result,” Twillman said (32).

On August 29, 2016*, a group of scientists from the CDC itself* expressed integrity concerns about the agency’s data and its “the current state of ethics,” noting that “[i]t appears that our mission is being influenced and shaped by outside parties and rogue interests (34),” without specifically identifying PROP as one of those forces. Calling themselves the “CDC Spider Group (CDC Scientists Preserving Integrity, Diligence and Ethics in Research),” they reached out to Carmen S. Villar, MSW Chief of Staff, Office of the Director for the CDC, plainly stating that CDC “data were clearly manipulated in irregular ways” for political purposes (34). In October 2016, an article echoed similar concerns regarding CDC’s manipulation of data in a variety of projects, again alleging that the CDC was being influenced by corporate and political interests in a way that compromised its data collection (34). Despite these warnings, the 2016 CDC Opioid Prescribing Guidelines were implemented as planned.

Unintended Harms and the Backlash Against Misapplication of the CDC Guidelines

Just two years later, yet *another article* authored by CDC scientists was published in April 2018, again calling into question the methodology used by CDC to estimate opioid overdose deaths (35). The authors alleged that the CDC traditional method for calculating opioid overdose deaths *overestimated deaths due to prescription opioids* because the CDC failed to account for the emergence of illegally-manufactured fentanyl (IMF) as a cause of overdoses in its methodology (35). The authors proposed a method that would exclude IMF-related deaths for a more accurate estimate of total opioid overdose deaths (35). Using its traditional method, the CDC “estimated 32,445 prescription opioid–

involved deaths occur[ing] in 2016." Using these authors' proposed "more conservative method, 17,087 prescription opioid–involved deaths occurred in 2016." The concerned scientists concluded that "obtaining an accurate count of the true burden and differentiating between prescription and illicit opioid-involved deaths [was] essential to implement and evaluate public health and public safety efforts (35)."

In addition to concerns about the accuracy of CDC's overdose data, by 2018 it had become clear that misapplication of its Pain Guidelines had begun to contribute to deaths from "suicides within and outside of the Veterans Affairs Healthcare System in the United States" from forced or involuntary tapers off of opioid analgesics (36). Although the CDC had designed the Guidelines "as non-mandatory guidance for primary care physicians[,] legislators, pharmacy chains, insurers, and others [had] seized on certain parts of its dosage and supply recommendations and translated them into blanket limits in law[s] and mandatory policy (37)." These misapplications and unintended consequences prompted the passage of an AMA Resolution against ongoing, widespread misapplication of the CDC Pain Guidelines in November 2018 (38). Adopted by the AMA House of Delegates at its November 2018 Interim Meeting, the new AMA policy affirmed that:

1) "Some patients with acute or chronic pain [may] benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate,"

2) The "AMA advocate against misapplication of the CDC Guideline for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients' medical access to opioid analgesia," and,

3) "No entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids (38)."

In the months after adoption of this AMA policy change, more clinical professionals and medical societies would actively seek to reverse the harms of the CDC Pain Guidelines' misapplication.

In December 2018, a group of clinical leaders and international stakeholders in the pain management community signed an open letter calling for urgent action against forced tapering of opioids (36). On February 13, 2019, the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH) sent a joint letter to Debra Dowell, Chef Medical Officer of the CDC Opioid Response Coordinating Unit, to follow up on a stakeholder meeting that was held on November 8, 2018, during which those professional organizations called for CDC "to address unintended implementation and reimbursement consequences that have been occurring in practice" because of the misapplication of CDC's Pain Guidelines (39). On February 19, 2019, Dowell answered back in a letter that stated, "The Guideline is not intended to deny any patients who suffer from chronic pain from opioid therapy as an option for pain management (40)." She also wrote, "CDC encourages physicians to continue to use their clinical judgment and base treatment on what they know about their patients, including the use of opioids if determined to be the best course of treatment (40)." This response letter was embargoed for release until April 9, 2019 (40), to coincide with other anticipated press releases related to federal actions regarding misapplication of the Pain Guidelines (see below).

Similarly, on March 6, 2019, a group identified as Health Professionals for Patients in Pain (HP3) called upon "the CDC to follow through with its commitment to evaluate the impact by consulting directly with a wide range of patients and caregivers, and by engaging epidemiologic experts to investigate reported suicides, increases in illicit opioid use and, to the extent possible, expressions of suicidal ideation following involuntary opioid taper or discontinuation (41)." HP3 also urged "the CDC to issue a bold clarification about the 2016 Guideline – what it says and what it does not say, particularly on the matters of opioid taper and discontinuation (41)." The CDC responded on April 10, 2019, noting that "the Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm (42)."

FDA Warning and CDC Clarification About the Pain Guidelines

FDA Warning Against Rapid Tapers

One day prior to the CDC response letter to HP3 (42), on April 9, 2019, the FDA posted a safety announcement warning against sudden discontinuation of opioid pain medications (43). In the announcement, the FDA noted that it had "received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide (43)." This information was also released via a special FDA podcast on 4/17/2019 (44).

CDC Warns Against Misapplication of its Pain Guidelines; PROP Gets Defensive

In view of the embargo for release of the CDC response to the NCCN-ASCO-ASH, which occurred on April 9, 2019 (40), and the CDC response to HP3 (42) on April 10, 2019, it seems likely that the FDA and CDC coordinated their communications to response to the Pain Guideline backlash. CDC then released another embargoed statement on April 24, 2019, in which it advised against the misapplication of its Guideline for Prescribing Opioids for Chronic Pain (45). More explicitly, CDC sought to raise "awareness about the following issues that could put patients at risk:

- Misapplication of recommendations to populations outside of the Guideline’s scope.
- Misapplication of the Guideline’s dosage recommendation that results in hard limits or ‘cutting off’ opioids.
- The Guideline does not support abrupt tapering or sudden discontinuation of opioids.
- Misapplication of the Guideline’s dosage recommendation to patients receiving or starting medication-assisted treatment for opioid use disorder (45).”

On the heels of this media release, the CDC referenced a companion article published in New England Journal of Medicine (NEJM), co-authored by PROP member and CDC Core Group member, Roger Chou, which was available online on April 24, 2019, and in print on June 13, 2019 (46). Those authors also admitted that “some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations (46).” But in contrast to the contrite note struck by the CDC media release, the NEJM article vigorously defended the Pain Guidelines, noting that “the medical and health policy communities [had] largely embraced its recommendations” and that “the guideline was rated as high quality by the ECRI Guidelines Trust Scorecard (46).” The NEJM article also dismissed allegations about the lack of transparency in the Guideline creation, noting that the CDC had “engaged clinicians, health systems leaders, payers, and other decision makers in discussions of the guideline’s intent and provided clinical tools, including a mobile application and training, to facilitate appropriate implementation (46).” Notably, the article ended with this disclaimer: “The views expressed in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (46).”

Undeclared Conflicts of Interest

Less than a month after the printed publication of the Chou’s NEJM article defending the Pain Guidelines, the US Department of Justice (DOJ) announced obtaining a record-setting $1.4 billion settlement against Reckitt Benckiser, the manufacturer of Suboxone, an opioid addiction treatment drug (47). For years, critics had alleged financial connections between PROP members and Reckitt Benckiser, with suspicions driven by comments by PROP’s Kolodny, who in 2005 - when asked about his financial relationship with the company - replied, “They are not a pharmaceutical company. They make Lysol (48)." In 2015, Reckitt Benckiser had spun off its Suboxone manufacturing to a subsidiary that it named Indivior (49), more commonly identified as its manufacturer currently. Additionally, in recorded testimony during government hearings, Kolodny had encouraged the use of Suboxone as a measure to combat the opioid crisis. In 2011, at a New York State Senate Hearing, then-PROP President Kolodny testified, ““If we want to see a decline in overdose deaths, you have to [sic] provide effective treatment for people who are opioid-addicted. And for this epidemic, that’s probably going to mean buprenorphine (50).” Likewise, during a US Senate Hearing in 2018, Kolodny testified, “The first-line treatment for opioid addiction is buprenorphine, also called ‘’Suboxone.’ Access to this treatment is not sufficient (51).”

Testimony from hearings encouraging the use of Suboxone and deflective comments, like Kolodny’s dismissal about his relationship with Reckitt Benckiser, were less suspicious as betraying conflicting interests before it was revealed that PROP members failed to disclose relevant conflicts of interest when authoring several articles printed in medical journals. Kolodny failed to disclose conflicts of interest pursuant to his executive directorship of PROP and provision of expert witness testimony in malpractice cases involving opioids when he published two articles in the Journal of the American Medical Association (JAMA) in October 2017 and April 2018 (52). Similarly, PROP President, Jane Ballantyne, failed to disclose her affiliation with PROP in an “Ideas and Opinions” article, co-authored with PROP members, Anna Lembke and Roger Chau, in Annals of Internal Medicine in 2019 (53, 54). Moreover, PROP’s Mark Sullivan failed to declare a conflict of interest regarding his work on a opioid tapering device, which occurred during his participation in the drafting of the CDC Pain Guidelines, until he was participating in a CDC-sponsored Clinical Outreach and Community Activity, after the Guidelines’ publication (55). More recently, the British Medical Journal (BMJ) updated a “Rapid Response” that accused the AMA of a pharmaceutical industry bias when creating opioid policy, written by several members of PROP, when it was revealed that one of the co-authors, PROP’s Sullivan, did not disclose his competing interest related to his work as an expert witness in cases in Maryland and Missouri (56).

Despite their collective tendency to under-report relevant conflicts of interest in publications, PROP members continued to place themselves successfully in key positions to enhance their ability to shape opioid policy. In early April 2020, the Agency for Healthcare Research and Quality (AHRQ) disclosed for the first time the identity of the authors of the controversial report, “Opioid Treatment for Chronic Pain,” which had concluded “opioids were no more effective in treating pain than nonopioid medication, and that long-term use of opioids increases the risk of abuse, addiction and overdose, especially at high doses (57).” The lead author of that report was revealed to be Roger Chou, a PROP member who has been described as “a vocal critic of opioid prescribing for years (58).” This revelation was especially concerning at the time, because CDC had announced its plans to review and possibly revise the 2016 CDC Pain Guidelines, which were co-authored by Chou, and because the AHRQ study had reaffirmed many of CDC’s still-disputed conclusions about opioid therapy (58).

CDC Begins a Reassessment of the 2016 CDC Pain Guidelines

Open Docket for Comments

On April 17, 2020, the CDC announced “the opening of a docket to obtain comment concerning perspectives on and experiences with pain and pain management, including but not limited to the benefits and harms of opioid use, from patients with acute or chronic pain, patients' family members and/or caregivers, and health care providers who care for patients with pain or conditions that can complicate pain management (59).” Eventually, it received 5,392 comments from patients, physicians, medical organizations, and other stakeholders with feedback about its 2016 Pain Guidelines (60).

The AAHPM did not mince words when commenting about its concerns of misapplication of the CDC Pain Guidelines: “The 2016 Guideline has been broadly misapplied, with devasting effect on patients and prescribers. Forced tapering of patients’ opioid prescriptions has been incentivized and/or mandated, violating ethical and evidentiary norms of medical practice. This has resulted in many patients’ medical deterioration, loss of care relationships, turning to illicit substances/alcohol, and suicidality. Swapping products and formulations to reduce opioid prescriptions where not medically necessary has also led to medical errors. At the same time, prescribers have faced professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the morphine milligram equivalent (MME) thresholds included in the CDC Guideline (61).”

The AMA echoed these concerns, writing “It is clear that the CDC Guideline has harmed many patients—so much so that in 2019, the CDC authors and HHS issued long-overdue, but greatly appreciated, clarifications that states should not use the CDC Guideline to implement an arbitrary threshold (Italics mine, 62). It also noted that “the CDC Guideline has been misapplied as a hard policy threshold by states, health plans, pharmacy chains, and PBMs,” and that “these policies, moreover, have not withstood any meaningful evaluation or data analysis as to whether they have improved pain care or reduced opioid-related harms (62). There also are no data to suggest that payers have increased access to non-opioid pain care options. If one of the goals of the CDC Guideline was to increase access to non-opioid pain care, that has not been realized (62). Rather, there is evidence that payers continue to erect and support barriers to non-opioid pain care (62).” The AMA urged the CDC to rescind policies employed by “many health insurers, pharmacy chains, and PBMs” based on the concept of a hard MME threshold to avoid “harms done to patients as a result of inappropriate tapering or denials of care (62, 63).

In its comments, PROP conceded that reduced opioid prescribing was associated with downward trends in “prescription opioid related morbidity and mortality (64),” but did not acknowledge a concomitant, upward trend in total opioid-related morbidity and mortality from illicit drug, including illegally manufactured fentanyl. They further argued, “For some patients, continued opioid use is necessary not because it effectively manages the pain that prompted opioid prescribing initially, but because continued use averts the negative effects of opioid discontinuation (64),” a claim advocates for patients with chronic pain have labeled as a gaslighting strategy (65). Furthermore, as discussed later in the article, PROP also incorrectly predicted, “The downward trends in new starts of chronic opioid treatment achieved by the 2016 guideline should be seen as a positive development that will encourage people to find alternative means of controlling chronic pain, which though harder to employ than the prescription pad, will ultimately result in better outcomes and less distress (65).”

The BSC/NCIPC Workgroup

On July 6, 2020, the CDC announced the formation of a new Opioid Workgroup and the Board of Scientific Counselors, National Center for Injury Prevention and Control Centers for Disease Control and Prevention (The BSC/NCIPC Workgroup), which would “review the Opioid Workgroup’s report, discuss, deliberate, and provide advice and recommendations for CDC to consider as part of the potential update and/or expansion of the Guideline. The updated and/or expanded Guideline is anticipated to be released in 2022 (66).” This announcement was followed by the release of a PowerPoint Presentation entitled, “Update on the BSC/NCIPC Workgroup,” on July 22, 2020, which elaborated on the process of choosing the new Opioid Workgroup (67). An additional update from October 13, 2020, identified the membership of the Opioid Workgroup – NCIPC BSC Committee Members (68). The updated and/or expanded Pain Guideline was anticipated to be released in 2022 (66), but that timeframe was projected before the full impact of the COVID-19 Pandemic.

Increases in Overdose Deaths and CDC Data Flaws

The February 2021 MMWR Report

While the world anxiously awaited word on any new or revised CDC Pain Guidelines, on February 12, 2021, the MMWR Report (1) mentioned at the top of this commentary quickly captured the attention of those already hungry for news from the CDC, including patients with chronic pain and clinicians who manage that pain. In the setting of a 1,040% increase in “age-adjusted overdose death rates involving synthetic opioids, psychostimulants, cocaine, heroin, and prescription opioids during 2013–2019 (1),” it seemed prudent to critically question PROP’s assertion that “The downward trends in new starts of chronic opioid treatment achieved by the 2016 guideline should be seen as a positive development that will encourage people to find alternative means of controlling chronic pain, which though harder to employ than the prescription pad, will ultimately result in better outcomes and less distress (64).”

On February 16, 2021, in what felt like an effort to draw attention away from the stark reality of the MMWR Report, PROP wrote a letter to AMA President, Susan R. Bailey, regarding “AMA’s Opposition to Dose & Duration Guidance for Opioid Prescribing (69),” based on AMA’s comments to Dr. Deborah Dowell in the CDC Open Docket (61). PROP concomitantly published this letter to the AMA as a “Rapid Response” to an article entitled, “UK recommendations on opioid stewardship (70, 71).” The letter alleged that AMA Opioid Policy was inappropriately influenced by donations from the pharmaceutical industry (69, 70). AMA President, Susan Bailey, quickly responded back to PROP, in a letter dated February 19, 2021, saying “With respect to the issue you raise in your letter, it might be helpful to point out that the CDC authors of the 2016 CDC Guideline themselves have recognized it has been misapplied (Italics mine; 72, 73).” Additionally, Bailey pointed out, “When policies or organizations focus only on the restriction of a legitimate pharmacologic option to help patients with pain, they miss the chance to address the complexity of policies needed to truly help patients with pain. That misguided focus also has led to harmful stigmatization and other stressors. That is why the AMA provided comprehensive recommendations on the 2016 CDC Guideline and why we continue to advocate for policies that support comprehensive, multidisciplinary, multimodal pain care, including opioid therapy when appropriate. If you choose to cite the AMA's policies in the future, we encourage you to cite them in their entirety to ensure accurate context (72)," and Bailey provided the link for the AMA's comments to Deborah Dowell to guide PROP when referencing AMA policy in the future (62).

Inaccurate CDC Data on Opioid Deaths

Just a few weeks later, PROP's troubles worsened, with the publication of an article by John Peppin and John J. Coleman in Pain Therapy (74) that detailed fundamental methodological shortcomings in CDC's data on prescription overdose deaths (35). The authors held that "CDC erroneously reported prescription opioid overdose deaths in 2016 and for more than a decade before (74)" in a way that overestimated overdose deaths due to prescribed opioids. They further assert that "the CDC ignored the problem until 2016 data showed serious inconsistencies with other, more reputable, data for prescribing volumes of opioids (74)." Furthermore, in "2018, the U.S. Congress mandated the CDC to ''modernize'' its system for reporting drug overdose deaths but this has not yet occurred (74)." They concluded: "For more than a decade, millions of Americans were misled into believing that—as a White House report once characterized it— 'opiate overdoses, once almost always due to heroin use, are now increasingly due to abuse of prescription painkillers.' Little did they know or suspect that the CDC's coding of prescription painkillers included non-prescribed illicitly manufactured fentanyl and fentanyl analogs and non-prescribed methadone administered or dispensed to patients being treated for opioid use disorder (74)."

This report again exposed PROP's and CDC's false narrative that overprescribing of opioid analgesics had driven the US overdose crisis (74). In a predictable response, Andrew Kolodny reacted quickly to soften the crushing blow and establish some semblance of plausible deniability for PROP's culpability. On March 22, 2021, Kolodny produced a webinar during which he "refuted" several alleged "myths and false narratives" about the opioid crisis (75). This presentation was swiftly characterized as "a rambling dialogue by Kolodny that gaslighted pain sufferers, doctors, patient advocates and anyone else critical of the CDC guideline (76)." For example, in a clear example of a Straw Man Argument (77), Kolodny alleged a myth that the "CDC Guideline forced millions of patients off opioids resulting in an epidemic of suicides (75)," when in fact both the CDC and FDA had publicly acknowledged the potential harms of forced tapers, acknowledging that the extent of the harm was not yet known (Italics mine, 42-45). In response to legitimate concerns about harms from polices influenced by PROP's advocacy, one of its individual members had responded with gaslighting (75), informal fallacies (77) and deflection, aimed apparently at creating plausible deniability for their contribution to those harms.

Conclusion

Despite being turned back from an effort to bluntly reduce opioid prescribing by the FDA in 2013 based on a lack of scientific evidence for its position (17,18), PROP has had a disproportionate effect on opioid policy in the Untied States for almost a decade. PROP found a willing federal regulatory partner in the CDC, and while PROP may not have "secretly written" the 2016 CDC Pain Guidelines (75), they certainly enjoyed disproportionate representation on CDC's review panels and Core Expert Group (23-25) in a process that lacked transparency (22, 23, 26, 27). When the CDC admitted that its Pain Guideline had been widely misapplied (40) and joined the FDA in a call against forced opioid tapers (42, 43, 45), PROP doubled down on its rhetoric (46), dismissing legitimate concerns about potential harms in a performative manner (75) that encouraged their ongoing misapplication, while assailing PROP's critics (76, 77). All of this has occurred as PROP members have repeatedly concealed relevant conflicts of interest, including key conflicts that should have been disclosed during the process of drafting the CDC Pain Guidelines (48-54).

Given this, at a minimum, PROP should no longer enjoy a prominent role in guiding future opioid policy in the United States. This is a particularly urgent concern, as Roger Chou has been linked to authorship of CDC's New Pain Guidelines, which have not yet been released to the public (78). Chou's involvement in yet another set of Guidelines and CDC's recurrent lack of transparency (79) in identifying the new Guidelines' authors should alarm all advocates who support access to pain medications for all patients with a medically legitimate indication for opioid therapy.

Beyond limiting PROP's role in developing future, potentially harmful opioid policy, a reasonable individual would be justified in wondering to what extent PROP bears culpability for the harms that arose from misapplications of the 2016 CDC Pain Guidelines. In our country, civil suits – like class action lawsuits, for example – only require a preponderance of the evidence – that is something is "more likely than not" - as the burden of proof for liability. It is more likely than not that PROP's efforts to affect opioid policy helped shape the CDC Guidelines, which CDC has admitted were misapplied harmfully (40). It is also more likely than not that PROP's performative advocacy efforts contributed to misapplication of the CDC Guidelines. And it is more likely than not that widespread misapplication of the CDC Guidelines resulted in harms with attendant civil liability. This would expose PROP to civil liability with a potentially enormous settlement if a class action suit were to arise from those harmed by the misapplication of the CDC Guidelines. Perhaps that is why PROP member, Andrew Kolodny, and others have worked so hard recently to create plausibly deniability (75) in the wake of the damaging February 12, 2021, MMWR Report (2).

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To cite this article: Kollas C. Mandated PROP's Disproportionate Influence on U.S. Opioid Policy: The Harms of Intended Consequences. Pallimed. May 2021. Available at: https://www.pallimed.org/2021/05/props-disproportionate-influence-on-us.html

Correction 5/4/2021: A date was incorrectly included in the original article as "April 9, 2021," which was incorrect. It was changed to the correct date of "April 9, 2019."

Addition 5/6/2021: A Twitter user was able to find the PDF link to Reference number 40. The reference was updated with this link.

Conflict of Interest (submitted upon publication, added here 5/4): Dr. Kollas had submitted a Conflict of Interest statement when submitting this article for publication. It was not originally included in error in the original article here due to editor error. You can find the conflict of interest statement here - https://twitter.com/ChadDKollas/status/1389616181762478080. We have a copy of the COI statement, if this link ever is removed or in error.

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Submission on updates/revisions to CDC Opioid Prescribing Guidelines.

July 22nd, 2021

Submitted by:

Cammie LaValle, Minnesota
Daniel LaValle, Minnesota

Thank you for the opportunity to provide public comment. This is an extention of my comment provided on July 16th, during the meeting.

Due to the severe collateral damage to date from the CDC Guidelines, I urge the CDC to immediately adopt both the AMA and Opioid Workgroup recommendations which have already been submitted to the CDC.

The MME thresholds have caused immense patient harm, forced disability, suicides, patient abandonment; in addition to patients throughout the United States turning to alcohol and street street drugs when their providers refuse to continue care.

The overdoses have drastically increased and the CDC Guidelines play a part in that. All while prescribing has been significantly reduced.

We're losing more lives. Unless and until there are more balanced policies which actually ensure patients, regardless of diagnosis or disease, receive patient centered care, individualized to their unique and specific healthcare circumstances; this crisis will only get worse.

Standard of care has gone out the window. It's unacceptable for any healthcare issue to not apply standard of care. This includes, yet not limited to, opioid analgesics.

Non-opioid therapies and treatments may work for millions of Americans, which is great. However, there are tens of millions of Americans who have exhausted these therapies and/or still require opioid analgesics in addition to other non-opioid treatments.

There will ALWAYS be a subset population with a vital medical necessity for opioid analgesics at doses based on their individual circumstances, when benefits outweigh the risks, when allowing more function and lowering severe pain in order to live a life, have a quality of life; and not be left undertreated or untreated equating to just existing in life and endure suffering.

There is no one size fits all in healthcare. Applying this mindset to pain and in medicine is only harming people; even killing people by way of suicides due to pain.

Having safeguards is one thing, but you know the MME thresholds outlined in guidelines have been misapplied and even mandated for over 5 years.

There has been no urgency by the CDC to fix the horrific "unintended consequences" and dire collateral damage that's been done. None. It's unfathomable the CDC has allowed this to continue. It's irresponsible, unethical, cruel and inhumane.

I, as a disabled, incurable painful rare disease(s) patient with inoperable, multi-level, severe spine damage, on Palliative Care; am caught in the crossfire. Millions like me are. When is my next force taper? Every month I worry. Every month my husband worries. Even exempt from CDC Guidelines, our states don't adhere to Palliative Care or Cancer exemptions. You've heard this before from so many, including AMA, but CDC has taken no serious steps to intervene.

It's gone too far. You all know it. Our country can absolutely address addiction, crackdown on the massive amounts of illegal drugs flooding our streets, at the same time of ensuring Americans with vital medical necessity for opioid analgesics, can continue have access; when benefits outweigh risks.

Our physicians are threatened by the state solely for prescribing over the CDC recommended MME dosage, regardless of having proper documentation and never doing anything unlawful.

DEA, States Attorney's Office, DOJ, State Health and Human Services; ALL cite CDC Guidelines and MMES, using threats of investigation, disenrollment, charges; and we wonder why physicians are dropping patients and pharmacies are denying prescriptions. This must stop.

Responsible prescribing is vital, but no prescribing, not filling legitimate prescriptions is not responsible and is harming people.

We can't continue down this path and expect a different outcome. Overdoses are at an all time high. This is tragic! It's clear the intent has backfired.

The CDC has an opportunity to correct this. It's dire.

We beg you to adopt AMA and Opioid Workgroup Recommendations.

Millions can not wait until 2022 for corrections. It's been over 5 years.

Take serious action immediately to stop misapplication of 2016 Guidelines and reach out to all states, insurance industry, our administration, pharmacies, medical boards; ALL stakeholders, and work together to halt the damage being done.

It's shameful the CDC has not taken this seriously.

You allowed people who call my medication "heroin pills", to help draft the 2016 Guidelines. You knew this and allowed it.

No chronic pain patients were interviewed to seek input, lived experiences, when developing guidelines. This was confirmed by Dr. Deborah Dowell in January of 2016 during a phone call with me. Reason? "We didn't have time". Unacceptable.

Millions harmed now. Tens of thousands dead by suicides due to they could not endure more suffering.

Here's your opportunity to do better. You have a moral and ethical obligation to do so.

I'd like to stay out of a wheelchair for as long as possible.

I'd like to get the treatments that will help address my horrific debilitating disease of CRPS, which has ravaged my body. IVIG is not FDA indicated for CRPS. In fact, nothing is. Insurance won't cover it. Nor Ketamine, nor Calmare. Due to Epilepsy, I can't get other treatments. Due to a heart condition, I'm not a candidate for other treatments either. Due to severe spine damage, I can't get neuro-stim.

Rare diseases with pain, with no cure & no FDA indicated treatments; and intractable pain, were left out of guidelines. It's as if we just don't exist and we're not worthy of consideration.

It's disgusting that my state of Minnesota refuses to even acknowledge the actual existing Intractable Pain Statute in Minnesota. The law supercedes the guidelines and any policies which are not also outlined in legislation. However, that doesn't seem to matter. It'll only get worse if the CDC doesn't follow AMA and Opioid Workgroup recommendations. I fear for what my future holds. Millions of us do.

Regards,

Cammie LaValle

From: Criss Lavia
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:40:48 PM

I will quit all my meds..if I can't have pain meds. This is cruel and unusual treatment. Pain is horrible and changes who you are.

Criss

From: Clasina Leslie Smith
To: NCIPCBSC (CDC)
Subject: updated opioid prescribing guidelines
Date: Friday, July 23, 2021 11:44:49 AM

Dear Dr. Walensky,

I was deeply concerned to read the draft of the updated CDC opioid prescribing guidelines for chronic pain.

Current best practices in pain management is recognized to be a multimodal, multidisciplinary, integrated and integrative model of care that includes a variety of options. There is no mention of these models other than to allude to non-pharmacologic therapy.

I respectfully request that you consider including such models and modalities more explicitly in the guidelines.

Thank you,

C. Leslie Smith, MS, MA, LAc, MD
Director, Integrative Medicine
Director, Culinary Medicine
SIU School of Medicine

From: cnd Lybrand
To: NCIPCBSC (CDC)
Subject: Comment on Updated CDC Guideline
Date: Friday, July 23, 2021 10:23:19 AM

Having worked for more than 20 years in medical education, I am asking that your review and corrections include those recommendations by the healthcare experts. Included within are issues:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain.

Also, I am a chronic pain patient - with multiple auto-immune diseases as well as ehlers-danlos, a very painful condition. I have never abused medications of any kind. If you could only walk a mile in my shoes, I believe you would be much more willing to make the appropriate corrections and take heed of the advice of experts. Human beings in pain need the appropriate treatment, as well as a society that cares and learns from mistakes of the past.

Please - take heed, as but for the grace of God, you or your family member might be the next patient impacted by the guidelines.

Cindy Lybrand

From: Cheri Mendes
To: NCIPCBSC (CDC)
Subject: Public comment, opiod workgroups
Date: Sunday, July 18, 2021 1:49:24 PM

I write today as an untreated chronic pain patient. Up until 2018, opiods had been part of my pain management for 28 years. I have 5 chronic illnesses, none of which have had any treatment for over 3 years. I'm in active decline as a direct result. I'm now disabled, and it didnt have to be. I suffer tremendously every day, and have very little quality of life. When I had my medicine, I was able to work and care for my home and family. Not anymore. When the DEA stormed my doctors office, my medical records were flagged, and I have not been able to find another doctor to treat me within 100 miles of home. No doctor will accept flagged charts. I cant even go to my local emergency room any more, as I've been asked to leave. The administrator refused to take my complaint, so I was forced to file with the Board of Medicine.
My death will be on your hands when it comes.

Cheri Mendes
8220 Briercrest Drive
Erie Pennsylvania 16509
814 868-2298
814 566-0793
cyren888@hotmail.com

From: Chardele Miller
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:21:15 PM

The guidelines are very outdated & as a fully disabled senior citizen & an incurable cancer patient I find the guidelines to be ridiculous.
Not to mention all the great alternatives that are out there that insurance doesn't cover and should.

I dont need another PT class or some physical therapy that only resulted in more damage to my body.

Please review these and making Real effective & efficient changes catering to those of us in pain.
This is outdated & the sign of a lackadaisical workforce.

From: Charles Mueller
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:41:25 PM

I have a diagnosis of severe and intractable pain since 2003. Before your “guidelines “ I was on proper pain management. Since your cuts I’ve have been Suffering every second of my life. Thank you for not caring. I’m sure, though, that people in your families are able to get what they need no problem. How many lives and families have been destroyed because of you? How many suicides? How many good citizens resorted to street drugs and died? That is something you don’t put in your statistics because it would make you look bad. Why don’t you say what you really want. To rid society from people who suffer. It’s on your souls not mine. Once again I want to thank you for countless suffering and deaths due to guidelines. May God have mercy on your atheistic souls.

Sent from my iPhone

From: Candi1767 P.
To: NCIPCBSC (CDC)
Subject: CDC's Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC)
Date: Thursday, July 15, 2021 4:57:02 PM

To whom it may concern,

I did not sign up to speak at the meeting on July 16th, 2021 because as with all days, I have a very hard time getting out of bed & moving around since being forced down/off my prescription opioid pain medicine(as well as millions of others). So I did not know if I would be able to speak at a certain time or not. Or if I could even sit there long enough to speak.

Myself as well as other family, extended family, friends & acquaintances, etc., who have been forced down/off of our effective prescription pain medicines & can no longer function.

I believe the CDC as well as other government offices have received the wrong information about the opioid epidemic. And are also promoting the wrong information. I also believe other people are trying to place blame on prescription opioid medicines(instead of the real cause from illegal street drugs) to wane people towards other medicines, so they can line their pockets from the sale of these other medicines.

As we know, doctors did not create the opioid epidemic by over-prescribing. Since EVERYONE has been forced way down/off of the prescription pain medicines that once greatly helped them, over-doses & deaths continue to climb. Not to mention suicides because people's bodies just aren't made to deal with SO much pain every day, day after day.

Also doctors are leaving their practices because they are too afraid of the DEA coming after them, taking their license & closing their practice. And when that happens, it leaves ALL of their patients out in the cold. No where to turn. Because other doctors will not take them in or treat them either. So where does that leave them? They have nowhere to go but to turn to the streets(illegal street drugs) which is what is causing the addiction, over-doses & deaths to begin with. Not to mention suicides. How no one seen that coming, is beyond me. Obviously this wasn't looked into properly. & its not being acted upon properly either.

Prescription opioid medication is safe & effective for millions & millions of people, when taken as directed & stored safely(even in higher doses). When you abruptly stop something that has greatly helped someone & you don't have a replacement of something that works just as effectively or even more so, that leaves those people searching for something else. & when there isn't something or someone to help them legally, they turn to the illegal stuff, adding to more statistics.

Also I'd like to know where they came up with a 90mg cap per day? Could you please tell me the research on that? Because I cannot find anything on that. I think someone just pulled that number out of their butt & everyone else just said, ya ok that sounds good.

Well, everyone's bodies are different. Their pain is different. And, they process medications differently. That's why different people need different medications at different doses. We are not robots & we are NOT all the same.

The 2016 CDC guidelines were supposed to be for PCP doctors

just starting someone out on opioids. How it became law & used as a weapon against our doctors to restrict us & ultimately tortures us, the American people, who have a right to humane & effective medical care, is beyond me.
I think for every suicide caused by these guidelines & doctors forcing someone off their medicines(because of the government & guidelines) the government should be held accountable for murder.
There are very few that are harmed by prescription pain medicines. Compared to the millions & millions it greatly helps. Being forced down /off prescription pain medicines that greatly helped has caused million to not be able to work or take care of their families, let alone be able to get out of their beds or homes.
A lot more people die from alcohol each year then prescription pain medicines. But yet alcohol is legal? Millions become obese from fast food but I don't see you closing down any McDonalds or Wendy's. Why?
I would like to reference a couple articles I think you should read.....

First .... (PDF) Evidence-Based Policymaking: What's Absent from the Opioid Crisis | Robert Schubring - Academia.edu

& the Second ... Microsoft Word - ResponseHHSPainManagementTaskForce_EDIT.docx (practicalpainmanagement.com)

Our bodies aren't made to handle SO much pain. You cannot just take away or force people down/off something that is proven to help, without there being a replacement that works just as well or even better & expect everyone to just be alright.
The 2016 CDC guidelines have harmed millions & million of people from false & misleading information.
The numbers of deaths where inflated. Because if someone who had taken a prescription opioid medication that day and they where hit & killed by another driver(probably drunk), it is marked as an opioid death because they had an opioid in them. It wasn't the opioid that killed them. But yet its marked as such(an opioid death). Which is completely wrong!!!
Also, how the government thinks it can just make a call to restrict doctors, to abruptly force taper or stop treating their patients with medicine(all over the USA) is beyond me. The government aren't doctors & they have no idea of our complex medical histories and needs, or what is best for us. We(ourselves) know our bodies best. We also shouldn't be forced to injections(that aren't FDA approved) or surgeries that could further damage or cause more pain. It is our bodies!!! & we should have a say if we think something might help or harm us & not be forced into something we are not comfortable with. We should be part of our treatment plans, not just told what to do or held from.
The 2016 CDC guidelines that where just supposed to be "guidelines" for PCP doctors just starting someone on an opioid, have turned into law & used as a weapon against people in pain that where already suffering & have caused major problems. Doctors won't prescribe, pharmacies won't fill prescriptions & that pushes everyone to the streets(illegal street drugs), the very thing this was "supposed" to stop. Well, it didn't. Its making it worse!!!

Please get the government out of the doctors offices!!! If it makes everyone feel better, millions of us would sign a release, that its our own responsibility if we are given/take an opioid prescription. The majority who are in pain & receive a prescription(opioid) take it responsibly & are safe with it. Why we are being tortured because we want to have our pain treated legally? ... is beyond me.
Please get rid of the "guidelines", unless they are really only going to be used as guidelines. Our medical treatment should be between our doctors & ourselves. Not the government! Please stop torturing million & millions of people who are in pain!!! PLEASE!!!

Thank you!!!

Candi Petelli

From: Cynthia Roberts
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 11:33:48 AM

I am writing to voice my continued disappointment in the CDC guidelines regarding opioid pain treatment. The majority of pain patients use their pain medication responsibly to achieve a life that allows them to function. With continued harassment of physicians who prescribe opioids for pain, these physicians are being forced to under prescribe, cut pain medication off, and basically leave their patients to suffer. This treatment has led to an increase in suicides, insufferable pain, decrease in function and quality of life. Restricting pain medication post-operatively is truly cruel. Restricting pain medication in cancer patients is heartless. This needs to stop. Your guidelines have not decreased overdoses. They have increased as patients cut off from medications have had to use unsafe, non-prescription alternatives. The majority of pain care providers offer steroid injections or implantable devices. Both have more risks than opioids for pain control. In most cases they do not provide relief of pain. I do not take opioids to abuse them. I take them so I can walk, stand up, take care of my dog, laundry, and live my very small life. Without these medications I would be bed bound, in complete constant pain, and more than likely will kill myself because of the pain. Please stop harassing and targeting pain patients and the physicians who are managing their care. My care should be between myself and my physician. It really isn’t your business. I believe your focus should be directed to the illegal street drugs and the people who are selling them. That is where your overdoses come from. Illegal fentanyl. I realize it’s easier to focus on individuals who go to a pharmacy with a prescription. Much easier to target and track. These individuals are not the problem. So please stop encouraging pharmacies to treat pain patients as drug seekers. Stop threatening physicians who choose to treat patients with pain medications versus invasive procedures. Let doctors be doctors for their patients. Let patients receive the care they need to live, to work, to enjoy parts of life they can’t without medication. I hope you listen. Please listen.

Sent from my iPhone

From: Christy Sebastian
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:38:41 PM

Dear CDC,

Please read! I am living proof that opiates can be used safely. I have been on a routine of Hydromorphone and Morphine for over 25 years and have been able to lead a relatively normal life. Without pain medication, I would probably have committed suicide. I don't say this lightly because I consider myself fortunate enough to have survived crippling pain with the help of these drugs; without them I would have been unable to function. I understand that the street use of opiates has created a serious problem and many deaths and that's where our concerns should be focused i.e. on stopping street drugs from entering the country. This has nothing or little to do with chronic pain sufferers who rarely abuse the terms of their medications. If the CDC continues to meddle with pain management doctors, there will be none and millions of chronic pain sufferers will suffer more. I think there is plenty of evidence that shows that opiate abusers are a different sect then chronic pain patients - unrelated in most cases. The CDC needs to understand that we who suffer from real pain should have access to real medications that work. I trust my doctor and you should as well. By limiting access to opiates, you place thousands of patients at risk.

The outcome of the last study put doctors in a terrible position forcing many of them to quit the business. As our population ages, there will be fewer and fewer doctors who sign up to deal with chronic pain. What will be your response to the increase in suicide? depression? elevation of street drug use? People who are afflicted with pain deserve to be treated effectively. Your guidelines are arbitrary and punitive. Is that the role of the CDC? Every doctor I go to now is concerned about prescribing anything because of your last study in 2018. DO NOT MAKE THIS MISTAKE TWICE. Doctors and their patients are sacred ground and should be outside the guidelines of the CDC. We all want the deaths from illegal drugs to end, but not at the cost of the millions of people who suffer from chronic pain. TWO SEPARATE GROUPS. Do not confuse the issue by lumping us together!

I think we all understand that the days of seeing many drugs as "bad" are over. The healing properties of cannabis, cocaine and other psychoactive drugs are being explored by well - intentioned scientists and I, for one, applaud the effort. People have been using these drugs for centuries for a reason - because they work. Who are you to assume what is best for those of us who seek relief. The first claim of medicine is to do no harm. Try to stand by that pledge.

Very truly yours,

Christy Sebastian

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Christy Sebastian
(720) 252-7007

From: Cindy Steinberg
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:14:49 PM
Attachments: US Pain Foundation Comment on Updated Guideline FINAL.pdf

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Dear CDC NCIPC Board of Scientific Counselors:

Thank you for the opportunity to comment on the Draft Updated 2021CDC Guideline for Prescribing Opioids. Our comments are attached and also copied below.

July 21, 2021

Board of Scientific Counselors
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Comments on the Updated Draft CDC Guideline for Prescribing Opioids

The U.S. Pain Foundation is pleased to provide comments on the Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC)'s Updated Draft CDC Guideline for Prescribing Opioids announced at the Board of Scientific Counselors meeting on July 16, 2021. The U.S. Pain Foundation is the largest 501(c)(3) organization for people who live with chronic pain from a myriad of diseases, conditions, and serious injuries. Our mission is to connect, support, educate, and advocate for those living with chronic pain, as well as their caregivers and healthcare providers.

The U.S. Pain Foundation is gravely concerned that the Updated Draft Guideline presented and discussed at the meeting is virtually identical to the original 2016 Guideline. All of the serious problems identified by numerous researchers, clinicians, pain management experts (including problems identified by the HHS Pain Management Best Practices Inter- Agency Task Force (PMTF) in the 2019 review of the 2016 CDC Guideline), patient advocates, and patients over the past five years are still present in the new Updated Draft Guideline released on July 16. These problems include:

- Restricting authorship to non-pain management injury prevention and addiction specialists
- Bias in selection of evidence
- Inappropriate use of GRADE System — strong recommendations with weak or very weak evidence
- Biased focus on risks and harms of opioids with no discussion of benefits of opioids for pain relief when appropriately managed, or the risks and harms of enduring prolonged pain when other treatments have failed
- Arbitrary use of specific MME dose limits ("careful ...when increasing dosage to =50 MME/day, and should avoid increasing dosage to =90 MME/day"). There is no scientific evidence supporting use of these MME dosages and even MME comparison and conversion has recently been called into question by the FDA. Further, there is wide variation in patient characteristics, disease and injury type, severity, and progression that

is optimal for pain relief

- Opioid duration for acute pain depends on the severity of the injury, the type and complexity of the surgical procedure, and individual characteristics of the patient. There is no scientific basis to the strong statement that “One to three days or less will often be sufficient; more than seven days will rarely be needed”
- Exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as more worthy of pain control where the stated “risks” and “harms” don’t apply. Pain is pain and must be considered on an individual basis. A person with any given pain condition could be in much worse pain for longer duration than a person with one of the excluded conditions

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, hundreds of documented suicides, sudden loss of access to medication triggering withdrawal, dismissal from physician practices, inability to find medical care, and loss of function and quality of life. The CDC, the FDA, patient advocates, pain and disease advocacy organizations, the PMTF, and even members of Congress and the White House have received numerous letters, email messages, and phone calls from desperate pain patients who have used opioids legally, safely and appropriately, in many cases for years, pleading for help and relief from their relentless pain.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Opioids certainly do not help everyone with chronic pain and for those who are helped by these medications, they do not completely eliminate their pain. Given the dearth of safe, effective therapeutic options for chronic pain, current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care in which the healthcare provider, working with the patient, develops an individualized care plan that includes a combination of treatments selected from a broad range of therapeutic options. This approach is well-documented in the widely praised 2019 PMTF Report.

It is unfortunate and a missed opportunity that the Updated Draft CDC Guideline has not discussed nor recommended the wide range of therapeutic options for acute, subacute, or chronic pain that could be used to reduce or complement the use of opioids. Given the broad reach and influence of the CDC’s 2016 Guideline, the CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

We hope the CDC will give these views serious consideration as it moves forward with this important work. Should we be able to provide additional information or assist the CDC’s efforts in any way, please feel free to contact me using the information listed below.

Sincerely,

Cindy Steinberg
Director of Policy & Advocacy
U.S. Pain Foundation
781-652-0146
cindy@uspainfoundation.org

U.S. PAIN
FOUNDATION

July 21, 2021

Board of Scientific Counselors
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
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We hope the CDC will give these views serious consideration as it moves forward with this important work. Should we be able to provide additional information or assist the CDC's efforts in any way, please feel free to contact me using the information listed below.

Sincerely,

Cindy Steinberg
Director of Policy & Advocacy
U.S. Pain Foundation
781-652-0146
cindy@uspainfoundation.org

From: Christi Usher
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:13:43 PM

I am a chronic pain patient with CRPS type II of both hands, neuropathy damage from CIPRO. Both my thumbs have been reconstructed. The Left one 8 times.

I have had the DNA GENE TEST for all medications that my body will metabolize. I also have several gene mutations that do not allow me to take NSAIDs, aspirin, Ibuprofen or Codeine. I carry a wallet card which all physicians and hospitals know is legitimate and appreciate so I can be treated properly.

I can not use steroids of any form except eye drops if necessary.

Gluten free Hydrocodone is what I take under excellent pain management. I can safely take certain opiates. I have NO QUAILITY of LIFE without my opiates, Tylenol and Endo Patches.

I am never NOT in pain as I have to use my hands, non-opposing thumbs for everything.

I cut Endo 5% Lidoderm patches small enough to secure with K Tape or a tegraderm film cover to help with the pain.
FYI..these patches are the ONLY PATCH that can be cut to size and taped down in the United States.
I have fought my insurance company and lost every appeal to cover this RX for my needs.

The ENDO PHARMACUTIALS representative was also ignored in my plea for coverage by BCBS.
The CDC, FDA needs to address the protocol for these patches. $700. a box. I live on disability.
A box last me almost a year.

Chronic Pain Patients are each one of their own.
No two can be treated the same.
How can the CDC group us all together?
That's like saying everyone Must wear a size 8 shoe.

True Chronic pain patients do not abuse their medications. They can not thrive or survive without them.
Some days are better than others. Weather is an enormous factor in our pain scale day to day.

Chronic pain increases our stress and cortisol levels causing SERIOUS health issues. CHRONIC STRESS is as dangerous as Chronic Pain. And we pain patients are depressed because no one understands our pain except us and our physicians that are properly informed, trained to listen to us and and treat us like they know how to do. We patients should fall into the PTSD category for CBD product availability in every State instead of taking another pill for that.

I am so very blessed to have such a caring, understanding pain Dr.

(Alan Silberberg)
My primary Dr of 21 years is also fantastic but you, CDC took control as to how he could treat patients. Shame on you CDC for punishing the Good Physicians!

The opioid epidemic is from true addicts who get drugs from dealers, Bad physicians who take cash for a prescription. CHINA and other countries feed the true addicts of heroin, non approved Fentanyl, bath salts etc.

I know recovering addicts and NONE of them got opiates legally. Most cooked their own product or paid someone to go to a dirty Dr for them.
They also had no place to go to safely withdraw when they wanted to get clean.

I believe the CDC needs to believe in our good Physicians, quit judging us CPP (chronic pain patients) as a group. We are a group only in our fight for a somewhat pain free life.

CDC should require free of charge the DNA test to see exactly what pain medication works for each patient.
I was prescribed Codeine for years after my traumatic hand injury with no relief. That made me appear to be taking alot which I was when I was actually taking a drug that my body would not metabolize.

I would be happy to share my medical records, show you photos of my disabled hands, read my journals of dealing with horrible pain that makes us insane.
I'm writing because I am living this stressful painful life. CDC has caused me more stress wondering each month if you are going to be the cause of my demise because of uncontrolled pain daily, hourly, waking me in my sleep on cold nights!

The CDC told my Dr in 1989 to put me on CIPRO for almost 2years. The damage that did, still does to my body with chronic tendon ruptures should get more CDC guidelines time than the proper use of opioids by well educated physicians like I have. CIPRO is Poison!

Thank you for taking the time to read this if indeed you do read it.
I would appreciate a response to prove you read it.

From: Conni Willcutt
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:13:43 PM

I have been lucky enough to have a doctor who trusts me enough and knows me well enough to continue prescribing me pain medication. I get 45 norco pills per month and that's the amount I have gotten for several years. Sometimes I take every one of them in a month and other months, I have a few left when it is time to fill my prescription. I know that there are people who aren't as fortunate as I am. I also know when my doctor retires that I will be in a horrible situation because I probably will not be able to find a doctor to prescribe my pain medication. Guidelines need to be updated for people who can be trusted to take medication without becoming addicted and needing more.

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Thanks,
Conni

From: cynthiawynkoop@gmail.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:58:56 PM

I am writing to provide my input to the CDC's suggested guidelines on the use of opioids in this country.

I experience severe chronic pain due to Vulvodynia (pudental neuralgia), as well as spinal degeneration. Vulvodynia is an extremely painful condition that is exacerbated when I sit and when even material touches me in certain areas. Access to opioids, specifically oxycodone, enables me to perform certain activities I would not otherwise be able to do; go out to eat, socialize with friends, sit for an hour, even have intimate relations with my partner. I do not use opioids on constant or even a daily basis, as I want them to remain effective and wish to use them responsibly. However, the medications are absolutely necessary for my survival.

I am on a myriad of non opioid medications to help with the pain, but they cannot cut through to the pain or relieve it as oxycodone can. There are days when I must have access to the relief provided by an opioid.

While I sympathize with the families who have experienced the loss of someone due to an overdose or misuse of the medication. please know that there are many, many responsible users of this medication who require it's pain relieving function, when no other medication will help. While you have proposed a few limited exceptions for use of the medication (end of life, cancer, sickle cell), there are many other conditions with exorbitant pain that you have not included (Vulvodynia, for example).

Please consider that by restricting access to this drug, you will be condemning me to a life of immeasurable, unrelievable pain. Some people with my pain would otherwise choose to end their suffering if they did not have the ability to relieve it.

Please know that this drug CAN be used responsibly. I have been told by my doctors that I am a perfect example of how to use opioids responsibly and effectively.

Should you wish to discuss this matter further with me, please do not hesitate to contact me.

Respectfully,

-Cynthia Ridley

From: Candi1767 P.
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:41:46 PM

As long as you continue with "guidelines" they will continue to be misapplied, continuing to harm people in pain.

You cannot put a cap on prescription medications since everyone is different, processes medicines differently, has different levels of pain, etc. Some people do alright on lower doses of rx pain meds. But there are people who need higher doses & you cannot put a cap since it holds them back from receiving the doses they need.

You really need to stop with the guidelines & wake up!!!

Doctors over-prescribing, higher doses, etc. of prescription pain medications is NOT the cause of the opioid epidemic.

ITS ILLEGAL STREET DRUGS!!!

You have caused SOOOO many problems with doctors & ultimately people in pain. You need to STOP!!! You are cutting people off from much needed, safe & effective prescription pain medicines & doctors practicing pain management.

Which is just pushing more & more to illegal street drugs(the cause of the opioid epidemic), in the first place.

You cannot just stop a form of medicine or considerably restrict pain medicines that greatly help millions & millions of people, without there being something else that's just as effective or even more effective to help them. Its just going to push more & more right to the streets to self medicate since they can't get their pain treated legally & adequately(where they will become addicted & another statistic). Or even worse, more & more committing suicide.

Quit taking away our rights to humane, legal & adequate pain relief. Our bodies aren't made to handle SO much pain every day. Opioids where here since the beginning of time to help us with our pain. It wasn't until illegal street drugs started, that caused & is still causing all of the problems. NOT prescription pain medicines that greatly help millions.

PLEASE, PLEASE, PLEASE STOP with the guidelines. They are just supposed to be guidelines. But as we've already seen, they are & will continue to be used as a weapon & harming our doctors & more so, people in pain! PLEASE STOP!!! & give us back out rights to legal & effective medical care/pain care relief.

& as far as the 90 mme cap, where or who came up with that number? There is absolutely NO scientific facts that everyone should be under 90 mme's. Again, everyone is different & requires different forms of medication at different doses. We are NOT robots or pieces of tin. Our bodies function differently. & therefore we each require different doses of pain medication. A doctor will NOT prescribe now because they are too afraid the DEA will come after them & close them down/taking their license to practice. That hold people back from receiving the care they need/deserve.

This whole opioid epidemic has been torture on people in pain, who just want their pain treated legally & effectively. But as long as you keep putting "guidelines" out there, they will be used the wrong way to harm us.

This has to STOP NOW!!! PLEASE!!!

Thank you,
Candace P.

From: Catharine
To: NCIPCBSC (CDC)
Subject: Pain management
Date: Tuesday, July 20, 2021 9:30:58 PM

I’m on a relatively low dose of an opioid. I have tried going without and the pain is unbearable. The State has found me disabled and I am on Disability. Taking away my pain medication would force me to take a bullet. This kind of pain can not be tolerated.

Please consider the patient who takes their medication as prescribed. Not everyone is a junkie. Don’t make everyone suffer. You will have blood on your hands from people taking their lives because they are unable to live with the pain on a daily basis. This is serious. Punish the abusers not the law abiding citizens who follow the rules and use their medication responsibly.

Thank you for taking the time to consider my concern.

Chronic Pain Patient

Sent from my iPhone

From: cathi M.R.
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 11:39:39 AM

My dr. Prescribes me the smallest amount. Of pain meds. A little more than Tylenol. I never ever want to feel like I am on meds. Mentally. After 2 failed neck and back spinal operations I am scared that he will have to drop me and put me into physical withdrawal because of the cdc guidelines. I have to take my meds. To be able to function. I have a family. My meds doesn't get rid of the pain but it makes the worst pain dull.

I only go to pain management because you all have scared the family drs.

I AM NOT A DRUG ADDICT! I do have chronic pain. I never asked for this and I do think there needs to be more understanding of people with chronic pain..this is not a choice that I made to be in daily, constant pain.

From: chavezmarth@msn.com
To: NCIPCBSC (CDC)
Subject: Opioid Restrictions
Date: Friday, July 23, 2021 12:28:02 AM

To Whom It May Concern,

I have stenosis of the intervertebral foreman and hip bruisitis not relieved by physical therapy or cortisone shots, or acupuncture or lidocaine patches or the limits of ibuprofen and Tylenol. Due to doctors' refusal to adequately treat my long term pain because of CDC guidelines, I'm forced to treat my pain outside of the field of medicine so I can have QOL and keep working. It's a shame that I pay so much for insurance to be denied the medications that I need. It's barbaric and inhumane to deny pain relief. Especially if there is proof of the medical necessity for such medications. Please correct this ASAP.

Thank you.

Sent from my iPhone

From: christinarn5
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 8:34:19 AM

I suffer from multiple chronic or rare invisible illnesses. Namely Ehlers danlos syndrome, hyperpots, autonomic dysfunction, tarlov cysts, Mast cell activation syndrome, and lipedema. In addition to be diagnosised at 28 with endometrial cancer. So many time I have been told my pain is not real or severe in a hospital because I look normal. I have suffered from pain delirium multiple times after surgery because they kept messing with pain meds or would not let me stablize. Pain meds have a purpose and it should really still be a 5th vital sign. My hospitals stays have been extended bc of lack of pain control. At times a 1 day stay had turned into a 5 or 7 day stay as my vitals began to destabilize along with my mental health. I have major GI issues and absorption is effected esp when stressed illness surgery and IV meds are needed. This is medical negligence and a form of abuse not to treat people's pain properly and adequately.

Sent via the Samsung Galaxy S21+ 5G, an AT&T 5G smartphone

From: Chronic Pain Voices
To: NCIPCBSC (CDC); Chronic Pain Voices
Subject: 2016 CDC Opioid Revision Draft Recommendations July 23, 2021 comments
Date: Friday, July 23, 2021 4:43:21 PM

Hello. We appreciate your time to hear from pain patients concerning the restrictive 2016 CDC Opioid Guidelines. We strongly request the current guidelines be rescinded due to the unnecessary suffering & harms to chronic & acute patients. Instilling misery on tens of millions is unconsciousable. Whether they are "legacy" chronic pain patients patients, acute & postop surgical pts , trauma pts, cancer pts in active & post cancer patients, Sickle Cell Disease & other painful diseases/conditions/illnesses or Veterans etc etc - severe harm is being done to them in the name of the "greater good". Greater good of whom - surly not any of these people mentioned in the past present or future. This madness must STOP. While you say this was "unintended," it was not unforeseeable nor is it unforeseeable in the future.

Patients are loosing access to their life saving medications by doctors, pharmacists, hospitals etc due to the guidelines fueling this false narrative "opioids are bad " or from the very real fear they'll be arrested. Even good practitioners aren't safe if they don't follow the "volunteer" "suggested" guidelines. You MUST undue this, no matter what you do with the draft.

Saying "oh well they were misapplied "does NOT relieve you of the CDC's responsibility in the past nor future disabilites, deaths & Suicides from forced tapers. Undertreated pain can often be just as horrible as untreated. Many more have been harmed than "saved." Pain prescriptions are at a 20yr low, cut by 44% since 2011 yet OD opioid deaths are at an all time high of 93,000. Only 13,000 were related to pain medications and within that number are suicides & illegal prescription drug use. Telling us it's really a fraction of 13,000 & that OD deaths are really from illegal street drug usage. Yet your entire focus is STILL on pain patients. With this stigma, along with states passing laws based on the guidelines- its literally killing us, forcing pts to find relief from illegal street pain meds or to take their owns lives to escape the extreme pain levels. Fear of the very real possibility of losing one's meds or to 50/90MME is now wrongly connected to addiction while it fuels the stigmatizing & false narrative even more. Some states set laws LOWER. No MME/dosage limits. They aren't scientific - they have no strong evidence in their support.... only "junk science." Rescind the restrictive guidelines & make sure every state follows.

2016 Opioid Guidelines should be also be rescinded for there has been transparency issues from their initial writing along with severe conflicts of interest. Dr Roger Chou, as well of many of the writers, has very close connections with the anti-opioid prescribing group PROP Physicians Responsible Opioid Prescribing. Now we learn he is tied into the funding/payment of these studies that support the guidelines (ex AHRQ). He has not only written but is about to update these recommendations. So he choses the studies that he funds to support his own opinions- this is unethical at best. He not only needs removed from any guidance on opioids, but this puts the entire CDC GL further under a microscope. We request a full Investigation & Congessional Hearings into this unethical behavior, his removal along with the GL being rescinded.

The AMA yesterday talks about all this & the harms , attacks & stigmas placed on all pain patients.
https://www.ama-assn.org/press-center/press-releases/ama-backs-update-cdc-opioid-prescribing-guidelines

Patients aren't "drug seeking" they're "relief seeking " HUGE DIFFERENCE. This also needs told by the CDC & written if you move forward. If you continue with the guidelines we support & agree & endorse the comments & recommendations submitted by the AMA both comments, Richard Red Lawhern, PhD, Jeffrey Singer, MD, Jeffrey Fudin, PharmD, the advisory panel OWG, advocaters &/or speakers -
Kate Nicholson
Tamera Stewart
Bob Sheerin
Mike McAuley
Claudia Merandi
Anne Fuqua
Kristen Ogden
Cindy McCalester
Peter Pischke
Terri Lewis
Shirley Buck

Jessica Minerd-Massey
Andrea Anderson
Maria Higginbotham
Syndee Damrosch
Lauren DeLuca

Part of our comment we are sharing various pain patient's harms caused by the prescribing guidelines. We hear them cry, scream & share their misery and sadly even their suicidal ideations. We don't share private messages to safeguard everyone's trust. If we did - they would be even more disheartening (If that is even possible).

Comments-

"I think I have hit the end of the rope. I can't think anymore or try anymore. I am not planning to do anything to myself but I just need to vent some of this ....feeling. I am so lost in a world I don't understand, I have nightmares everyday about not finding my way or knowing who I am. Last night at 4 am I broke down and took some of the precious meds I do have, the pain was riding a 10 and I couldn't take it. That left me wondering what will happen when there are no more meds. I realized my life has no purpose, I am expendable and living in a world that just wants me gone. The general public that think they are so above propaganda has swallowed the "drugs are bad" hook, line and sinker. Even at the expense of their family, friends and neighbors they stand by and watch and say how sorry they are but do nothing. I know I will end up deleting this but I just had to say it out loud."

"Why is this so hard for politicians and people like (Andrew) Kolodny to understand. I don't want to get high or escape. I want to control my pain enough so I can go to work and take care of my family. No one gets hurt because I get my pain meds. A lot of people get hurt if I can't work. "

"I was told by Walgreens that I can't get my hydrocodone filled because they had given out their quota of opioids for this time of the year. They couldn't/wouldn't say when they may be able to fill it. They said the DEA has new rules that they have to follow. Kroger pharmacy isn't taking new opioid patients' prescriptions. Walmart said they can't fill it. The people who take pain meds for fun are ruining it for chronic pain sufferers."

"Warren, Klouachar and other Senators need to remove the bills they have written. These Senators got Billions in Taxpayer Funding for a Fake Prescription Opioid Crisis based on inflated numbers and flawed data. In addition to that Warren and numerous others sued everyone they
could target with a member of Prop being paid to testify as a Consultant. They knew the numbers were inflated because the CDC Warned not to use the 2016 Guidelines or set mg limit and they still sued and got Billions in lawsuits and Warren still wanted to go after the Families"

"in a dying patient, how are they going to become addicted?! Use some common sense! "

Response to Andrew Kolodny PROP founder "Suicides by chronic pain patients is totally bogus" response -
"So when a person commits suicide a year after being abandoned by their doctor. How does his comment apply ?"

"I am PLEADING as a professional health care provider and the spouse of a paid Fire Captain and Homeland Security employee who sustained a severe injury and lives daily with the resulting agony. “My life will not be tolerable without the small bit of medicine I’m allowed, I will be forced to permanently end my nonstop suffering!”He GAVE so MUCH to so manyand ABSOLUTELY does NOT deserve the terror he undergoes just to be able to get his
medication! PLEASE, PLEASEHELP CEASE THE INHUMANETREATMENT OF INNOCENT PATIENTS!! I Thank You Graciously!"

""I want stats on the parallel of suicides/suffering going UP alongside the decline in PRESCRIPTION MEDS vs ILLEGAL DRUGS. They are lumped together for the infamous "opioid crisis."

"I hope the Sacklers NEVER back down -- there are 1 million+ chronic pain patients that used OxyContin with enormous success and zero addiction issues --I ceased taking it when they reformulated and didn't realize what had been done - my life just ceased 99% and I didn't know why but I NEVER went thru withdrawals or others; just indescribable pain for >90 days - inhumane care & treatment & notification by the Pharmacist "Oh by the way, the medication you have successfully used for 10 years has been changed - let us know if you have any problems" was NEVER heard - didn't read about THAT in the newspaper or hear it on TV - - thought I was going to die as no one should ever be in that much for >90 days nor should the govt be telling Purdue/Saclers HOW to create their effective medication for legitimate pain. I'm here to support them 100% - - I'd fly wherever to testify on their behalf. The DEA and CDC knew what they were doing - they wanted a Cash Cow like the tobacco companies that paid dearly for 2-3 decades and they thought they had one........at OUR expense. Go Get Em Sacklers - WE are in your corner cheering you on."

"me too. I got tricked into switching to op. What a disaster that was. Thankfully I went back to reg meds at a huge reduction and haven't worked or had a normal day since. That was 2016. Then I lost more than half of those in 2019 and was abandoned in 2020. I rarely leave my home and now get help from family. This is no way to live as an American citizen. My 14th amendment rights are laughable at best by the CDC ,FDA and other agencies. Prop is nothing but an aspiring political entity that should be dissolved."

"I still do it but I pay a severe price for it. Working full time doing heavy labor is killing me but I refuse to let them win. 13 years I had pain control and lived a normal life, 3 years of this BS propaganda is taking its on all of us. We deserve better"

"Yup. Getting to my car is the equivalent of climbing the Hillary Step on Everest"

"The cops don't listen and neither do doctors anymore. I've been a chronic pain patient for over twenty years. They all assume you're an addict."

" HPPA laws.... out the window. My CPP doc of only 3 months had his office raided and ALL his patients' records taken. The gov't violates our privacy laws just by requiring "pain contracts."

"Today is another debilitating Chronic Pain Day "

"This is BARBARIC!!! MENGELE would be pleased."

"Your local and state & federal government. have already judged you too be wanting of being a addict.. There for any pain treatment will turn you in to a uncontrollable addict at once , 59 here and seen the one earlier about the guy that was 89 yr=ears old Crionic pain suffers 89 and i or anyone else is going to worry about him. Shit just keeping him alive is what matters right. and that's pain free as much as possible ."

"It’s been about the $$$ from day one. Even when people committed suicide because of unbearable pain the CDC and Prop with Attorney Generals and Senators sued companies for cash!! The CDC should be investigated along with Prop. Follow the money, the settlements and campaign contributions!"

"This is exactly what my doctor did! She asked how I was doing. My skin disease had been so bad that I hadn't slept in awhile because of the pain. She said I was probably depressed and needed antidepressants! I said you would be depressed too if you were in constant pain and couldn't sleep for months at a time. I said no thanks and left just shaking my head!"

"Often the drugs substituted for actual pain medication have worse side effects that opioids"

"Sadly, the pain community & the APDF Group lost another pain warrior & advocate yesterday, Kimberly Derewenko-Freitas. May she forever be pain free "

"We sadly lost another Chronic Pain Patient CPP - Erin Gilmer, An Attorney & Patient Advocate who was abandoned by her doctor. Erin took her own life due to living with excruciating pain"

"a lifetime of being invalidated one would expect to be somewhat desensitized...it didn't turn out that way but instead presented as PTSD...."

"My whole life was taken from me by the opioid paranoia.i am a senior citizen with alot of metal in my back because of a tumor in my spine I am not an addict although I have been treated like one.I am not a criminal though they treated me like that also.this law has made people become invisible and suicidal.i haven't been out of my house for almost 2 years now not because of covid but because most days my pain is Soo we Xtreme I can't get out of bed and on my feet .I have died twice this year from my heart stopping.my body starts shitting down after so many nights without sleep from the pain and most nights my prayers are not to wake up in the morning.i want to commit suicide but I can't cuz my mom killed herself and it devastated me my brothers and sisters and I can't do that to my kids.so I'm stuck now with no life just existing for more pain and more pain until my body gets tired can't take anymore pain and shuts down.existing only for pain is not existing I have no life everything I love was taken away my grandbabies my softball riding my motorcycle with my hubby all gone now there is pain in the place of my former life only pain.and I am drowning in pain but no one will teach out their hand to pull me out keep my head above water and save me.please help there's lots more of us out here and we need someone to be our voice PLEASE."

"My story is Millions of Veterans and non veterans being harmed forced off our prescription pain medicine, we had productive life's now most are bedridden"

"One reason is people don't know what to say. So it's easier for them to either stay away or assume that since you put make up on or got dressed or did something yesterday, that you're doing just fine. You can't always see pain! We want to blend in with healthy people. We want to feel like we're a part of something and forget what we push through constantly. For just a little while...we want to forget and live, because tomorrow is coming and we will have to recover from doing something, from being stronger than normal and for showing up.So yes, we hide our pain. We will smile and live in that moment and it will be a happy memory that we wouldn't have otherwise had. "

"RIP My heart goes out to her and her Family and Friends. We must continue to make a stand for all the Chronic Pain Patients we have lost and all those who are suffering at the hands of some Prop members that use money to lobby the CDC, Certain Senators and Some AGs using hidden agendas to Profit leaving Chronic Pain Patients to suffer in unbearable 24/7 pain to the point of suicide! "

"or they come right out and tell you they dont care about the negative impact its going to have...
aware...
don't care....very niceThis is all to common these days, while I can understand why doctors worry, their decision not to help with prescribing pain medication is so wrong on so many levels."

"So sick of media intentionally lumping pain rx and illegal narcotics "

"Your group has caused severe pain and suffering to thousands of patients with your BS science. I hope that someday you will all know and feel the pain and suffering that you have caused to, not only the patients, but also their families."

"In response to a Alabama mom facing felony charges for taking pain meds in her last 6 weeks of pregnancy. She had limited functioning without her meds (that she stopped when first pregnant) & she had other small children to take care of. She also informed her OBGYN . Comment- " that headline fishing report tho! In all seriousness, this is insane, infuriating, and terrifying. I have several severe pain conditions that required me to be on round the clock pain meds during my pregnancy. All of my docs were aware and coordinated care, as well as having me consult with neonatal specialists. The delivery hospital was also aware-- my ob/gyn made sure every single nurse and doc on the floor knew what the deal was, that my condition was due to a drunk driver hitting me, and that every step of my pregnancy had been followed and approved by my docs so I wouldn't face any problems regarding my meds. Also, pregnancy makes it impossible to take the other meds used for pain, like gabapentin, and I had to stop getting the dystonia injections as well. Pain meds were my only option and the pain was worse with the elimination of the other meds and the hormone changes. Thankfully, I had the full support and awareness of my docs and hospital team, because the associated stigma is so insanely high. I still had to deal with some incredible ignorance-- I had a NICU nurse tell me I would have to join all sorts of support groups bc my kid was going to have all sorts of issues, which was completely inaccurate and unforgivable coming from a nurse caring for NICU infants-- but generally, the overall response was sympathetic, helpful, and supportive because my docs all coordinated their info and made absolutely certain the delivery hospital knew the story. My son is 8 now. He never had any of the issues the nurse mentioned. My pregnancy was uneventful and normal, as was delivery, even at age 37 and despite 2 prior miscarriages that happened before the pain conditions showed up. My kid is gifted. I cannot imagine having faced this kind of persecution over choosing to have a child while suffering from debilitating and disabling conditions. This kind of discrimination against pain patients, who are supposed to be protected by ADA, is unconscionable. And horrifying."

"As pain patients we are treated as scum, you can be an upstanding citizen, never in trouble and suffer from debilitating conditions and still have to fight to get treatment. I agree this would be a horrible situation to be in and I am so sorry you went through it also. Thank you for your response."

Concerning medical marijuana .....

"I’m worried about how I’m supposed to care for my 80 year old dad and kids on the MM… I might have to only take it at nighttime and just suffer more all day long. This whole prescribing limit thing is disgusting and inhumane! If my kids and my father didn’t need me? I’d be checking out of this world instead of endure this level of under treated pain 24/7.
Oh and btw this doctor had me leave his office yesterday in a neck brace, full back brace, 2 knee braces, 2 ankle braces and I have a brand spanking new TENS unit - I look like I just got into a car accident or something. I feel like I’m forced to do this simply because dr doesn’t want to go over the 90mme. I think I’ll try dispensary CBD but nothing else. The “legal” full spectrum hemp CBD oil I’ve tried is a total joke and waste of money."

"The problem with canabis is muscle control. I can take Norco and go about daily tasks just fine. Not so with cannabis. But Dr's are blind to the differences"

"My doc pushed medical marijuana, too. After he cut me off, I had no choice but to try it. It cost $600/month and made me deathly ill. A big nope for me. I hope you can work this out"

"I worked 35 years construction and only allowed less than 40 mme for I'm on SSI and they would not give me SSD I paid into."

"My pain meds got cut to over half of what I had been on for 20 yrs when these CDC guidelines started! My pm doctor hates these changes also but his hands are tied! Life has been unbearable since! I feel like our lives doesn't matter and descriminated against! Medical marijuana didn't do anything for me other than give me bad muscle spasms. I also didn't like feeling so high constantly. I can't function like that nor can I function without proper pain treatment!I'm so sorry yours were stopped all together! I was lucky to have a very compassionate pm doctor for over 20 yrs and he dropped me down to the 90 MME limit which has been hell on me! Not a day goes by that I think, what if I need surgery or break a bone. Nobody is going to give me any extra pain meds! I could understand new patients on the 90 MME limits but us long time Chronic pain patients that never broke the rules got thrown under the bus!"

"Even my pharmacist admits the conversions dont work like they are written on paper."

"I recently had a c-section and after the first day all they recommended was Tylenol and Motrin. I had to specifically ask for something stronger because I was in so much pain and it made me feel shameful and guilty because it wasn’t their norm. "

"Please do the right thing. My grandmother is 70 and she is very healthy, but her chronic pain is going to be the reason she quits getting out of bed. She has been to several doctors trying to find answers and she has been labeled as “drug seeking”. She is not “Drug Seeking”. She is Relief Seeking. All she wants to do is make it through a little league game for my kids. She can’t do it. She can’t finish her shopping. She has had 5 knee replacements and needs another. No doctor will touch her knees. They also won’t treat her pain. This is neglect."

Thank you for listening. Now we pray you take immediate action to STOP the pain patient crisis that's has been the result of the CDC Guidelines. HELP THE PEOPLE -STOP THE STIGMA & PATIENT DEATHS WHILE FIGHTING ILLEGAL STREET DRUGS. YOU CAN HELP THOSE WITH ADDICTION WITHOUT HARMING OTHERS BY REMOVING THEIR FUNCTIONING, QUALITY OF LIFE & HOPE.

Chronic Pain Voices

From: Rhonda Lewis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:55:15 PM

I am writing in response to your Updated Draft Opioid Prescribing Guideline. I am concerned about the lack of consideration for different diseases where pain is one of the symptoms. The current guideline attempts to suggest all diseases/illnesses for pain be treated the same when each disease/individual is different. As a person born with a rare genetic disease (XLH), I have spent a lifetime in treatment of this disease. Symptoms include fractures, osteoarthritis, bone demineralization, muscle wasting, enthesopathy, tendon & ligament calcification, dental issues. I have had 11 surgeries related to my disease, with more in my future. I have mobility issues related to this and am always in pain. I have been treated with opioid's on & off my whole life. I have tried all alternative methods of treatments, injections, anti-inflammatories, portable ten's unit, heat/cold, physical therapy, different non narcotic therapies including LDN, lidocaine patches, CBD, acupuncture. All with limited success. Unfortunately, opioid medications have helped the most for keeping me mobile and working. Since your 2016 guidelines were put into effect, I have had more trouble getting opioid medications when they were needed, causing missed work and inability to build strength through exercise and physical therapy. I am hearing the same thing from others within the XLH network. Your guidelines are creating a lot of unnecessary suffering. As a suggestion, you should revamp the pain scale as it doesn't accurately reflect pain. I also suggest maybe people who do need to use opioid medication for a chronic disease use a fitbit or something like that to help hold them accountable and show they do increase a person's activity level. On opioids my activity level is approx. 4 miles a day. On LDN/Tylenol it is approx. 1.5 mi.
Thank you for your time.

Sincerely,
Rhonda J Lewis
Rhonda_lewisf@hotmail.com

From: Lucky run
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:56:49 PM

To whom it may concern,

I have read the updated draft of the opioid prescribing guidelines presented at the CDC National Center for Injury Prevention and Control (NCIPC) presented at the CDC Board of Scientific Counselors on July 16, 2021. As a chronic pain patient I would like to request that the guidelines be reassessed to include the benefits of opioids for pain relief when used appropriately. The new version appears to have very few changes accommodating chronic pain patients like myself for whom these medications mean the difference between functioning, working and receiving humane treatment versus total disability without any relief from pain. The biased and skewed current and proposed guidelines have left patients with legitimate chronic pain out of the equation. Our physicians are fearful of disciplinary actions and/or losing their licenses for treating pain appropriately. This should not be the case especially when patients have exhausted and/or combined alternative and multidisciplinary approaches (e.g., acupuncture, steroid injections, cognitive behavior therapy, physical therapy, etc...) in efforts to manage pain. The current climate, in large part borne out of inadequate biased guidelines to address one problem/need has, by default, created another by deeming the needs of chronic pain patients insignificant, nonexistent. We live in fear of our doctors, who know us well and who know us to be responsible users of these medications, retiring or leaving their practices and being unable to find providers willing to continue effective and helpful regimens due to these skewed guidelines. Even picking up an opioid prescription at a pharmacy has become a trigger for negative assumptions and judgements toward individuals just trying to function and remain contributing members of society despite pain and disability. This stigma has even made it difficult to contribute these comments without feeling vulnerable which is really quite sad.
Sincerely,
ND

From: Concerned Nurse
To: NCIPCBSC (CDC); concernednurse216@gmail.com
Subject: Public Comment- Draft recommendations CDC Revision of the 2016 Opioid Guidelines July 2021
Date: Wednesday, July 21, 2021 9:12:42 AM

Thank you for this time to comment on the CDC Revision of the 2016 Opioid Guidelines.

I am a former nurse & a Pain Patient PP for over 10 years.

I believe our nation would be a safer place if the 2016 CDC Opioid Guidelines GL would be completely revoked. They were based on low quality studies & even it's own data proved the opioid crisis was due to illicit street drugs - they are flawed. Illicit street drugs continue to be the driving force of OD deaths 6 yrs later. In many states ie Massachusetts at 92%, IMF is the cause of the high majority of OD deaths, not pain medication.

In 2019 pain medication was responsible for apprx 12,000 OD deaths & in 2020 while there was a 30% increase in overall Opioid OD Deaths to 93,000, pain medication ONLY rose to just 13,000 approx. It's clearly a illicit street drug problem yet Pain Patients are being persecuted, harmed & dying. Right now, these pain med stats combine legitimate pain scripts along with Illegally obtained pills plus they don't differentiate how many where suicides. Meaning, these stats should be much much lower still. I highly recommend the CDC differentiate & separate these statistics to gain a TRUE representation of pain medication overdoses OD. Repeal the GL.
https://www.acsh.org/news/2021/07/19/2020-drug-deaths-spiked-30-and-pain-pills-had-nothing-do-it-15669

The majority of Pain Patients PP are female and older while the majority of OD deaths are male & much younger. Even when the much much lower OD's where pain medication is the cause, it usually involves polypharmacy, which again is not common among pain patients. The CDC must claify the true cause of the OD deaths as illicit & not those of legitimate pain prescriptions. Better data must be collected, organized , be tallied and the truth told.

If The CDC Guidelines GL are not revoked, then I've also made recommendations. But many of my arguments are for removal.

Pain Patients PP- whether they suffer from injury, disease ie SCD, cancer or trauma from war , they all have one thing in common - harm caused from the CDC GL. Even Palliative & Hospice Care Patients who are also supposed to be exempt, are no longer safe from harm/injury, meaning by premature death & suicide.

Too many PP are being forced to buy their pain meds from the streets due to doctor abandonment &/or forced tapering. Too many are now dying from accidental IMF toxicity/accidential street drug OD. No PP is safe from unconsented forced taper or abandonment. The Opioid Crisis/CDC GL has caused an emergent Patient Care Crisis. PP can't wait until 2022 w/o respite from the GL or many more will die needlessly. WE NEED HELP NOW BEFORE MORE HARM IS DONE.

The CDC GL are written for Primary Care Physicians ONLY, yet pain management physicians are dropping like flies in an already thin field. Either thru early retirement, leaving the field of practice due to fear or being arrested (fear is very real. No doctor is safe). Pain Management patients need fully & completely exempt with explicit & bold language making this so.

I also Highly recommend stronger language used for those Pain Patients PP excempt from the GL (cancer, SCD, Palliative Care/ Hospice). Also it needs written more frequently, preferably in bold print. Since so many other's that are adversely & severely affected by the GL are Chronic Pain Patients CPP suffers, I highly recommend they also are excempt from the GL. These CPP are also referred to as high impact pain patients /legacy patients/Intractable Pain Syndrome IPS etc.

Without adequate medication/pain control I am totally dependent, non functioning & unstable. Even using every alternative therapy & assisting device at my disposal. At 50-60 MME I have a very poor QOL. When I lost my other associated meds, things got so much worse, add suicidal ideations. These types of limits harm me personally & other PP as well.

At 90 MME & associated meds my QOL & functioning is much improved as is my mental health & well being. NO suicidal ideations. Suicide to pain patients is about stopping the intolerable pain , not stopping life. It's often misunderstood & blamed on depression/ anxiety. While these may be a factor it still boils down to insufferable pain levels. When my pain isn't sky-high the majority of time, my thoughts aren't spent on "stopping it."

I am also more stable as evidenced by lab work, testing etc. I will never be fully independent, for I am a disabled chronic patient. I have more better days but I still have bad days & flare days. Would I improve even more with less limitations if I could go above the 90 MME? Could I be MORE independent & function at a higher ability? We will never know. Disabled PP have a chain around their necks - this is discriminatory.

No one's claiming pain medication is a cure. Even if I didn't function better because of a disability/illness/handicap- this should not be held against me or any PP. This thought process is prejudiced against the disabled. I recommend the " functioning" requirement be removed as there are other much more important parameters to be considered.

All MME limits or parameters should not be used. They do not support individualized care, there isn't a set standard making them very unreliable "junk science."(the 50 & 90MME limits are harming people suffering from pain. Such as myself.

These very real fears are being weaponized by the GL against patients assigning them to "addiction." New diagnoses are being made to give credence to this branding. When a cancer survivor "fears" their cancer returning - that's called a rational & understandable fear. But when a PP fears their excruciating pain returning along with Quality of Life QOL loss - that is suddenly unfairly connected to "addiction." The meds control the pain, nothing more. PP are craving functioning & QOL not "chasing a high." Rarely do PP experience euphoria with pain medication, only relief from pain. No fake diagnosis.

The media & public often confuse pain medication with illegal opioid street drugs. When speaking about pain medications, in place of "opioids" I strongly suggest "pain medication" if opioids must remain then perhaps "opioid pain medication" or "opioid medication therapy" would work the best. The stigma attached to pain meds can partly be due to this wordage problem.

Please also differentiate between IMF & medical Fentanyl better & more often. People are scared to receive Fentanyl during surgery or falsely believe people wearing a Duragesic Patch are causing the opioid crisis. Please stop using the singular word Fentanyl unless illicit &/or counterfeit is infront of it when speaking about OD deaths.

I also want to address the huge conflict of interest COI with Dr Roger Chou , the GL, funding/studies AHRQ etc. Chou removing himself from "the meeting" is not enough- he needs to remove himself from ANY advisory board /panel etc that involves opioids due to his extreme bias & prejudice. Chou chooses which studies are considered to go into the guidelines, he writes them, and then gets to approve them.”

Tamara Stewart, Director of P3 Alliance, spoke of this during her public comment. Here are her words roughly translated. I endorse her concerns & recommendations demanding a Congessional Hearing & investigation along with the draft being withdrawn as well as the original guidelines.

Tamara's words -

"Let me see if I got this straight"

"(Roger) Chou's been involved in calling for opioid guidelines or restrictions since around 2011. The CDC gets funding for these guidelines"

"The CDC pays AHRQ to write reviews for which the guidelines are going to be based"

"AHRQ not only contracts with Dr Roger Chou to conduct reviews of the opioid studies"

"But Chou also helps sets the AHRQ priorities"

"Chou is one of the 5 authors who wrote the draft of the guidelines , based on the reviews he was paid to create!"

"Last but not least, Chou was on the Board of Scientific Counselors BSC which approves or denies any opposition comments from the Opioid Workinggroup" (OWG)

"Being on the BSC, Chou has a say in the final approval of the guidelines themselves"

"All this and there's no mention of conflict of interest until today July 16, 2021 around 0900, even then the source of the conflict isn't revealed in order to determine whose interest Chou is serving"

"This is not managing conflict of interest, this is sufficient enough information that P3 Alliance insist that the process is corrupted & the draft guidelines need to be considered illegitimate & biased. Any further effort on this guideline draft should be abandoned"

"We further call for Congessional investigation into institutional conflicts of interest due to ongoing lack of transparency"

"Finally the P3 Alliance insist any further action on the Opioid Guidelines Best Practices be removed from the CDC & placed where transparency & stakeholder involvement will be guaranteed & respected and the scientific pursuit of truth trumps the pursuit of financial interest of the CDC Guidelines on the part of the creators & enablers"

The end.

Chou's COI information was confirmed & collaborated by the PNN News Service
https://www.painnewsnetwork.org/stories/2021/7/16/advisory-panel-warns-cdc-revised-opioid-guideline-ignores-risk-of-undertreating-pain

Thank you for taking the time to read our comments. The pain community is in dire distress - a crisis! We need this wrong immediately addressed without room for further "misapplication."

Signed,

Concerned Nurse

From: Concerned Nurse
To: NCIPCBSC (CDC); Concerned Nurse
Subject: CDC DRAFT RECOMMENDATIONS
Date: Friday, July 23, 2021 5:03:32 PM

Hi,,

Because of my pain & disability I was unable to finish my comment for my recommendations. I must send it as is with my sincere apologies. The emails took me over 10 days of very serious effort. I did my best. Luckily I have pain medication or this would've been so much worse. For the record I had these issues BEFORE I started my regimen of medications. These issues are from my condition, just like other pain patients. I hope you remember this when people try to blame pain pills for everything that's wrong with us. My life is absolutely horrible untreated/undertreated with suicidal ideations.

My first ask is for revoking the CDC GL due to the enormous harm, bias, deaths, arrest & QOL removed by these. It's a Street drug problem, mostly Illicit Fentanyl. The pain patient has suffered enough.

If you won't revoke I make the following recommendations.
I also endorse Richard "Red" Lawhern, the AMA's & the Opioid Workgroup recommendations.

Recommendations are in regular font- Answer in bold.

¦ Recommendation #2:

Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider
initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before
starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate.(Recommendation Category: A, Evidence Type: 3)

THIS IS CAUSING STABLE & FUNCTIONING CPP TO BE FORCED TAPERED, OFTEN BECOMING BEDRIDDEN &/OR HOMEBOUND. IT DOESN'T MATTER HOW WELL THE PP/CPP IS FUNCTIONING OR HOW WELL THEIR LEVEL OF PAIN'S CONTROLLED. #1 REASON - FOLLOWING CDC GL.

THEN MAKING PP/CPP SWITCH TO NSAIDS OR TYLENOL ALONG WITH A HOST OF OTHER MEDS BECAUSE OF THIS RECOMMENDATION.

PP GO FROM 1 OR 2 PAIN MEDS THAT WORKED EFFECTIVELY W/O SIGNIFICANT SIDE EFFECTS TO 5-7 NEW MEDS TO REPLACE THEM THAT A) DON'T WORK NEAR AS WELL LEAVING PAIN UNCONTROLLED B) COST A LOT MORE MONEY C) OFTEN COME WITH MANY TERRIBLE SIDE EFFECTS.

VETERANS, PP, EVEN DOCTORS & NURSES ARE DYING MORE BY SUICIDE DUE TO THIS INHUMANE TREATMENT. ALSO FROM STRESS RELATED CONDITIONS DUE TO THE EXTREME LEVELS OF UNRELIEVED CONSTANT PAIN - INCREASES IN HEART ATTACKS & STROKES (BACKED UP BY VA. STUDY). DOCTORS & NURSES FROM FEELINGS OF HELPLESSNESS FROM NOT HELPING THEIR PATIENTS REMAIN STABLE , SAFE & FUNCTIONING NOR HELP CONTROLLING THEIR AGONY & PAIN.

NON-OPIOIDS CAUSE TERRIBLE SIDE EFFECTS & RARELY WORK FOR CPP/HIGH IMPACT /IPS/ETC PATIENTS. DUE TO NON CONSENSUAL FORCED TAPERS, MANY PP/CPP TAKE TYLENOL WAY ABOVE THE RECOMMENDED 4,000 MG/DAY, SOME TAKE UP TO DOUPLE OR MORE. WHILE OTHERS TAKE (OFCTOGETHER WITH TYLENOL) MOTRIN 1,200 MG A DOSE 3X DAY (MAX DOSAGE IS 800MG 3X DAY OR 3,200 MG/DAY). SOME TAKE 1,600MG PER DOSE TRYING TO GAIN IMPROVED FUNCTIONING, GO TO A KIDS EVENT OR TO GET SOME RELIEF FROM THE EXTREME PAIN.

I WAS TOLD "PAIN MEDS ARE ADDICTIVE , YOU'RE TOO YOUNG" & DENIED EFFECTIVE PAIN CONTROL. I COMPLAINED & COMPLAINED OF STOMACH PAIN, HEARTBURN & UNCONTROLLED HIGH LEVELS OF PAIN. DIDN'T MATTER. THEY ALSO SAID FALSELY THE PAIN "WAS IN MY HEAD." FOR ALMOST A YEAR I SUFFERED WITH UNCONTROLLED PAIN , DECREASED FUNCTIONING & STOMACH ISSUES. FINALLY THE NEW DOCTOR FOUND THE PROBLEM, FIXED IT & CHANGED ME TO PAIN MEDS. IT WAS NOT "IN MY HEAD." BUT MY PHYSICAL RECOVERY WAS SO MUCH HARDER & LONGER DUE TO THE DELAY OF TREATMENT. IT COST ME APPROX 3 LONG YRS OF MY LIFE SUFFERING, W/ INCOME LOSS PLUS LIFELONG COMPLICATIONS FROM NSAIDS. INSTEAD OF 3 MTHS MAYBE 6 TOPS. AT THE END I NO LONGER NEEDED PAIN MEDS SO MY DOCTOR & I DISCUSSED IT AND THEY WERE D/C'ED WITHOUT ISSUE. LONG TERM USE - NO SIGNS OF ADDICTION. ANOTHER REAL LIFE EXAMPLE TO BACK UP STUDIES THAT THE OCCURRENCE OF ADDICTION IS LOW.

OTHERS LIKE MYSELF TOOK 800MG 3X DAY AS ORDERED, BUT STILL DEVELOPED ULCERS & GI BLEEDING. EVEN TAKING THEM WITH ANTACIDS & FOOD DIDN'T PREVENT IT. I HAVE A HEART CONDITION TOO. I SHUDDER AT THE THOUGHT OF HOW MANY WILL DEVELOPE LIVER & KIDNEY PROBLEMS OR EVEN FAILURES. JUST FROM TYLENOL/NSAIDS AS ORDERED AROUND THE CLOCK - DAY IN & DAY OUT. NOT TO MENTION THE ONES TAKING HIGHER DOSES. IT'S OTC THEY SAY SO THEY FALSELY BELIEVE IT WON'T HURT THEM OR THEY SAY THEIR ONLY OTHER CHOICE IS ILLEGAL STREET PAIN MEDS. SINCE ABANDONED BY THEIR DOCTORS OR DENIED PAIN MEDS DUE TO THE CDC GUIDELINES.

15,000 DIE ANNUALLY FROM NSAIDS - 12,000 TO 13,000 DIE FROM OD TO PAIN MEDICATION. THE RISK IS HIGHER WITH NSAIDS THAN ADDICTION & OD.

MINE & MANY OTHERS ONLY SIDE EFFECT WITH PAIN MEDS IS CONSTIPATION. CREATING MORE PROBLEMS WITH LESS BENEFITS FOR PP/CPP DOESN'T MAKE ANY MEDICAL NOR COMMON SENSE. THE GL ARE CAUSING MORE PROBLEMS THAN THEIR HELPING ACUTE OR PP/CPP. OD'S ARE AT A RECORD HIGH.

RECOMMEND CATEGORY B.

¦ Recommendation #3:

When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. (Recommendation Category: A and
Evidence Type: 3) -

THROUGHOUT THE MEDICAL FIELD WE KNOW THROUGH PRACTICE, EXTENDED RELEASE PAIN MEDICATIONS PROVIDES ROUND THE CLOCK RELIEF TO KEEP EXCALATING LEVELS LOW. IT PROVIDES BETTER PAIN RELIEF THAN INSTANT RELIEF IR MEDS.

YET THE CDC GUIDELINES GL RECOMMENDS IR USE INPLACE OF ER - NOT FOR IMPROVED OR EVEN EQUAL PAIN MANAGEMENT, BUT TO STOP A POTENTIAL FOR FUTURE ADDICTION. WHICH IS BASED ON LOWER QUALITY STUDIES & AGAINST PRIOR MEDICAL PRACTICE.

BEFORE THE CDC GL, ATLEAST THE THE HIGH INTENSITY/INTRACTABLE PAIN SYNDROME IPS /LEGACY/ CHRONIC PAIN PATIENTS CPP THAT WHERE ORDERED PRN IR MEDS, WHERE ORDERED PAIN COVERAGE FOR 16-24HRS A DAY. THIS DOES WORK FOR SOME PATIENTS.

BUT NOW WE KNOW THROUGH PRACTICE, POST CDC GL- THESE SAME HIGH INTENSITY/INTRACTABLE PAIN /LEGACY/CHRONIC PAIN PATIENTS, NOT ONLY HAVE BEEN SWITCHED TO IR'S , MANY ARE ONLY RECEIVING COVERAGE FOR 4-8 HOURS A DAY.

PATIENTS ARE LIVING IN EXTREME PAIN ON 2 - 4 PERCOCETS A DAY - IF LUCKY. SADLY TOO MANY ARE GIVEN 1-2 PILLS FOR 24HRS. THAT'S 4 RS COVERAGE, POSSIBLY A FAR STRETCH TO 6 -8. WHAT ARE THEY TO DO FOR THE OTHER 16 - 20 HOURS? SUICIDAL IDEATIONS ARE LIKELY TO FORM AS ARE DEPRESSION & ANXIETY.

WORSE , MANY ARE NO LONGER GIVEN THOSE FEW PILLS FOR A FULL 30 DAYS BUT A MERE 20 DAYS "SO NO LEFT OVERS". YET THEY NEED EVERYONE WHEN ORDERED SUCH LOW DOSAGES.

AND IF THEY RUN OUT EARLY - THEY ARE NOW GIVEN THE "ADDICTION" DIAGNOSIS INSTEAD OF LOOKING AT WHO REALLY CAUSED THIS ISSUE - THE PRESCRIBER. BECAUSE THEY EITHER LIVE IN FEAR FROM BEING ARRESTED OR THEY'VE BOUGHT INTO THE CDC NOTION "THAT ALL OPIOID PAIN MEDS ARE "BAD."

IF THE PP DOESN'T HAVE SUCCESS ON IR MEDS, I SUGGEST WRITING IN THE GL- THAT THEY CAN RETURN TO PRIOR ER USE &/OR TRY ADDING ER MEDS. MANY HAVE THE BEST SUCCESS WITH EXTENDED RELEASE AROUND THE CLOCK ALONG WIT

YOU SAY YOU DON'T SAY THEY ARE "BAD, " BUT THE LANGUAGE IN THE GL SAYS DIFFERENTLY. IT USES WORDS LIKE "TAPER" HARM" "AVOID" "DANGEROUS " OVER & OVER WHEN REFERRING TO PAIN MEDS. THE GL MENTIONS DEATHS FROM OPIOIDS 144 TIMES -IMPLYING THAT PAIN MEDS ARE THE CAUSE VS ILLICIT MEDS - WHAT ELSE ARE PRESCRIBERS, GOVERNMENT OFFICIALS & LAW ENFORCEMENT SUPPOSED TO BELIEVE? I STRONGLY RECOMMEND REMOVING ALL SUCH LANGUAGE IN RELATION TO OPIOID PAIN

MED USAGE.

TO THE SUGGESTION OF WORRYING ABOUT THE "GREATER GOOD, " I MUST DISAGREE. NOT CORRECTING THE GL ISSUES BECAUSE IT GOES AGAINST THE "GREATER GOOD" CANT APPLY HERE WHEN SO MANY PATIENTS ARE BEING HARMED BY THE GL ITSELF.

DURING THE PUBLIC COMMENTS, ANNE FUQUA TOLD US ALL HOW SHE HAS OVER 500 NAMES OF SUICIDES DUE TOO PAIN. 500 IS A LOT. RECOMMEND THE CDC COLLECTING THIS DATA.

I WONDER IF SHE INCLUDED THE RECENT SUICIDE OF ERIN GILMER? YOU MIGHT RECOGNIZE HER NAME, SHE WAS A LAWYER & ADVOCATE WHO WORKED FOR AHRQ AT ONE TIME. SHE WAS ABANDONED BY HER DOCTOR & IN EXCRUCIATING PAIN, DENIED PAIN MEDS.

HAVE ANY OF YOU EVER HEARD YOUR PATIENT OR FAMILY MEMBER SOB, CRY , MOAN CONSTANTLY &/OR SCREAM FROM EXCRUCIATING PAIN? FOR HOURS, DAYS SOMETIMES WEEKS ? UTHIS IS HARD ENOUGH WHEN IT'S BEYOND OUR CONTROL TO ELEVIATE IT - BUT WHEN WE HAVE THE ABILITY BUT PURPOSELY CHOOSE NOT TOO USE IT , IT BECOMES AN UNBEARABLE HAUNTING WEIGHT. IT'S NOT HEALTHY FOR THR DOCTOR, NURSE OR OTHER HEAKTHCARE WORKRF HCW .

¦Recommendation #4:

When opioids are started for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to
=90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day. (Recommendation Category: A & Evidence Type: 3) -

NO MME DOSAGE, LIMIT OR CAP RECOMMENDATION. CURRENT MEDICAL PRACTICE, STUDIES, HHS PAIN MANAGEMENT BEST PRACTICES TASK FORCE

NOR AMA RECOMMEND MME DOSES OR LIMITS.

NEITHER DOES THE FDA MME WORKSHOP PROVING THEIR INCONSISTENT(NO SET STANDARDS) AND VERY UNRELIABLE.

Myself included am severely undermedicated at 50-60MME - life is Hell with 2-3 days in bed . Majority of time pain levels are 8-9/10. Poor functioning, requires full time caregiver. Muscle spasms are severe. QOL is very poor. With or without muscle relaxers I have suicidal ideations, but more frequently without. Other meds & every alternative therapy that's available along with Motrin/Tylenol.

Life at 90 MME with muscles relaxer pain level ave 7, 8-9 during flares, sometimes 5 & 6. QOL much improved, Muscle spasms decreased. NO suicidal ideations. Life so much more enjoyable.

Thank God for individualized care. No dosage Recommendations, completely remove off of GL.

The AMA does not endorse MME DOSE LIMITS EITHER.

Recommendation #5:

For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not
outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation Category: A and Evidence Type: 4) -

FORCED TAPERING IS THE #1 HARM TO PP/CPP - HIGH INTENSITY/INTRACTABLE PAIN SYNDROME IPS /LEGACY PATIENTS. AGAIN GOING FROM FUNCTIONING TO NONFUNCTIONING , STABLE TO UNSTABLE IS GREATING GREAT HARMS. INDIVIDUALIZED CARE & CONSENT, ALONG WITH QUALITY OF LIFE QOL IS IMPERATIVE TO THE PTS PHYSICAL & EMOTIONAL WELL BEING. THIS RECOMMENDATION MUST INCLUDE STRONG LANGUAGE TO UNDUE THE HARMS ALREADY DONE & TO STOP THE FUTURE ONES.

MANY OF THE GL REASONS FOR TAPERS ARE PRESENT WITH PAIN ALONE, WITHOUT OPIOIDS. YET THEY'RE LISTED AS THOUGH THEY'RE SPECIFIC TO PAIN MEDS. EXAMPLE - THE BENEFIT OF ONES FUNCTIONING BEING JEOPARDIZED OVER CONSTIPATION IS EXTREME. IT'S A COMMON OCCURRENCE AS IS INSOMNIA ETC .UNLESS VERY SEVERE, THE BENEFIT CLEARLY OUTWEIGHS THE "RISK" OF EACH.

THE #1 REASON DOCTORS GIVE FOR FORCED TAPERING - "FOLLOWING THE CDC GL." COUNTLESS PUBLIC SPEAKERS CONFIRMED THIS FRIDAY AT THE MEETING.

THERE ISN'T ANY "GREATER GOOD" HERE BECAUSE NOW THERE'RE MORE PEOPLE DYING &/OR DISABLED FROM INENTIONAL HARM.

Suicidal ideations stop when pain returns to tolerable levels. Force tapering against one's concent is counterintuitive & cruel.

Recommendation #6:

When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed

for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed. (Recommendation Category: A and Evidence Type: 4)

I had surgery and was denied any postop pain medication. It was horrible. I spoke up in postop visit on how painful it was and questioned it. Was told quote " you were very inflammed, for a very long time along with your previous surgery it was an expected outcome, we knew this would happen." My next question "And yet you ordered me nothing for pain expecting I would be in misery?" He would not do eye contact, looked at the floor & wouldn't answer my question.

What the GL have done is make a ton of people avoid healthcare & surgery due to this denial of basic human needs. I met a daughter whose Dad had a bilateral above the knee amputation and was denied anything stronger than Tylenol/Motrin. No history of addiction but said they didn't want to "make him one either." She fought but they would not budge.

I've personally seen big tough Ranger Marines cry when getting their ONE stump rapped WITH IM pain medication, this is inhumane & insane treatment.

Women aren't getting mammograms because they've heard or read about bilateral mastectomies being denied adequate or any pain control.

There are cancer patients being denied, even with bone cancer one of the most painful cancers, all over social media & the news.

https://www.statnews.com/2018/08/15/oregon-medicaid-tapering-opioids/

¦Recommendation #8:

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan
strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose, such as historyof overdose, history of substance use disorder, higher opioid dosages (=50 MME/day), or concurrent benzodiazepine use, are present. (Recommendation Category: A, Evidence Type: 4)

REPEATEDLY USING HARM IMPLIES ALL OPIOIDS OR ABOVE 50 MME/90 MME CAUSE HARM. THIS IS FALSE & POSSIBLE REASON FOR THE MISAPPLICATION OF THE GL BY STATES, GOVERNMENT, LAW ENFORCEMENT, HEALTHCARE , MEDIA & THE PUBLIC. ALL THRU THE GL IS SOUNDS LIKE PAIN MEDICATION IS A BAD IDEA, WHERE IN FACT IT HAS MANY SAFE USES.

NARCAN PRESCRIBING STIGMATIZES THE PATIENT AS AN ADDITIC. LANGUAGE NEEDS STRONG TO NOT FORCE ON PATIENTS. LIFE INSURANCE POLICIES ARE REFUSING NURSES WHO CARRY IT JUST TO HELP OTHER PEOPLE. CPP HAVE ENOUGH STIGMA - SCRIPTS SHOULD BE VOLUNTARY.

¦Recommendation #10: When prescribing opioids for chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for

prescribed medications as well as other controlled
prescription drugs and illicit drug -

MANY PAIN PATIENTS REPORT THEY ARE FORCED TAPERED DUE TO FALSE READINGS. OFTEN ACTUAL TESTS ARE SHARED AND THEY'RE THE METABOLYTES THAT ARE NORMAL BUT MAY NOT BE COMMONLY SEEN. OR JUST FROM OTHER MEDS THAT THE LAB WOULD CATCH AS FALSE POSITIVE. SURPRISINGLY MANY DOCTORS DIDN'T FORWARD THEM TO THE LAB & THE PATIENT IS FOREVER BRANDED AN "ADDICT" & NOW WITHOUT MEDS. UNABLE TO GET A DR.

OTHERS ARE ULTRA METABOLIZERS BUT NO ONE BOTHERED TO CHECK. FLAGGED AN ADDICT BECAUSE OF HIGH DOSAGES

TOO MANY ARE GETTING UDS EVERY 2 WEEKS TO EVERY MONTH AT UNGODLY COSTS.

SUGGEST STRONGER LANGUAGE TO DECREASE UDS USAGE & EDUCATION.

Recommendation #11: Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants. (Recommendation Category: A, Evidence Type: 3) -

MANY PATIENTS USE BENZODIAZAPINES & PAIN MEDS SAFELY & EFFECTIVELY FOR 5, 10, 20 YEARS. MUSCLE RELAXERS TOO. TO BE FORCED TO CHOOSE BETWEEN TWO OR MORE DEBILITATING CONDITIONS BECAUSE A FEW (NOT ONESELF) ARE HAVING ISSUES WHEN TAKING ACCORDINGLY (ANXIETY/CHRONIC PAIN/MUSCLE SPASMS) MUST BE HEARTBREAKING. WHAT IS THE RECOMMENDATION?

FORCING PATIENTS TO TAKE MORE MEDS WITH OFTEN AWFUL SIDE EFFECTS TO REPLACE EFFECTIVE MEDS THAT YOU HAD ZERO OR A SMALL SIDE EFFECTS FROM HAS NEVER BEEN COMMON PRACTICE FOR A REASON.

REMOVE STIGMA.

¦ Recommendation #12: Clinicians should offer or arrange treatment with medication for patients with opioid use disorder. (Recommendation Category: A, Evidence Type: 2)

OUD - RECENT STUDY 40% DID NOT MEET OUD CRITERIA . PAIN PATIENTS RECEIVING ICD 10 CODES FOR PHYSICAL DEPENDENCE BUT OTHERS & MANY STUDIES TAKE MOST DEPENDENCE ICD CODE EXAMPLE F11 & COUNT AS OUD, EVENTHOUGH DOCTOR IS GIVING PHYSICAL DEPENDENCE DIAGNOSIS, NOT ADDICTION. DEPENDENCE IS A NORMAL OCCURRING CONDITION WITH PAIN MEDS.

https://www.sciencedirect.com/science/article/abs/pii/S0376871621000788?via%3Dihub

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CONCLUSIONS

THE CDC MUST RESCIND OR ATLEAST THE REVISION MUST SUPPORT, WITH STRONG LANGUAGE THE HIGH IMPACT/IP/LEGACY/CPP PATIENTS & PAIN MEDICATIONS.

THE GL IS STIGMATIZING PAIN MEDS & MANY TAKING THEM NOW OR IN THE PAST. DOCTORS ARE REFUSING PATIENTS EVEN IF THEY WERE PRESRIBED PAIN MEDS 10-20 YRS AGO. PLEASE UNDUE THIS BIAS.

●#2 & #5 FORCED TAPERS & REASONS FOR FORCED TAPERS NEED REEVALUATED. CONCENT A MUST. IF NOT SUCCESSFUL PUT BACK ON PRIOR DOSAGE. THESE FORCED TAPERS ARE CAUSING THE GREATEST HARM. FAST OR SLOW . UNDERTREATED CAN BE JUST AS BAD AS UNTREATED IF DOSAGE LOW ENOUGH. SUICIDAL IDEATIONS ARE MAINLY DUE TO EXTREME PAIN - ONCE PAIN TORABLE MOST GO AWAY. IT'S ALL ABOUT THE PAIN.

THERE ISN'T ANY "GREATER GOOD" HERE EXCEPT NOW THERE ARE MORE PEOPLE DYING &/OR DISABLED.

#2 RECOMMEND CATEGORY B

●#3 EXTENDED RELEASE WORKS BETTER FOR PAIN MANAGEMENT IN PRACTICE. ALLOW DOCTORS TO DECIDE WHAT IS BEST FOR THE PATIENT- IR VS ER. INDIVIDUALIZED CARE A MUST

● #4 REMOVE ALL MME CAPS, LIMITS, MENTIONS - THEY ARE NOT INDIVIDUALIZED- WHAT MME I FUNCTION WELL AT YOU MAY BE ON A WALKER OR HOMEBOUND. POOR QUALITY STUDIES ALSO, NO STANDARD MATH. CURRENT MEDICAL PRACTICE, STUDIES, HHS PAIN MANAGEMENT BEST PRACTICES TASK FORCE NOR AMA RECOMMEND IT.

NEITHER DOES THE FDA MME WORKSHOP PROVING IT'S INCONSISTENT(NO SET STANDARDS).

●#6 Postop patients are being denied pain medication due to stigma attached with acute prescribing. They also fear being arrested. DROP 3-7 ACUTE DAYS & WORDAGE CONTRIBITUTING TO BIAS. TON OF PATIENTS FEAR SURGERIES & AVOID CHECKUP IE MAMMOGRAMS BECAUSE OF CDC GL PRESCRIBING RULES HAS STOPPED ADEQUATE PAIN CARE FOR MANY.

●#8 REPEATEDLY USING HARM IMPLIES ALL OPIOIDS OR ABOVE 50 MME/90 MME CAUSE HARM. THIS IS FALSE & POSSIBLE REASON FOR THE MISAPPLICATION OF THE GL BY STATES, GOVERNMENT, LAW ENFORCEMENT, HEALTHCARE , MEDIA & THE PUBLIC. ALL THRU THE GL IS SOUNDS LIKE PAIN MEDICATION IS A BAD IDEA, WHERE IN FACT IT HAS MANY SAFE USES.

●#10 UDS - SUGGEST STRONG LANGUAGE TO DECREASE UDS USAGE & EDUCATION ON HOW TO READ & INTERPRET. PATIENTS LOSING CARE

BRANDED "ADDICTS" DUE TO FALSE POSITIVES

●#11 BENZODIAZAPINES & PAIN MED USAGE. MANY USE SAFELY UP TO 20YRS, SOME WITH MUSCLE RELAXERS TOO. REMOVE LANGUAGE THAT'S STIGMATIZING PATIENTS TO HAVE TO CHOOSE BETWEEN THESE MEDS.

●#12 OUD RECENT STUDY 40% PAIN PATIENTS DID NOT MEET OUD CRITERIA. PAIN PATIENTS ARE BEING STIGMATIZED, DROPPED AS PATIENTS, LOSING FUNCTIONING, CUSTODY OF CHILDREN, MARRIAGES, PAIN CONTROL DUE TO THIS WRONG BIAS.

https://www.sciencedirect.com/science/article/abs/pii/S0376871621000788?via%3Dihub .....

Again my apologies,

A very Concerned Nurse

From: cppadvocate2831
To: NCIPCBSC (CDC)
Subject: Guidelines
Date: Friday, July 23, 2021 10:58:57 AM

Agency: FOOD AND DRUG ADMINISTRATION (FDA)
Document Type: Notice
Title: Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; Public Workshop; Request for Comments
Document ID: FDA-2021-N-0275-0001

Comment:
To the OWG Members: I'd like to begin with the obvious: this was never a CDC issue to begin with. This is the FDA's business.

I personally find the guidelines INSULTING to patients and their providers-particularly pertaining to the issue of co-prescribing benzodiazepines and muscle relaxers concurrent with opiate pain medication. One of the biggest struggles that goes along with chronic pain is anxiety and depression.

Our providers have obviously considered the risk versus benefit aspect. As patients, we are familiar with the risks and benefits, as not only our providers and pharmacists review such information; but we know how these medications work (or don't work) for us. In addition, benzodiazepines are often very helpful with neuropathy and problems like tarlovs cysts. Most of the patients affected by these guidelines are "Legacy Patients", such as myself.

I've been in pain management since 2006 for severe, intractable, debilitating chronic spinal pain, multiple herniated discs, DDD, severe fibromyalgia, spinal stenosis, nerve damage, spasticity and several other related conditions.

Each one of them is extremely painful on its own...together, they make life a living HELL. Simple tasks are exhausting. Completely exhausting.

Fortunately, I have an intrathecal pump that literally keeps me alive. The medication delivered directly to my spine keeps me comfortable enough to sleep for a few hours at a time. In addition, I take anxiety medication...and without it, I would have constant heart palpatations and other problems. I use it responsibly, as most legacy patients do.

Because of the guidelines, my doctor took away my break through medication. Though the pump does a fairly decent "job" controlling my spinal/nerve pain, I still have neck and all-over fibromyalgia pain that affects me quite considerably.

The dose in my pump has been lowered too, as my doctor is afraid to be "flagged" and targeted-as are most these days. (PLEASE remove the MME limits!!!)

Since when does DEA equal M.D.? It seems as though doctors are being targeted because they have addresses and assets and much easier to find and indict than cartels and drug dealers. The biggest problem we face is the illicit abuse. Many will "blame" doctors and rx opiates, but this has been proven to be false over and over again.

What have we come to when a child with bone cancer is only offered Tylenol for pain???

I am not only fighting for my own rights to adequate and proper healthcare, but for future generations as well. I worry that one of my children will end up with my condition(s). That scares me so much, it's indescribable. Without my children, I would have given up years ago when the entire healthcare system started to fail us.

I have a 16 yr old neice with severe spina bifida whom I also fight for. She is not currently on daily pain medication, but what happens when she ends up needing something? She cannot take NSAIDS and we all know that Tylenol is pretty much only good for a fever.

I have friends and family who are Veterans-they've either been forced to an addiction clinic for minimal pain relief (which only flags them as having OUD, and interferes with their healthcare across the board) or left with no options. These folks have or are fighting for YOUR FREEDOM!!! Why are you supporting a document that harms them?!

This has become such a tangled mess and only you can begin to untangle it. We are dealing with so many issues, including insurance companies denying payment and/or requiring pre-authorization for opiates, surgeons being paid more to NOT prescribe, pharmacies not wanting to get in trouble with the DEA, therefore claiming to be "out of stock".

Now with the enormous settlements by the manufacturers, we are worried the "well will be run dry" and it will be even more difficult to receive treatment.

Addiction, though very serious, is a separate issue. So many addicts go to rehab and are told it's "not their fault" for the choices they made. They blame a doctor who did surgery years prior to them choosing to seek out and use heroin or other illicit substances. We do not divert our medications because we need them!!! We are [partially] being punished because of others' bad choices.

PLEASE end the war on our healthcare!!! We are real human beings, please treat us as such-see the harm that has been done!) I could write on and on as this is multi-faceted, but I will spare you. Again, please understand the incredible harm that this one document is doing to millions of people, not just here in the states but globally.

I know that it is hard for others to understand what we go through, so I ask that you please consider all of the comments with compassion and understanding.   Thank you.

From: david becker
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:32:13 PM

The paradoxical counterproductivity of the CDC anf their thick as theives rubber chicken dinnered epistocratic dehumanizing irrelevantificationizing colleagues in academia and DHHS is part and parcel of the depersonalizing dehumanizing automaticity revolution of Big Brothers new militarism against people in pain. It goes way beyond the testimonial epistemic injustices Fricker and other care ethicists have warned Americans about. It makes Wilsons committee on public information look like amatuers as the big lie techniques of the CD are beyond acts of imagination and beyond the pale of civilization. Asps have a Catholic spirit compared to those in the CDC involved in regulating opioids. They epitomize everything our Framers worked to protect our Nation from. The mean rapacity and arbitrariness of the CDC is what Hamilton wrote of in the Federalist Papers on "pertinacious minority" and that Roosevelt spoke of of those "frozen in the ice of their indifferentism. Its remarkable to me that the Big Brother fascist epistocrats have such little regard for our Framers and have long since forgotten the memory of freedom. QUite frankly the CDC is posthuman characters that would serve our NAtion starring in theater of cruelty plays- but they have no rightful place in civil society. Let them boast of their underfit underpowered evidentialism and scientific realism- anyone who speaks of Pareto Optimality or Multimodal optimization or even multiobjective opttimization will put them in their place with their regressive underfit scientific realism and rapacious evidentialism. Yeah tell me about kurtosis or about confidence intervals- lol. Your clueless about Austin Bradford Hill criteria.Read a book your demon oppressed clueless dehumanizers should audition for theater of cruelty plays- you certainly have lots of experience and are perfect for those parts. Debate me anytime- ill tie my basomedial amygdala behind my back- to make it more fair- you clueless bums will still lose the debate.

From: debra bertolino
To: NCIPCBSC (CDC)
Date: Wednesday, July 21, 2021 7:16:32 PM

How the cdc guidlines and the dea have ruined my life. With proper treatment using opiods I was able to get out of bed. I was able to shower. I was able to cook. I was able to live my life. Never completely pain free as cpp will tell u the pain is never completely gone. However, with opiod medication I was not constantly thinking about ending my life. It is inhumane to let a living being suffer as I do with opiod medication. I believe it is soppose to b elligale to let a human buing or evan an animal suffer as I am suffering. Now I barely can get out of bed, take a shower every few days or try to live my life. If cdc is going to slowly kill us with pain why not have doctor assisted suicide legale n all states? Let us end our suffering give cpp back medications that gave us ability to have a life.

Deborah Bertolino
Houston Tx.

From: Dan Bly
To: NCIPCBSC (CDC)
Date: Monday, July 19, 2021 1:42:12 PM

Hi..was fine for many yrs.able to function and work.raise family.now..soma and pain meds taken away and forced cold Turkey and labeled a possible addict..then kicked out..my life is now hell..recent tbi dx..25yrs to late.
Surprised am even alive today..horrible pain everywhere.head spinning..multiple organ failures..and all drs can say is you jus need to exercise more.and..we do things diff.
Now..bs..same ole nasty dangerous meds offered.but no pain meds for people in pain WTF ? DUH
WE NEED OUR MEDS BACK..NOW..NOT YR FROM NOW WHEN THOUSANDS MORE DIE.AND.THE EVERGROWING CRAZIES WHO ARE ATTACKING HOSPITAL PHARMACIES.DTS.ETC..YOU ARE CAUSING DEATH AND DESTRUCTION OF SO MANY LIVES..IT IS SICK..EVIL..CRUEL.AND INHUMANE..AND IT WILL GET EVEN WORSE
.HOW MANY WILL DIE JUST BECAUSE THEY CANT GET RELIEF.HOW MANY ARE DRUNKS.ILLEGAL USERS ETC.ETC..FOR EVERY ACTION.AN EQUAL AND OPPOSITE REACTION ?? YES..YOU ARE THE PROBLEM..YOU ARE KILLING AND RUINING PEOPLES LIVES..ALOT OF VERY GOOD PEOPLE..IT IS SO WRONG N EVIL..HELP US NOW..DO NOT WAIT..WE ARE DYING FAST
.AND SUFFERING 24/7/365..HELP US NOW !!!!!!!!!!!!!!!!!!!!!!!!!!!!
PLEASE.GOD HELP US !!!

From: bubblesd1
To: NCIPCBSC (CDC)
Subject: Living with chronic pain
Date: Thursday, July 22, 2021 11:04:42 PM

To whom it concerns,
I have been living in chronic pain for 8 years. I have tried everything available to me to alleviate pain including two surgeries.
Literally the only option for me to live a life outside of my bed 24/7 has been pain medication (opiods).
I can no longer work, go to school,or enjoy many hobbies that I did in my life before pain.
I live in a place of high altitude and an extremely cold environment with alot of snow. The altitude and cold extremely increases my pain.
I am forced to stay here because of the restrictions on opioid pain medication. I do much better and a very good quality of life in a lower altitude and warmth but the place I wish to live does not allow opioid treatments, so I am stuck where I am.
The opioid overdoses are a result of drug addicts abusing them and NOT pain patients who depend on this treatment for some quality of life.
Chronic pain is lifelong and we who have it will suffer with it the rest of our lives. It's inhumane to cause us to suffer further. The restrictions need to be lifted for pain patients and we have the right to be treated medically the same as others. We have the right to be able to get our medication everywhere in the United States just as any other patient who requires medication in their daily lives.
Thank you for your time,
"Don't Punish Pain "
D. Brown

From: Daniel Busch
To: NCIPCBSC (CDC)
Subject: BSC-NCIPC Meeting July 16 2021, comment.
Date: Friday, July 23, 2021 4:35:31 PM

Although the previous CDC Guideline was “The CDC Guideline for Prescribing Opioids for Chronic Pain,” the Guideline shied away from the question of whether opioids are effective in the treatment of chronic non-cancer pain. Nor did it make the point that even under the best of circumstances, the differences in pain with opioids vs. placebo are so minimal that efficacy in chronic pain has not been demonstrated in RCTs.

Severe chronic pain presents enormous challenges to the sufferer. Among them is the fact that no one experiences the pain of another, and patients often feel that the severity of their pain is being minimized by others.

Opioids have a mystique attached to them that is not attached to other treatments for pain. For many patients, being prescribed opioids provides validation of the severity of their pain. It means to these sufferers that their pain merits the prescription of a potentially addictive substance. That sense of validation, that the patient really does have severe pain, may even be amplified in an era of increased reluctance to prescribe opioids.

Even in EERW studies, which are designed to enhance assay sensitivity, differences between opioids and placebo in reduction of pain intensity are relatively minor. It is therefore vital that patients be made aware that not only are opioids dangerous but their efficacy is questionable, and realistically will provide only minor improvements in their pain.

Daniel A Busch, MD
Clin Asst Prof of Psychiatry and Behavioral Sciences
Northwestern University Feinberg School of Medicine
Chicago, IL 60611
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(c) (312) 909-0199
Mailing address:
737 N. Michigan Ave., Suite 1200
Chicago, IL 60611

From: Danie Carolina
To: NCIPCBSC (CDC)
Subject: The other victims of the opioid crisis CPP
Date: Thursday, July 22, 2021 11:01:43 PM

C-chronic P- pain P- patients, the other victims of the opioid crisis. In case it hasn't been brought to anyone's attention please let me tell you about the CPP community. The patients that have been responsibly taking opioids and or both opioids and benzos for years without any form of abuse.

I suffer from a degenerative disease, in which I will not heal from. The only real solution is surgery. It's an extensive surgery with an extensive healing time. But I'm also the mother of four boys two, of them are still small. I have been off and on hope you always for years without abusing them. Every time I go to my pain management doctor I take a year analysis and my prescription logs are accessible. I'm given a small dose of opioid pain medication thank goodness because I couldn't live without it. But I certainly would have a better quality of life if my doctor was able to give me more. My doctor and doctors all over the country are restricted to what they can give their patients for pain due to the fear of the FDA coming into the exam room and putting them away for treating pain patients with pain medication.

Opioids have their place in medicine. Although they can be addicting to some people they are also a very helpful to people that do not become addicted to them. I think it's unfair to punish people in great pain who do not use their medication because people take advantage and become addicted, in which they're addicted anyway. If they're not getting it from the prescription pain medication then they're getting it on the streets. I think a lot of measures have been put in place that would reduce addicts from obtaining opioid pain medication. I think that's great, but I think the pendulum has swung too far in the other direction and we have to come to the middle a little bit so patients in pain can be properly treated.

I have two small children and I can't keep up with them because I'm in pain. I had to cancel family vacation because I'm in pain. I can't work because I'm in pain. I can only do a little bit at a time because I'm in pain. My quality of life it's not what it once was and is deteriorating Day by day. We need to please please put something in place that allows our doctors to treat their patients for pain with pain medication without the fear of being arrested or having their medical license taken away. We need to give our doctors a little more control back, we need to take the FDA out of the exam room. Again as I said some measures have been placed that I believe will limit addicts from obtaining pain medication prescription, but that does not stop them from becoming an addict. They will be an addict and they will get their hands on whatever they can to fulfill their addiction. I don't think that that means genuine patience and pain should suffer. I think we need to trust our physicians to treat their patients the way they learn to and to first do no harm treat their patients with compassion and care.

Some people don't get any medication at all and live in agonizing pain, I think that's inhumane I think going to a doctor and telling them I'm in pain and they send you out the door without helping you knowing they could but don't, I think it's inhumane. I think that's doing harm. We have to find a place in the middle where patience can go back to getting cared for and reclaiming some of their life.

I really hope you take my words into consideration when you make the new guidelines, I really hope what I have said makes a difference.

Thank you for reading,
Danielle Mabe

From: Donna Corley
To: NCIPCBSC (CDC); Denise Molohan Arc Group
Subject: Updated CDC guidelines.
Date: Friday, July 16, 2021 2:50:17 PM

Thank you all who have worked on these much needed updated guidelines.

I feel it is imperative that we keep in mind that patients metabolize these, and many other medications differently.

Some patients are rapid or ultra rapid metabolizers, poor or slow metabolizers, and normal metabolizers. Now this has nothing to do with medication intolerance or dependency. It has to do with a patients metabolic rate, and genetic make-up period. This has been severely confused with dependency, and opioid use disorders. We need to make sure all treating physicians are aware of this possibility and patients should be tested on how they metabolize these medications!

We need to change the way we talk about opioids in general. We need to make sure prescribing physicians are safe to do so without fear of becoming a target from the DEA.
All these suggested alternative therapies are a good idea for quite a few patients in pain, but not all, and most insurance companies do not pay for alternative treatments.

Many patients who suffer with rare diseases (Adhesive Arachnoiditis, Tarlov Cyst disease, RSD, CRPS) that cause intractable pain syndrome have to be treated with a combination of therapies including pain control. These diseases have no cure and cause permanent nerve damage, but without proper pain management including prescription opioids, many patients health can rapidly decline, cause stroke, heart attack, and even affect the body as a whole.

We desperately need more research on Arachnoiditis/Adhesive Arachnoiditis, and Tarlov Cyst Disease.
There is only ONE known researcher in the United

> > > States who is actively researching Arachnoiditis and intractable pain. https://intractablepainsyndrome.com/
> > > http://arachnoiditishope.com/about-us/
> > >
> > > We need more physicians willing to research (and treat) these diseases!! We as patients who suffer with these diseases deserve more!
> > > We do not need less medications
> > > (i.e. Prescriptions opioids if they help patients). We need MORE RESEARCH!!
> > >
> > > Too many physicians have the misconception about these diseases as it is most physician’s beliefthey cause little to no pain, or they find them as incidental findings which is the furthest from the truth to patients who suffer with these diseases. Especially Arachnoiditis and Tarlov Cyst disease! This ~~.~~ leaves patients with no option to be treated for these painful, debilitating conditions!
> > >
> > > There is also a misconception regarding patients who take long term opioids.The misconception of needing to increase said opioids due to dependency, or addiction. Thousands of patients who have been taking prescription opioids for years and decades have been stable with NO INCREASE IN DOSAGE AND HAVE FOUND GREAT BENEFIT WITH THESE MEDICATIONS!
> > > These statements should not be allowed when there have been no long term studies involving these debilitating rare diseases listed above with patients who depend on prescription opioid medications to help them function better.
> >
> > —
> >
> > We must do better to address the needs of both chronic pain patients and the physicians who treat them. To date, the current CDC Guidelines have caused tremendous harm across the pain patient community with little to no redress of changes to rectify the profound damage.
> >
> > You now have the opportunity to correct the overwhelming misconceptions put forth in the current Guidelines with regard to MME’s, dosages and duration by putting the decisions for treatment back into the hands of the physicians and their patients without fear of prosecution or persecution.

> > We are asking for a full rewrite of the Guidelines to protect the lives of millions of American pain patients and thousands of the physicians who had treated them in line with the AMA's recommendations.
> >
> > Thank you for your time and consideration.

Best regards,

Donna Corley
Director of ASAP - Arachnoiditis Society for Awareness and Prevention.

Administer and Creator of Tarlov Cyst Society of America support group.

Creator of Tarlov Cyst Society of America Awareness Page.

Administer of Arachnoiditis Together We Fight support group.

Patient Advocate

donnacorley43@yahoo.com
asap_aa7@yahoo.com
601-325-6120

From: Donna Corley
To: NCIPCBSC (CDC); Denise Molohan Arc Group
Subject: Update to 2016 cdc guidelines
Date: Friday, July 16, 2021 3:48:26 PM

My name is Donna Corley and the Director of ASAP Arachnoiditis Society for Awareness and Prevention.

Thank you all who have worked on these much needed updated guidelines.

I feel it is imperative that we keep in mind that patients metabolize opioids and many other medications differently.

Some patients are rapid or ultra rapid metabolizers, poor or slow metabolizers, and normal metabolizers. Now this has nothing to do with medication intolerance or dependency. It has to do with a patients metabolic rate, and genetic make-up period. This has been severely confused with dependency, and opioid use disorders.

We need to make sure all treating physicians are aware of this possibility and patients should be tested on how they metabolize these medications!

We need to change the way we talk about opioids in general. We need to make sure prescribing physicians are safe to do so without fear of becoming a target from the DEA.
All these suggested alternative therapies are a good idea for quite a few patients in pain, but not all, and most insurance companies do not pay for alternative treatments.

Many patients who suffer with rare diseases (Adhesive Arachnoiditis, Tarlov Cyst disease, RSD, CRPS) that cause intractable pain syndrome have to be treated with a combination of therapies including pain control. These diseases have no cure and cause permanent nerve damage, but without proper pain management including prescription opioids, many patients health can rapidly decline, cause stroke, heart attack, and even affect the body as a whole.

We desperately need more research on Arachnoiditis/Adhesive Arachnoiditis, and Tarlov Cyst Disease.
There is only ONE known researcher in the United States who is actively researching Arachnoiditis and intractable pain. https://intractablepainsyndrome.com/
http://arachnoiditishope.com/about-us/

We need more physicians willing to research (and treat) these diseases!! We as patients who suffer with these diseases deserve more!
We do not need less medications (i.e. Prescriptions opioids if they help patients). We need MORE RESEARCH!!

Too many physicians have the misconception about these diseases as it is most physician’s beliefthey cause little to no pain, or they find them as incidental findings which is the furthest from the truth to patients who suffer with these diseases. Especially Arachnoiditis and Tarlov Cyst disease! This . leaves patients with no option to be treated for these painful, debilitating conditions!

There is also a misconception regarding patients who take long
term opioids.The misconception of needing to increase said opioids due to dependency, or addiction. Thousands of patients who have been taking prescription opioids for years and decades have been stable with NO INCREASE IN DOSAGE AND HAVE FOUND GREAT BENEFIT WITH THESE MEDICATIONS!
These statements should not be allowed when there have been no long term studies involving these debilitating rare diseases listed above with patients who depend on prescription opioid medications to help them function better.

One of the worst consequences of the 2016 guidelines have been minipulated and misused by pain management physicians who have and are STILL forcing epidural steroid injections (which are NOT APPROVED BY THE FDA) on patients in order to receive their prescription opioid medications. If these patients refuse to have more epidural steroid injections then they are refused their prescription opioids and are then dismissed by that treating physician due to "their pain contract" implemented largely by your CDC 2016 guidelines!
More patients are being harmed due to this immoral, incomprehensible act of holding patients hostage, forcing them to have invasive procedures in order to receive their opioid prescription! This should be illegal!!

——

We must do better to address the needs of both chronic pain patients and the physicians who treat them. To date, the current CDC Guidelines have caused tremendous harm across the pain patient community with little to no redress of changes to rectify the profound damage.

You now have the opportunity to correct the overwhelming misconceptions put forth in the current Guidelines with regard to MME’s, dosages and duration by putting the decisions for treatment back into the hands of the physicians and their patients without fear of prosecution or persecution.

We are asking for a full rewrite of the Guidelines to protect the lives of millions of American pain patients and thousands of the physicians who had treated them in line with the AMA’s recommendations.

Thank you for your time and consideration.

Best regards,

Donna Corley
Director of ASAP - Arachnoiditis Society for Awareness and Prevention.

Administer and Creator of Tarlov Cyst Society of America support group.

Creator of Tarlov Cyst Society of America Awareness Page.

Administer of Arachnoiditis Together We Fight support group.

Patient Advocate

donnacorley43@yahoo.com
asap_aa7@yahoo.com
601-325-6120

From: Delorse Croissette
To: NCIPCBSC (CDC)
Subject: Recommendation on 2016 guidelines
Date: Monday, July 19, 2021 1:17:39 PM

My name is Delorse Croissette I am a chronic pain patient who suffers from a rare neurological autoimmune disease that 1/million can have and who can no longer obtain effective pain treatment because of the errors and bad policy introduced by the 2016 CDC Guidelines. I wish to endorse Comments for Record submitted by Richard A Lawhern, Ph.D. concerning the July 16, 2021 Meeting of the NCIPC Board of Scientific Counselors. Rather than attempting to update these guidelines, CDC should withdraw and repudiate them entirely

Sincerely,
Delorse Croissette
870-421-8421

From: D Cunningham
To: NCIPCBSC (CDC)
Subject: Repudiate and toss the CDC Opiate Guidelines
Date: Tuesday, July 20, 2021 1:11:23 PM

There were two more reported suicides in the chronic pain community last week. Those are the ones we know of. I do NOT want to lose my daughter who is sinking into a state of hopelessness after having been a compliant pain patient for a decade with a less than 10% increase in her medication over that time period.

With the aging of the population, Business Insider listed Pain Mngmt as a likely growth specialty in medicine. Against BUSINESS expectations, the profession has grown by less than 2% over the last several years. The over 60 population - least prone to addiction and most prone to the various pains of an aging body - are suffering from a lack of pain specialists on top of limited access to proven pain relief.
Why would any physician voluntarily go into a specialty where he/she is prohibited from helping their patients and under continual threat by an inappropriately weaponized DEA and pharmacists and legislators practicing bad medicine?
Why would anyone want to create a system to allow our aging citizens, many of whom are still productive, and certainly have wisdom, to die in pain?
Why is it acceptable to torture our veterans, who 'gave their all'?
And why has it even become acceptable to allow those who are terminal to die in agony, or prohibit opiate pain management for children with cancer, unless they are at death's door.

All of the above are the result of the badly applied, carelessly and unscientifically crafted, CDC Opiate Pain Medication guidelines.

- Debbie Kahn Cunningham

From: Diane D.
To: NCIPCBSC (CDC)
Subject: comment about CDC opiod guidelines
Date: Thursday, July 22, 2021 8:46:59 PM

Hello,
As the overdose epidemic increases due to the illegal fentanyl and addiction, I believe that the report and recommendations for doctors that were enacted over the past years has not done anything to stop the illegal drugs, but instead hurt patients in severe pain to the extent that no pain medication is offered after many invasive surgeries and chronic pain patients are on a roller coaster of being able to work and function, play with grand childrem, to losing everything.

The report mentions cancer pain but does not mention pain due to AIDS. Most scientific, health articles never mention AIDS/HIV. It is almost like it does not exist. It does and people are suffering.

There are dozens of intelligent papers and articles from doctors and patients, advocates that say that anywhere from 50 -70% of people living with HIV , especially long time survivors, suffer from untreated pain. The medications that PLWA/HIV took in the beginning of the AIDS epidemic, before newer and better medications were developed, caused nerve damage, neuropathy, kidney loss, liver damage, bone loss and muscle and joint pain. Current medications still have these side effects.

The recommended medication treatment for this pain is gabapentin or SSRIs. Gabapentin is not recommended for people with CKD or liver damage. Gabapentin and Lyrca may help some with neuropathy, but the complexity of the AIDS related pain goes beyond nerves and gabapentin is supposedly effective at the higher dose which is not recommended for CKD. Gabapentin high dose leaves many just sitting looking out the window with out a thought in their head.

After trying all these medications along with the physical therapy, hot baths (if they are fortunate to have a bath tub...believe it or not many people who are low income do not have a tub, shower only in their tiny low-income apartment) massage, acupuncture, chiropractor, exercise, mindfulness, therapy, counceling, support groups nutrition etc, they cannot afford to pay for these things....there comes a time where nothing helps but a low to moderate dose of opioids.

Those medications have side effects that are not tolerable for many. SSRIs and Cymbalta are very hard to wean off of and take a long time. If you miss a dose the side effects and withdrawal are terrible. How is that different than being dependant on a low dose opioid?

Not everyone that has HIV got it from doing illegal drugs.
PLWA/HIV are denied even low doses of 20 mme opiates and treated like an addict the minute they walk into the doctor's office.

I agree that many people are on high doses of OT for chronic pain and yes they can probably come down a little, but giving none at all for PLWA/HIV is just leaving them to not be able to work, nor care for the home, family, basic needs and hygiene.

Cooking and eating is extremely hard when in pain and the nutritional needs are not met causing weight loss and wasting. Laying in bed crying alone, after trying all the non opioid medications is inhumane. Many have had to leave the work force and live on an average of $800 a month disability. They have depleted their savings and sold their homes and possessions. They can't rent on that income and housing vouchers take years.

Many of these people are over 55 years old and live alone. The few who get pain management do not abuse their medication. they take it as prescribed for the 30 day period. Without it they lay in bed and cry, alone. I know many that have had the opportunity to receive pain management with low doses of oxycodone and are doing well. Able to eat, function, work and provide for themselves.

I think that whenever recommendations of medications and treatment for pain, nutrition, heart, kidney, liver, the CDC, FDA, to public health, needs to include the people living with AIDS.

Thank you
Diane Denby
PWA advocate

From: Denise Denslow
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:07:32 PM

Hi, my name is Denise and I am a patient that struggles with pain. I am concerned about the new guidelines. Yes, we need to ensure that people are careful with opioids, but there needs to be an honest discussion about pain treatment and the benefits of opioids. I know of several people that have completed suicide because they were in pain and were unable to get any type of reasonable pain relief because of the new guidelines. Opioids need to be managed but they have been the only relief I have been able to find for my pain, and believe me, I have tried every other treatment. I don’t have much faith that this will sway you, but please don’t disregard me. Many people find meaningful relief from pain with opioids and they can be beneficial as part of a comprehensive pain management plan.

Thank you,
Denise

From: Donald Devers
To: NCIPCBSC (CDC)
Subject: Guidelines
Date: Monday, July 19, 2021 8:16:40 PM

To whom it may concern,
Im writing to let you know the CDC has made my life and others very hard almost unbearable!!! Yon need to have a heart and some common sense about patients.... Thank You ......
Sent from Yahoo Mail on Android

From: Dave Dockery
To: NCIPCBSC (CDC)
Subject: ncipcbsc@cdc.gov
Date: Friday, July 23, 2021 8:54:28 AM

Comment on updated guideline

I had commented earlier on my situation but would like to add a suggestion please. If someone has as much wrong with them as I do they most likely have a caregiver like me. My caregiver picks up my scripts. If there is a concern about abuse or overdose than why not have a provider only write for a short time period such as one day or two or use a time lock bottle. I was told in Michigan I could grt any type of narcotic I needed as long as I was committed to a nursing home I'm which case I could not receive my entire VA pension. That I not an option for me. I enjoy and have earned ny freedom with my service. Please help those in need. I have been treated very cruel for over 12 years now. Thanks

From: Danny Elliott
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:43:13 PM

I was electrocuted in a flooded basement in 1991. My father literally saved my life by performing CPR on me until the EMTs arrived. The EMT report shows that, once I was revived, I immediately complained of a "bad headache". What I leaned many years later was that I had suffered a Traumatic Brain Injury.

I spent a decade seeking out leading experts on electrical injuries in an attempt to resolve the severe, chronic head pain (not "headache") using every treatment available, including hypnosis, acupuncture, biofeedback, relaxation, and a myriad of prescription medications, but with only occasional pain relief treatments.

In 2002, I found a Pain Mgt doctor who, after looking at all of the previous treatments, chose to pursue pain management with extended-relief meds and breakthrough meds. This was the first time that either of these medications were tried on me. After about 12 months, we found a combination of these two medications that were successful in providing relief, which allowed me to have a semblance of a "normal" life.

In June, 2018, my doctor was arrested by DEA. The charges against him included this specific sentence: "overprescribing that exceeded the CDC's Guidelines for Prescribing of opioids". It took 6 months for me to get my medical records from DEA, which seriously inhibited me from finding another doctor. When trying to find treatment for my pain after my doctor's arrest, I was turned down by 12 doctors. I finally found a doctor willing to take me on, but he was in Houston, Texas, and I was living in North Carolina. I had no other options, so I had to travel to Texas every month to see this doctor. This was financially difficult due to my reliance on Social Security Disaster benefits.

Within 3 months, this new doctor informed me that he would have to stop prescribing the medications that were successful, and that I would have to submit to having a pump surgically implanted. The research I did about pain pumps informed me that this was not a good option for TBI pain, so I, again, had to find another doctor, and the only one I could find willing to prescribe the successful meds was in California. So that's what I did. This whole scenario took a tremendous toll on my physical health as well as on my emotional health.

Ever since my original doctor was arrested as a result of the Guidelines, my life has changed dramatically. Before, I attended church as often as I could, I delivered food for shut-ins, and I had a bit of a social life. However, all of that had changed. I'm unable to do much of anything anymore. Because of issues with my last California doctor and her refusal to do Prior Authorizations for insurance purposes, I nearly bankrupted my wife and I. I cannot survive without the medications that I began using in 2002.

The stress of knowing that, at any moment, my current doctor could be shut down and/or arrested by DEA due to the Guidelines, is overwhelming for me. I've lost all contact with people who have been my friends for 30 years or more. I am unable to attend church. I rarely leave my home. I am often depressed and unhappy.

Please - please! - get rid of these Guidelines! They are ruining lives. They are leading people who suffer from chronic pain to commit suicide. The DEA is scaring doctors so much that many refuse to even consider taking a chronic pain patient into their practice. Most of all, overdose deaths have skyrocketed since the Guidelines were enacted, so it's quite obvious that prescribing by doctors is not, and never was, the reason for the so-called "opioid epidemic".

Americans are suffering and dying as a direct result of the CDC Guidelines. This must be stopped! Now is the time for you people to end this madness.

Sincerely,

Daniel P. Elliott
51 Cohen Walker Dr #2303
Warner Robins, Georgia 31088
478-951-0332
dano1330@gmail.com

Pitt Pain Conference **17-Mar-2021**

Background

Age 77, married 54 years to my best friend Carol, one child, a wonderful daughter.

Doctorate in Theoretical Chemistry, University of Wisconsin

Project manager 19 years, designing analytical instrumentation, for Fisher Scientific – now Thermofisher. Patents.

As an adjunct prof, taught calculus-based physics at Pitt and chem at WCCC and Univ. of Wisconsin.

Started an electronics manufacturing company, grew it to 35 employees. Sold it in 2005 to a much larger company.

In spite of my technical background, I was always much happier doing heavy physical work. Specifically, as a sideline, I *personally* built spec houses and a duplex.

Source of Pain

June of 2012, fell off a ladder. Imaging showed a herniation at L4/L5, adjacent discs bulging. Unrelenting pain resulted.

Shortly after, began developing peripheral neuropathy. Surgeries worsened the pain.

Then, developed a pinched nerve L5/S1. Pain in both feet.

Treatments

Physical therapy: no effect. Meditation: If your hair is on fire, do you look to meditate? Psychologist Referral: His reaction was quote: “I don’t know why they sent you here.” Truth is: I didn’t know either.

A back surgeon then recommended, that while I was a candidate for surgery, I should first try a pain clinic. Immediately, and for the 9 years since referral, UPMC’s remarkable pain clinic, and specifically Dr. Scott Brancolini, restored a good quality of life, based on *managed* opioid therapy.

Effect of Chronic Pain on My Life

Before the pain clinic, I found it difficult to concentrate on anything but my pain. For example, tournament bridge, once a favorite hobby, had become impossible. All significant physical activity ceased. As a devout Christian, I am ashamed to admit it, but I was considering suicide.

Personal Recommendations for Treatment

In no way do I represent my pain clinic, so my comments reflect solely my own opinions.

For patients with chronic pain, I do believe their PCP has a major role to play.

But, foremost, the PCP should refer the patient to a pain clinic. For a variety of reasons, pain management always is best left to the specialists. Patients should be counseled that, for most, pain-free is *not* a reasonable goal. But, reduction to a tolerable level is possible and should be a basic right.

The PCP should regularly, not just at a once-a-year physical, communicate with both the clinic and the patient as to progress and planned treatment regimen.

Effect of Treatment on My Life

While I can no longer do physical labor, the pain clinic otherwise has restored my quality of life, including my bridge hobby.

Outrageous Personal Experience

My father was subjected to chronic pain in later life. At age 76, he was hospitalized for the condition, and in deep pain. I asked the hospital doc to give him something for his pain. The doc's response: "We wouldn't want to turn him into an addict, now would we?" My dad died in the hospital, in constant agony *but unaddicted*, two weeks later. Does the CDC find this a satisfying outcome?

A Few Observations

1. The distinction between dependence and addiction routinely is not recognized. I am *dependent* upon prednisone and opioids. For example, others are dependent upon insulin. They are not addicted to their med, nor am I addicted to mine. It has been estimated that only roughly ½ % of the population is genetically pre-disposed to opioid addiction, although the literature is very sparse on this subject.
2. 70% of drug overdose deaths are from fake oxycodone, utilizing fentanyl (often admixed with heroin); *specifically, not legally prescribed opioids.* Why fentanyl? It's much easier to make than oxycodone, the precursors are roughly 64 times cheaper, and its potency makes it easy to smuggle into the US. Hence, the problem: fentanyl is so powerful that it is very difficult to make even remotely consistent oral dosages.

3. Mortality risk from *managed* exposure to medical opioids is 0.02% per year -- too small to even reliably measure.
4. Chronic pain is second only to bipolar disorder as a medical cause of suicide. Watch for signs of depression.
5. Diagnoses of post-surgical substance abuse are less than 0.6%.
6. With legally prescribed opioids becoming much harder to obtain, in desperation many chronic pain patients have turned to street drugs---and died.

Concerns about the Future

- Worst fear: grandstanding politicians/bureaucrats looking for an issue to get them face time on cable will seek a niche issue, like opioids, and misrepresent/misunderstand the problem. I live in day-to-day terror that they will destroy my lifeline.
- **Second worst: another ill-conceived set of guidelines like that published initially by the CDC.** They have since clarified (read: retracted), but “unringing the bell” hasn’t worked out well. Thirty-six states enacted legislation based on those initial guidelines. It has been suggested that the guidelines were created solely to move forward with opioid lawsuits.

From: carolgib2014
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 1:44:07 PM
Attachments: Pitt Pain Seminar Mar-2021.docx

The following is a summary of a presentation I made to first year Pitt Med students:

Thank you for taking comments,
Dennis A. Gibboney, PhD Theoretical Chemistry

From: Dell Glenn
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:19:04 PM

To whom it may concern,

I am one of millions of Americans who have to deal with pain every day and have seen over the years (10) how the government has interfered in my pain control. Please allow my doctor to do what is best for me and my situation. A one size fits all approach is not the answer when it comes to pain management. Surely someone on the panel at the CDC has the medical wisdom to understand this. Once again, please allow my pain doctor to do what is best for me. My everyday quality of life depends on it. Please don't continue to take that from me.

Dell Glenn

From: David Hall
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:04:23 PM

Dear Sir or Madame,

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16. This is should be a sobering statement. This is in part due to a lack of understanding (or delving into) the “why’s” behind conclusions specifically made regarding prescription drugs (not including cocaine, heroine, meth, etc.). There must be a distinction AND segregation between those in chronic pain needed relief and those seeking the thrill of getting high. There is no such distinction made to date as both are heaped into the same bucket regarding prescription medications.

My issues with the proposed version include:

- A biased focus on risks and harms of opioids with NO discussion of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication triggering withdrawal. This evidence should be included in any discussion or documentation of any recommendations.

Further, two specific terms require clear and absolute clarification, **up front**. First is making the distinction between “addiction" and "physical dependence." Those with conditions such as diabetes, epilepsy and chronic pain conditions may be physically dependent on their medication, but must not be assumed to exhibit the behaviors and mindset of an addict resulting in overdose, addiction, abuse, or misuse by patients with chronic pain.The two are significantly different and the data must be treated separately. Also assumed in the guidelines is a drop in efficacy. There is no such data offered in the recommendation to support eliminating opioids based on an assumption of lost efficacy.

Second is making the important distinction between “guidelines” and “mandates" and to whom they should apply (again, up front). The “guidelines” were initially intended for the PCP (primary-care physician) or GP (general practitioner), NOT those board-certified in pain management and specifically trained in drug delivery for pain management. However, this distinction was not made clear to the general public, including some legislators. Sadly, some legislators did not understand these significant differences and made the “recommendations” into law. This knee-jerk reaction has had severe unintended negative consequences to both patients and providers resulting in unwarranted prosecution of physicians and unnecessary suffering for patients (potentially of leading to illegal addictive-like behaviors that didn’t previously exist).

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version **with very few changes**. Also still lacking is a deep dive into the “why’s” behind trends. What is needed is the segregation of data (and analysis) of patients in need pain relief versus the criminal behaviors of those simply seeking a not-so-cheap thrill. Again, all of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16. As such, due to the subtle nature of changes offered in the new guidelines, one would not expect any significant positive changes or improvement in outcomes.

According to the CDC, the latest provisional drug overdose death counts through May 2020 suggest an acceleration of overdose deaths during the COVID-19 pandemic.(1) Please keep in mind this conclusion was made **before** the Biden administration opened the U.S./Mexico boarder. **With the recent opening of the southern U.S. border by the Biden administration, we’ve seen an outrageous increase of illegal drugs making their way into the United States. We’ve seen forced tapering not safely or properly performed drives patients to the streets**

resulting in an increase of fentanyl (and other drugs) deaths. We're seeing more of this taking place. This is a serious unintended consequence of government intervention in an area where an objective analysis based on science is lacking, without taking into consideration patient's needs and physician training and experience. This is not only necessary but critical. We are now seeing politics taking priority over national security and patient safety, specifically regarding the influx of illegal drugs. As such, the changes proposed will have little to no positive effect.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. **However, there is no mention of therapeutic options in the new Guideline.** The CDC's endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help eliminate barriers to access for many of these therapeutic options.

I expect when drafting the final Guidelines, the CDC takes these views into consideration of the patient struggling in chronic pain and the practitioners trying to help them have a better quality of life.

Kind regards,
David Hall, CHWC
Cert. Health and Wellness Coach
Striving to Thriving
480.861.1082
david@strivingtothriving.com

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(1) • Centers for Disease Control and Prevention. CDC Health Alert Network Advisory: Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic. CDCHAN-00438, 2020 Dec 14.

From: Daniel Holder
To: NCIPCBSC (CDC)
Subject: CDC guidelines rescinded/amended
Date: Thursday, July 22, 2021 10:29:40 PM

7-22-21

My name is Daniel R Holder Jr, and I have written the CDC before regarding the opioid guidelines that are currently in place for the use of opioids in treating chronic pain. I am a pharmacist (PharmD) who was forced out of my career as a pharmacy manager and pharmacist by the development of my chronic pain conditions. I suffer from 3 incurable, progressive, chronic pain conditions that have resulted in my developing Intractable Pain Syndrome (IPS). Patients who suffer from IPS represent a subgroup of individuals who are in much higher levels of pain than the average chronic pain patient. The use of high dose opioids (higher than the guidelines of 90MME) is the only way to provide me any relief from living in daily torture. I also was diagnosed with opioid malabsorption syndrome which further necessitates my being on high dose opioids just to get a little pain relief. It is an absolute travesty that the current CDC guidelines neglect the miserable suffering that myself and other IPS patients are in while focusing so much on the OD patients who may also be taking other medications including street drugs and other prescription drugs. I am not saying that OD patients are not important as the death of one individual is too many. However, patients who are being forced to live in constant miserable pain (due to the limits of the CDC guidelines) are being exposed to a disease state which will result in an early death for many of them. Therefore, I request that the CDC guidelines be rescinded. If that is not if that is not possible, please amend the guidelines to prevent deaths among IPS patients and others who are suffering from undertreated chronic pain. The amended guidelines should consider patients individual conditions and needs. This should be decided between a doctor and the patient.

Thanks,
Daniel R Holder Jr, PharmD

From: Doug Hughes
To: NCIPCBSC (CDC)
Subject: Comment on the MME, Opioid Limit
Date: Thursday, July 22, 2021 5:55:52 PM

Email to ncipcbsc@cdc.gov

Dear CDC & FDA,
Concerning the Opioid Prescribing Guideline and its rewrite:
* my apologies for not being professional in this statement, but I am hanging on to life by a thread at your own hand as are 19-million other Intractable Pain Sufferers you took Patient Centered Care from carte blank!

Like contemporary western wildfires, not caused by lightning igniting them, but rendered incendiary from decades of Global Warming, history will not glean CDC's innocence because it published a recommendation which was promoted with the PPR Firm.

The little old lady no longer capable of baking Apple Pies for her family because she lost arthritis treatment for her hand, or the mechanic unable to earn a living for the same reason, the CDC caused a disgruntled society and disabled more than you lost.

Morbidity skyrocketed in countless ways from the zeitgeist you created, a decade's drug control expense of $250-billion Federal and the same by States, and yet reprisal exists in this rewrite being allowed you.

Data incompetence since 2005-7 for IDC-10 codes, OTC, polysubstance, alcohol, methadone, counterfeits, 8% autopsies, and IMF these 16-years, the 4th Estate parroted 10-million times. Are retractions realistic?

Your "appeal to possibility": left this excoriated machination, and further track into this maelstrom, futile. Right the ship!

You know damn well Dentist's first exposures of adolescents and theft in the supply chain & Hospitals caused this, and not overdose of legacy Chronic Pain Sufferers!

Where doctors like John Freedman on April 10, 2021, corrupted your already corrupt data by stating;
"According to the Centers for Disease Control and Prevention, since

1999, nearly 850,000 people in the United States have died from overdoses related to prescription drugs involving opioids."

"In 2020, in the middle of lockdowns and quarantines in states nationwide, the CDC reported 81,000 opioid overdose deaths in the 12 months ending May – the highest ever recorded in a 12-month period."

When a friend called to the attention of Dr. Freedman, that next day, the Charleston Gazette-Mail's changed their "archived record version", removing the word prescription from the first paragraph, and changing the date of publication to April 9, 2021 instead of its actual publication on 4/10/21 !

I am sending you a hard copy of this letter, and this Newspaper and another column, as only my copy is proof these lies are promoting the "All Payers Claims Databases" soon to be Total Personal Surveillance, the death of democracy, and CDC's lasting legacy!

I followed the big three Opioid Distributor's Trial in Charleston, WV from May to July, 2021 and among the scores of half-truths, CDC misquotes, and outright lies, one truth was missed, which portrays your zeitgeist's lasting axiom.

The testimony of Kevin Murphy, a health economist for the Distributors made a statement during questioning by Cabell Attorney Paul Ferrell, Jr., which others made the similar unremarkable statement in the 3-month trial, but it was never examined, because it was what they had all believed in years of your PR efforts to cover your collective asses.

Though this reporting by Courtney Hessler was about Mr. Murphy's testimony, she always editorialized more than quoting the statements of the Distributor's witnesses.

"Murphy said the people who are getting the pills are not the ones dying from them later. Ferrell (Plaintiff's attorney) said, it could also be true that the people receiving the pills were diverting the pills to others, who later move to the illicit drug market."

"It tells you there is other stuff going on, he (Murphy) said.'

"The other stuff was the suffocation of pill supply, Ferrell countered. As demand, in this case for opioids goes up, so does the supply, he (Ferrell) said."

“He (Ferrell) then asked where in Murphy’s evaluations he accounted for government restrictions, which around 2011 dramatically cut the number of opioid pills allowed to be shipped each year. Without the supply to fill demand, he (Ferrell) said, people with opioid use disorder were forced to find an outlet.”

Aside from the obvious reporting of the Plaintiff’s views instead of the witness statements themselves, Ferrell gives us what all of society have been brainwashed to believe: that **everyone taking prescription opioids have Opioid Use Disorder!** They never elaborated to say legacy pain patients also were forced to replace legitimate Opioid Therapy with often lethal street drugs.

A similar statement was made three other times, confirming they all believe everyone taking prescription opioids have Opioid Use Disorder!

The DEA have consultants on both Plaintiff and Defendants legal teams in the Drug Trials, ensuring DEA impacts closing Pain Clinics and Pain Specialists intimidations to lower prescribing since 2003, that I can prove, never sees the light of day.

The sheer extent of DEA and State Medical Board’s Pain Clinic closures over the last two decades, each with a thousand patient abandonment forced to replace legitimate treatment, has been tracked by multiple offices of the CDC. You have the proof of what has happened in your data and this “Guideline Rewrite” is your opportunity not only to rescue the former stellar reputation of the CDC, but also to save the United States from the complete societal collapse we see before us!

In many areas Officials, News Media, and Police Departments are covering up the existence of counterfeit pills laced with Fentanyl. You risk yet another generation of our youth who will see these counterfeit pills as a safe buy on the streets, merely because of ignorance to their existence! This is all in the States, CDC and DEA. Let the FDA have this problem, by using your data the right way and ending this!

A recent July 11, 2021 article in the Washington Post, “violent Crime is up, There’s no one cause” (It’s to pat to blame any one cause for the recent surge in violent Crime), by Aaron Chalfin & Mac Donald, examined the 25% increase in homicides in 2020, without a conclusion other than it must be caused by a systemic change.

The 54% decline in such murders from 1991 until 2014, was noted. The long decline waned from 2010-12 when Opioid Prescribing began massively reduced across all societies, lastly homicides crossing the threshold to increased homicides in 2014 as a result. From 2014 to 2019, homicides increased 13%, and was not deemed a factor in analysis of 2020, yet it is easily explained by taking pain treatment, a first ever in a society. It is easily proven intentional at this point!

Taking pain control from all of U.S. society, has caused an overdose epidemic from former legacy patients naïveté in replacing legitimate pain treatment, a Suicide Epidemic disgruntled from suffering untreated pain conditions from simple to complex pain syndromes since 1.39 million Veterans lost long-term treatment in 2013, a Fentanyl (IMF) overdose Epidemic, a Homicide Epidemic, as well as elderly were being tortured to death in Hospitals with nondisclosure policies in order to curtail death malingering. Either fix it, or take credit. The CDC will be blamed because there is more proof this is intentional than any other justifiable explanation.

Dentists had by far the most “First Exposures” of adolescents of any medical discipline, without follow-up to insure drug abuse was not caused. Pain treatment by Dentists was one of few that CDC, DEA and Medical Boards did not investigate because you needed this treatment. As well, Health Insurances, the big winner in this fiasco, had no liability in dental work, and thus they were never part of this Faustian nightmare.

I'm nobody, and I doubt you read thus far. Rest assured with the growing descent against the CDC Guideline as the primer, this Rewrite is your last chance to correct this conflagration you had no business controlling in the first place.

CSA excrement desecrated medical disciplines and only the CDC in confession can lay bare its turpitude. I know you have even tracked it, you track everything!

Whatever possessed this permuted canard is being exposed as I speak. You knew this intrigue would never hold up!

Do you truly believe the disabled tortured to death instead of taxing the wealthy and establishing personal surveillance, the death of democracy, makes your efforts worthwhile?

The overdoses, suicides, torture, and even gun murders in this disgruntled society your zeitgeist made, will condemn the CDC, it’s staff and democracy itself, forever!

No PRR effort can emboss this duplicitous collusion to forestall history condemning your dereliction of morality!

Clean your own house if you must, but end this serrate now, by blaming State’s for the data & the lack of autopsies (only 8% nationally), misapplication, and DEA for its enforcement, while you are being called on for this last do-over as a democracy !

Now with the $26-Billion Opioid Supply Chain Settlement, you have someone to pay for your mistakes, or about 5% of it, it's time to save democracy, do the right thing and end this!

You already have the Guideline amendment finalized, show it now and get blamed for this GREATEST EVER CRIME AGAINST HUMANITY later, or stop this bonfire of servility by blaming the responsible States and Agencies you protect.

All working at the CDC with knowledge of this travesty and murder of innocents are condemned for all eternity and should consider becoming carillonneur’s, to serenade eternally with Hell’s Bells!

~~~~ END ~~~~

Douglas Leigh Hughes
Logan, WV

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From: Denise I
To: NCIPCBSC (CDC)
Date: Saturday, July 17, 2021 8:59:03 PM

Good day,
I
There are many people like me in the world. We have chronic pain and are allergic to NSAIDs.
My life has reached the point where 90%is spent in bed and the remainder is spent at the Dr trying to get pain relief. I do not have even one spot in my body that does not hurt. I have severe degenerative disc disease with osteophytes growing all over every area of my cervical to lumbar spine.in addition I have osteoarthritis in every digit in every toe in my wrist ankles hips knees everywhere. The only pain pill I can take that's over the counter is Tylenol. There is a limit to how much Tylenol you can take before it starts to affect your liver. Earlier this year it started affecting my liver. I also suffer with severe chronic aura migraines. I cannot take the normal medications that they've just come out with because they cause many strokes in my brain. So the medication I take for that also has Tylenol in it. I must calculate every day based on how much Tylenol I will need to take in my migraine medicine versus what I can take for pain. It doesn't really even work to help my pain. On Mondays I see a spine pain specialist. Every other Monday she gives me injections in my thoracic spine so that I can get some relief from the thoracic osteophyte pain in my spine. Every two months she gives me injections in my lumber and cervical spine to stop the pain there. After you get these injections at least me I'm in pain for a good week before they go into effect. On Tuesdays I get massage for my back primarily thoracic and lumbar, Because the pain I have there is so intense if I don't get the massages I can't move at all. On Wednesday I go to a doctor that does internal physical therapy because of the osteoarthritis in my hips. SHe tugs at the muscles inside through my vagina and sometimes rectally so that they can be loosened up. The same thing that was considered abusive to the gymnastic students I have to have done to me.Thursdays I get dry needling done to the trigger points all over my body. So far nothing has been found that can help my hands. Opioids work for that. If I take a Tylenol 3 in the morning and a Tylenol 3 in the evening it takes care of all my pain everywhere two pills. Drug addicts take way more than two pills. in the 30 prior years that I took Tylenol 3 I never ever took more than two pills sometimes I only took two half pills. Those two pills made it possible for me to be a school principal and teach students for 35 years. Now I have to lay down and say to myself how bad is your pain can you just suffer through the pain so that you keep the Tylenol 3 you have the 30 pills you get that are supposed to last 90 days. Can you suffer so those pills will last? I'm being made to feel as though I am a drug addict because I don't get relief from my pain. I really can't even take more than the two pills because then I would get rebound migraines and I would be over my limit in terms of the amount of Tylenol I'm allowed to take. The doctor prescribed toradol for me and I could get as much of that as I wanted. That is way more addicting and all I did on that pill was sleep and itch because it turns out I was allergic to it. It is really unfair that you've left so many of us who are legitimately suffering in chronic pain with no help. I could take steroids but you can only take so many steroids before I start to get diabetes and it affects my eyesight and my kidneys and my liver. You have got to give doctors the right to deliver the opioid medication to those of us who really need it. A doctor who knows their patient knows whether they're addicted to a drug or not if they're a good doctor. I once asked a doctor for 10 pills 10 Tylenol 3's to help me make it through to the point where I was going to get my lumbar injections. He laughed he said it's so obvious you're not addicted no drug addict would come in here and ask for 10 pills. There is a database every time someone gives me a Tylenol 3 that it's recorded in. the doctor doing the prescribing can go to

this database and see where I've received the drug and when I received it last. Doctors are afraid even in big universities to give opioids out because you've made it so difficult for them to actually treat their patients. I am 68 I think my life is worth more than laying in bed all day long. I can no longer sew. I can no longer play tug with my dog.

When I change my sheets I have to strip the bed one day wash the laundry, and then make it the next day because I'm in too much pain to do it all at once. I normally have to use paper and plastic utensils because I can't do the bending over to use the dishwasher or stand at the sink long enough to wash the dishes. I tried antidepressants I tried to kill myself while I was on them. I'm one of those people that get a bad reaction from antidepressants. Lyrica and gabapentin these drugs are highly addictive. When I take those it's like somebody gave me too much to drink and I feel drugged. I can't take those either I took gabapentin once a very low dose and the next day I fell down the steps to my house. I'm telling you if something doesn't change I don't want to live to be 69 because I'm doing nothing. I have a lot that I could offer this world still yet I'm forced to not be able to because I'm in so much pain all the time.

I implore you to please fix it so that doctors can prescribe these medications to patients who legitimately need it. Think about yourself,would you want to live in the pain I am in when I could get relief?

Denise Irwin

From: D JAEGER
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:35:12 PM

I suffer from CRPS, also a senior citizen. I developed CRPS after a work injury. My brain protects the injured limb as if it is still a injured. It’s been 8 years of pain pills and needing more and pain clinics providing more pills. After all this time of getting worse and wanting to cut my leg off or die, I tried marijuana. It helps so much that you wouldn’t believe it. It should get FDA approved and should take as long as these vaccines for use. Now WI it’s not legal and needs to be changed. Also I had to withdraw from all the opioids I was on. It was beyond horrible to do until clean. Please help me to get this a schedule1 drug to help so many many people.
Debra Jaeger
Modified01@hotmail.com

Sent from my iPhone

From: David James
To: NCIPCBSC (CDC)
Subject: regarding the Board of Scientific Counselors, National Center for Injury Prevention and Control Meeting of July 16, 2021 - Opioid Prescribing Guidelines
Date: Friday, July 23, 2021 9:07:46 AM

Centers for Disease Control and Prevention, Department of Health and Human Services, regarding the Board of Scientific Counselors, National Center for Injury Prevention and Control Meeting of July 16, 2021,

There isn't an ongoing debate about Opiates among experts. Instead, there are a handful of organizations and academics with clear conflicts of interest that continue to ignore the preponderance of evidence.

TRUE addiction is a genetic predisposition to hyper-respond in the reward center and might trigger obsessive seeking to satisfy the craving. WE KNOW only 4 in 1000 have that genetic predisposition to addict 996 in 1000 do not.

Opiate use disorder is the kind of trouble someone who is not sick gets into when withdrawals come around, they fear withdrawal and so take and take. They are not addicts in any way, they simply fail to complete withdrawals and focus on a better life with their otherwise good backs.

The story about Portugal is very interesting. The problem was so bad that they HAD to try decriminalization of small amounts, ...and to everyone's surprise, it worked. It seems counter-intuitive but it is just what we already know; Prohibitions of anything kills.

It is unfortunate that the flood of illicit fentanyl and heroin paralleled the proper realization of under-treated severe pain and that instead of picking out the tangle – a blanket cut-off of medicinal opiates began and even became a major opportunity for greedy, insincere, or misguided 'self-styled' anti-opiate zealots to rape pharmaceutical manufacturing and steal assets of individual doctors, even imprisoning them, thinking NOTHING of devastated incurable severe pain sufferers.

"Simplifying the complexity of prescription decisions into a framework of guidelines transfer the focus away from the care of the patient and towards the guidelines themselves."

Regards,
David James
Waukesha, Wisconsin

From: Dave Jones
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:31:24 PM

Ladies and Gentlemen,

I urge you to reconsider this, yet another draconian abridgement of valid medically required pain control and management.

As an Army Veteran and former helicopter pilot, this is necessary for those who have injury to their backs and/or spinal columns!

I fought the drug war "down South " for this country as a contract pilot and do not abuse drugs.

Due to several aircraft accidents, I sustained debilitating lower back damage resulting in surgery to repair and install hardware after almost becoming partially paralyzed with sciatic nerve crushing.

These moderate dose opioids, along with heat and cold application are the only thing that limits the debilitating pain, and allows me to continue to work versus being dependent on government aid or welfare !

Enough pain and suffering has been endured and increased horribly with the over zealous politically motivated, reduction in valid, medically necessary opioid overcontrol, including changing the status of several excellent, and LOW COST PROVEN medications !

Please consider those who suffer with chronic pain and suffering, but are, or, should, be allowed to be treated by competent medical Doctors, not politicians.

Best regards,
Doug Johnson
Ft Worth, Tx

From: Dan Jones
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:44:20 PM

To Whom It May Concern,

It is my understanding the U.S. Pain Foundation is gravely concerned that the Updated Draft Guideline presented and discussed at the meeting of the CDC Board of Scientific Counselors this past Friday, July 16, is virtually identical to the original 2016 Guideline, and fails to adequately safeguard the appropriate use of opioid pain medications for chronic pain patients who need such medications to function in life.

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusive attention on certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control than many other causes of chronic pain. Pain is pain!

Doctors should be encouraged to utilize opioid medications as an appropriate tool for patients on a case-by-case basis, and should be encouraged to prescribe those medications when they are appropriate and necessary to achieve the desired results of pain relief for their patients.

Since the introduction of the CDC Guideline in 2016, there has been considerable evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

In drafting the final Guideline, it is my hope the CDC takes these views into consideration.

Dan Jones
Greeley, CO

From: David Kenberg
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 2:18:57 PM

Hello, I want the cdc to understand the suffering of full-body Rsd,Crps is complete hell for myself and my family. Taking important meds away from us rsders. I'm burning to death for 19 years. I need help. My disease is severe and Global. You can't even begin to understand the wrath of this monster. I have no life whatsoever. RSD/CRPS is a very serious disease and I have multiple sensations that I have to fight every day like hell. I have it from my brain to my toes. Why hurt us more? This has been dangerous and horrific ect. I want to live. Your blocking the innocent people who suffer for real.There has to be some way for us and the toll it has taken on my family and friends and for me. I deserve to live and I need help Now. It's been complete hell for 20 years in Sept. I did everything I could to help myself and my family. I don't get it. Its number 1 next to cancer on the McGill pain scale. Help us please. I'm very sick and I can't do anything to stop the pain. I have a lot to say about this. It's a very serious situation. My body is falling a part and I think 20 years is enough. We call it a suicide disease because that's how we feel. I am demanding that you take action now!!!! I don't deserve this and it was a bad car accident. Driver on phone while driving and pulled out in front of us and that's all she wrote. Disabled for life. I'm 54 and I think the CDC should let Dr.s takecare of there patients that really suffer. Rsd/crps has been around since the civil war and were in 2021 and till this day our bodies are killing us. It has to be taught to all medical personnel .Rsders can teach a whole lot. I'm very tired and sick for to long. It's taken everything I worked so hard for. It is ruined my husband of 30 years and my 26 year old daughter is angry,sad,scared,it's a nitemare for both of them. I'm demanding the CDC do something please. Iv had enough after 20 years. I deserve help with my situation. I don't want to fight anymore. I want peace and no pain. It is my right to be out of hell and pain no matter what it takes. I have rights as a patient. RIGHT??? Theres so much more but my hands are going numb and I'm very tired of dragging my body around and my brain is torture as well as my body with many injuries and lots of artifacts in my body. I want my family at peace. They deserve it and so do I. I want to live!!! PLEASE Stop the cold buring,and very severe pain ect. I want a response from someone please. It's urgent at this point. My body and brain are torturing me. Please Help us. It's far to long. Learn from serious patients in severe pain. Let us teach this. You can't keep doing this and ignoring it any longer. Why??? I will wait for a reply from the CDC! Please contact me. I'll be waiting so I hope someone will respond. I have more to say .My life matter's. I hope you think the same. WAITING RESPONSE! RSDERS HAVE RIGHTS TO. Suffering emmencly! My name is Kimberly and I'm 54 years old,wife of 30 years and a mother for 27 years. My family is terrified and scared every day. We don't know what will happen to me. I'm so scared to. This is hell. I know I'll go to heaven because we, I live in hell. I hope I did ok with trying to tell you about me. Please have a heart!!!! HELP!! 911. Kimberly K. 48 kathy court brick nj. 08724. 9082789905 or 9082789906. CONTACT ME!! Thankyou for your time and understanding. Very serious condition and getting worse by the day! Kimberly k.

Sent from Yahoo Mail on Android

From: Denice LaCoste
To: NCIPCBSC (CDC)
Subject: Pain Medication
Date: Friday, July 16, 2021 11:30:38 PM

To whom it may concern. I am a 50 year old chronic pain patient, I was injured 26 years ago (4 MVA accidents) My story is similar to every other chronic pain patient, except I also have panic disorder and am 'Co-Prescribed', which wasn't a problem until your 2016 guidelines were enforced. Both conditions are debilitating and indescribable to people who do not have these conditions. I've been living a somewhat normal life - I work and have somewhat of a social life. Low MME's (only 30 MME'S) make it hard, but I get buy. I've been cut off both medications and really wanted to not be alive. Laying in bed for 9 months in severe pain was horrid for me and horrid for my family to watch. Thank god I am my daughters only parent, she kept me from doing the worst!! Eventually I found new Drs and returned to a somewhat normal life. Back to work, and back to being able to leave my house. I'm agoraphobic without my benzo, and I cannot stand for long without my pain medication. What's happening to chronic and cancer patients is absolutely unacceptable. Its disability discrimination and completely inhumane!! You and I both know that the 'opiate epidemic' is now a counterfeit fentanyl problem, not a prescription medication problem. Please, I beg you, revise the prescription medication guidelines!! Our Doctors are to scared to treat us how they know we should be treated. Our Doctors are retiring out of fear. There are not enough Pain Management Specialists to treat all of us. This could be you, your child, your mother. Cancer or a 2 second accident will change your lives and you will be very sorry! Our doctors need to stop being arrested. A heart doctor sees only heart patients, and may write prescriptions that total 20,000 heart pills a month. A Pain Management Specialist only sees pain patients, and the may write prescriptions totaling 20,000 pain pills a month. The only difference is the type of doctor they are... Please, I beg you, let us have our quality of life!! And please, let us have our doctors decide what is best for us as we are all different. I BEG you.

From: Dawn Moreno
To: NCIPCBSC (CDC)
Subject: 2016 Opioid Guidelines
Date: Friday, July 16, 2021 9:50:18 PM

The CDC can attempt to UNRING this bell over and over to appear something is actively being done to address the chronic pain patients across the US being treated as collateral damage as a result of those misleading guidelines. Who knew ADDICTS would just switch their drug of choice chasing a high? EVERYONE. So 63,000 people became the talking point while over 26 MILLION people were ignored.

States and doctors are STILL actively looking to REDUCE opioid prescriptions, no matter the condition if it's NCCP. You choose the studies that best fit your message. Meanwhile millions of patients, that aren't at risk for addiction have seen meds that help them function taken away more and more every day. Even pain MANAGEMENT doctors are adhering to guidelines while we just suffer. I SAW A NEW POSTER JUST LAST MONTH.

Meanwhile, overdoses have gone UP. NOT by NCCP patients.

My body, my choice, unless my body is in pain. Then it's the governments choice. THEY get the last word in how much I get to suffer. Is that what's costing us billions every year?

I'm one of those lucky patients that got to experience the most horrible recovery of my life after a 90 minute outpatient procedure to implant an SCS turned into a 5 hour OPEN THORACIC SPINE surgery. BECAUSE I was under the care of a pain management doctor and I was SUPPOSED to be discharged home and able to take prescription pain meds in the afternoon imagine my horror that there was NOTHING in the chart to ease my pain waking up from that surgery. 8 hours since I'd last taken any pain medication. DISCHARGED the next day without a SINGLE prescription for surgical pain. I wish your "panel" got to experience that trauma.

NOW, I IGNORE serious medical issues, already diagnosed because I can't stand going to the doctor unless it's absolutely necessary. I can't put myself through the anxiety anymore.

Ehlers Danlos, 3 herniated discs, scoliosis, occipital neuralgia, keratoconus, stenosis, bone spurs. I can't even finish this list. It's pointless. I'm a 56 year old grandmother of 5, worked 3 DECADES. BUT EVERY MONTH, my meds are on the table to be reduced. Thanks to your guidelines and MME. It's a proven FACT, NOT EVERYONE METABOLIZES at the same rate. The polymorphism testing isn't covered by insurance which would JUSTIFY why some patients require higher dosage or more frequent dosing. How about doing something about THAT. HOW ABOUT FORCING STATES TO ROLL BACK THEIR LEGISLATION. HOW ABOUT FORCING INSURANCE COMPANIES TO COVER MORE MEDS !!! MINE COVERS MORPHINE. WE CANT EVEN FIND AN ALTERNATIVE MY INSURANCE WILL COVER. So that TOLERANCE really isn't the issue is it ? Because a different form may be more beneficial, but NCCP can't get anything covered by insurance now because of those 2016 guidelines. The AMA agrees.

Thanks.

From: Dasgupta, Nabarun
To: NCIPCBSC (CDC)
Subject: Public Comment: MME/day calculations
Date: Monday, July 19, 2021 3:54:24 PM
Attachments: Dasgupta et al 2021 - MME definitions - Clin J Pain.pdf

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Dear CDC:

We are writing to comment on the BSC/NCIPC meeting on July 16, 2021. Recommendation #3 in the Opioid Workgroup report summarized deliberations on MME/day thresholds.

Attached to this email is our new analysis in *Clinical Journal of Pain* (n=4 million opioid receipients). We reviewed the scientific evidence underlying the 90 MME/day metric. We discovered major variation in how "MME per day" was calculated among the 18 studies used to establish that threshold. Even using CDC-standardized conversion factors, how the denominator (per *day*) is calculated has a 3-fold difference in which patients are identified as "high dose." Every published meta-analyses missed this definitional variation completely. We are not sure if the AHRQ reviewers were aware. We feel that our new work may have considerable importance in interpreting the evidence base. GRADE assessment, in light of our findings, would likely need to be downgraded.

Please let us know if you have any questions or if we can provide further detail.

Best,
Dr. Nabarun Dasgupta
on behalf of co-authors

Dasgupta N, Wang Y, Bae J, Kinlaw AC, Chidgey BA, Cooper T, Delcher C. **Inches, Centimeters, and Yards: Overlooked Definition Choices Inhibit Interpretation of Morphine Equivalence**. *Clin J Pain*. 2021 Aug 1;37(8):565-574. doi: 10.1097/AJP.0000000000000948. PMID: 34116543; PMCID: PMC8270512.

Objective
Morphine-standardized doses are used in clinical practice and research to account for molecular potency. Ninety milligrams of morphine equivalents (MME) per day are considered a "high dose" risk threshold in guidelines, laws, and by payers. Although ubiquitously cited, the "CDC definition" of daily MME lacks a clearly defined denominator. Our objective was to assess denominator-dependency on "high dose" classification across competing definitions.

Methods
To identify definitional variants, we reviewed literature and electronic prescribing tools, yielding 4 unique definitions. Using Prescription Drug Monitoring Programs data (July to September 2018), we conducted a population-based cohort study of 3,916,461 patients receiving outpatient opioid analgesics in California (CA) and Florida (FL). The binary outcome was whether patients were deemed "high dose" (>90 MME/d) compared across 4 definitions. We calculated I^2 for heterogeneity attributable to the definition.

Results
Among 9,436,640 prescriptions, 42% overlapped, which led denominator definitions to impact daily MME values. Across definitions, average daily MME varied 3-fold (range: 17 to 52 [CA] and 23 to 65 mg [FL]). Across definitions, prevalence of "high dose" individuals ranged 5.9% to 14.2% (FL) and 3.5% to 10.3% (CA). Definitional variation alone would impact a hypothetical surveillance study trying to establish how much more "high dose"

prescribing was present in FL than CA: from 39% to 84% more. Meta-analyses revealed strong heterogeneity (I^2 range: 86% to 99%). In sensitivity analysis, including unit interval 90.0 to 90.9 increased "high dose" population fraction by 15%.

Discussion

While 90 MME may have cautionary mnemonic benefits, without harmonization of calculation, its utility is limited. Comparison between studies using daily MME requires explicit attention to definitional variation.

Nabarun DASGUPTA, MPH, PhD
True Stories About Health, With Numbers

Innovation Fellow, Gillings School of Global Public Health
Senior Scientist, Injury Prevention Research Center

Nabarun is an epidemiologist at the University of North Carolina at Chapel Hill (USA)
He studies drugs (OpioidData.org), medicine side effects, and infectious diseases
Nab also develops new tools for digital health
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From: david olshefski
To: NCIPCBSC (CDC); dvd_olshefski@yahoo.com
Subject: Comment on I Updated Guideline
Date: Thursday, July 22, 2021 4:26:27 PM

I was in a pain clinic that treated me for a Legally Chronic Disability and I was Forced off one of my treatments Opioids (I used chiropractor and a stimulator) that was effective for me to function and have a better Quality of Life ! I would like to say that the CDC guideline was too harsh for people under the care of Pain Clinics . There was a crisis at street level Addicts Heroin Fentynal and yes irresponsible Primary Care Doctors on prescription Opiods and the Fake Oxycotin pills that killed too many people .Things are clearer now with all the Data the CDC has , I hope you would loosen these Guide Lines and Allow Doctors to do their Jobs and Treat people the way they see fit for Certain Disabilities in Pain Clinics. During this Crisis Disabled Chronic Pain Patients were a Part of the Solution Not the Problem in fact in 12 years I only knew of 1 person who sold their prescriptions and they got what they deserved ! I would like my life back and be more active with less Pain than being in Pain Fatigued and always napping Thanks for Your Time to Listen !

Sent from Yahoo Mail for iPhone

From: Dawn Reaume
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:38:11 PM

To whom it may concern;
My name is Dawn Reaume and I am a pain patient for the past 14 years!
I have been dealing with unrelentless neuropathic pain!
I have Several comorbidities diabetes, spondylolisthesis , degenerative disc disease, spinal stenosis, bulging disc's, 4 root nerves from my left side being compressed, Fibromyalgia, Charcot foot deformity, and even an amputation 1 1/2 years ago Of my right leg!
Both my lower extremities and my upper extremities are involved!
Since the 2016 guidelines were put together it has excluded people like me who have followed all their pain specialists protocol this includes drug tests and not excepting pain medication from any other doctors! I give him copies of all my medical records from other doctors who are involved in treating my diseases, this includes all tests lab work MRIs EMTs, etc…
I have been with the same pain management doctor for 15 years I never had a problem but when the new guidelines came out I was quickly reduced to 1/2 The medication I has been taking for 9 years!
The pain medication helped me immensely have a better quality of life and I was able to continue raising my three children! As the reduction in pain medication begin I slowly begin not being able to do much of anything even taking a shower is much too painful!
To have the water falling on my skin is almost unbearable the neuropathy seems to have taken over my entire body!
I spend much of the time in bed in pain! I'm afraid if they lower my pain medication anymore I may have to make the decision to go to Colorado to have the assisted suicide procedure as I can't bear to live with this kind of pain and it is extremely sad that the resources are there to give me more comfort but I am unable to receive it due to restricted opioid measures! These measures were put in place to weed out the people who were taking drugs just for the hell of it but when it comes to extremely well documented cases like mine I don't think that we should have a capped limit and it should be based on the patient's need and history And the advice of my pain management specialist doctor!
Patients in my situation have been completely ignored by the guidelines I believe measures should be put into place so that we are not forced tapered or have a capped limit that is much lower than I had for the previous nine years!

Thank you for taking the time to read my story I know there are tens of thousands of other people out there with similar situations!
I feel in this day and age we have the resources to limit a persons amount of pain and help with their quality of life!

Dawn Reaume
Www.dawnreaume28@gmail.com

Sent from my iPhone

From: Donna Shields
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:36:53 PM

To Whom it May Concern,
I just read your NEW guidelines for prescribing opioids which, basically are NO different from the guidelines from 2016.
I am a 64 year old Stage IV cancer victim who, also has (Fibromyalgia, Osteoarthritis, both Cervical and Lumbar disk deterioration, Bursitis, Torn Meniscus, in need of Bilateral Hip Replacement, Addisons Disease, etc etc etc!!!!)
I was prescribed Opioids before contracting Cancer in 2014 and having my Upper Left Lobe removed due to a Melanoma Tumor. Three months later Cancer returned with a vengeance it metastasized and I am alive today due to qualifying for a Clinical Trial for Immunotherapy. However in 2015 the immunotherapy attacked my liver and was taken off the trial.
During this time my PCP was my prescriber for Opioids for Chronic Pain and EVERY TIME I went in this new Nurse had me submit a urine sample, I mean EVERY TIME such as picking my RX up, she would hold that RX until I submitted a urine. So a few times I drove there to pick my RX up and she had gone for the day and I had to come back next dY to get it AFTER submitting to a Urine Test!
This happened after I reported another Nurse who would also plat games with my RX and I felt as if she judged me for being prescribed Opioids and years later I was told I WASNT THE ONLY ONE COMPLAINING OF THIS NURSE!
Mind you, I NEVER TESTED POSITIVE FOR ANYTHING I WASN'T PRESCRIBED!!!!! One day I had an office visit and my PCP, whom I love and respect told me she was told by her Manager I had to be taken off of opioids and I have NO QUALITY OF LIFE. I am a very law abiding citizen and I feel that given my medical complexities I need these types of medications to exist!
Now I am forced to take Buprenorphine/Naloxone which, BARELY takes the edge off my pain. This all happened when the CDC me out with their new prescribing (or should I say NOT PRESCRIBING guidelines!) How is it possible to lump EVERYONE into the same mold, it isn’t possible! I have been blessed to have these years with my family due to Immunotherapy but on the other hand I have been seriously impacted by what happened to me and I now cannot do one sixteenth of what I was able to do having relief from my intense chronic pain!
You might say “Find another prescriber,” well I tried finding a DR willing to prescribe Opioids, HA that is impossible due to these CDC Guidelines, NO DOCTOR is willing to take on a patient like me who worked hard my entire life, never did anything illegal, just would like some relief before I die, I guess thats too much to ask.
However, in the years since this happened I have run into people who are prescribed Opioids by lying to the prescriber and in some cases sell their pills. SOMETHING HAS TO CHANGE, people are still dyeing at a HIGHER rate than before 2016, what does that tell you, WAKE UP!!!!!

Suffering in Massachusetts

Sent from my iPhon

From: Donald Terrien
To: NCIPCBSC (CDC)
Subject: 2022 Opioid Recommendations - Patient/Public Comment
Date: Friday, July 23, 2021 4:20:31 PM

Dear NCIPC Board Members,

I would like to state my opposition to any further restrictions to the Opioid Guidelines that would limit patient access to properly indicated medications.

I have personally suffered due to the current restrictions and, in fact, it has become virtually impossible for me to receive pain treatment when needed, which affects my ability to work and impacts my quality of life.

While there may have been some pharmaceutical companies, in the past, which did not properly emphasize the risks to more irresponsible patients, the ramifications of opioid use inconsistent with labeling is now known to virtually everyone and further restrictions are not necessary.

I am especially concerned that the CDC policies on this matter have been disproportionately influenced by third party organizations with self-serving interests in interfering with the doctor-patient relationship with regard to pain medication, for example "alternate therapy" vendors, rehabilitation and drug counseling industries and pushers of "detox" drugs (i.e. Suboxone). To be even more specific. Dr. Roger Chou was directly involved with these groups.

What's most disturbing is that these conflicts of interest were barely hidden and should have been acted upon long before by an agency so critical to the well being of Americans.

Please consider my concerns along with those of other patients when making your decisions.

--
Best Regards,
Donald Terrien
(804) 387-3809

From: Deborah Vick
To: NCIPCBSC (CDC)
Subject: Pain Management, Access to pain management for Chronic Pain Patients
Date: Friday, July 16, 2021 10:38:51 AM

As a rare disease and patient advocate options to create access to proper and whole person treatments of pain management is an absolute must.

I, on a regular basis, have numerous people reaching out to me expressing severe issues relating to proper pain management and suicide ideation. For many of these individuals, they believe, that suicide is not suicide but rather euthenasia as they have no means for managing their irretractable pain. Especially as many of these individuals have little to no support by clinical specialists and/or treatments.

As one living with chronic pain for 33 plus years, I have been fortunate to have a complimentary whole person approach to pain management. However, I have access to great medical insurance, live in a geographical area in which I have options in care, have the financial ability to cover the cost of several holistic methods and teach Mindfulness, Mindset, Gratitude and Breathwork Programs. My journey is different from so many others with my chronic illnesses and conditions. (This includes Ehlers Danlos, RSD, Severe cranial instability, kyphosis and stenosis and multiple surgical procedures for fusions, decompressions and other surgical procedures.)

In spite of all my experience in the chronic pain world and the rare disease communities (I also have Myasthenia Gravis.), I too am often not believed as to the level of my pain. As I have learned, to be able to be present, communicate and interact with others alongside my pain. My experience is not isolated as this is something that frequently is mentioned and discussed in many of my support groups.

I strongly and respectfully ask that we work with patients, alongside advocacy groups to develop patient centered care.

Thank you for your time,
Deborah Vick
--
Deborah Vick, M.Ed

RareABILITY - Non-profit Co-Founder and CEO
....Mindfully Creating Empowering Communities

From: Debi Warner
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 8:30:40 AM

To whom it may concern:

Having been a RN for over 30 years and a chronic pain patient for 20 years. Before you update a guideline for patients that fall into the categories of Chronic Pain or end of life pain management it needs to be a team effort. These are not added in new guidelines. We need to address each issue and patient.

Some of these people are Veterans. There are not enough facilities to help those with Chronic Pain.

NO One should have to live in pain. Especially if it’s effecting every day life. I agree that other things support groups, massage therapy, physical therapy yoga and acupuncture should be utilized as well as medications. It also needs to be covered by insurance which it is not.

Most people in Chronic Pain are on disability and cannot afford these extra costs.

I would be happy to help with coming up with guidance to help with these to include all.

Please do not put labels on all people that take daily pain medications.

Please let me know if you have any questions!

Thank you

Debra Warner

From: Debra
To: NCIPCBSC (CDC)
Subject: CDC opioid prescription guideline revision
Date: Wednesday, July 21, 2021 10:57:47 AM

I would like to share our experience with these guidelines:

My husband has had 2 stem cell transplants for mantil cell and. He was given 3 years to live after each transplant and has had massive chemo and radiation, leaving permanent painful damage. He has survived 21 yrs so fare.

We were doing grate, saw our provider 1x a year, he was stable with grate quality of life. I was able to go back to school and get my nursing degree.

Now our lives revolve around his monthly Dr appointments and fighting to keep him on opioid pain medication, to prevent pain from flaring his graft vs host... Stress from uncontrolled pain does this to him. Takes him from being independent to bed ridden, unable to preform any daily activities of life... no self care.

My husband was put in the position to have to try lying and gabapentin, also antidepressants for his pain... EVER thoe he had been stable on opioids for 12 years. We had tried alternatives before he was put on opioid medication, that did not help. He had every adverse reactions and side effect for those medications: Angioedema, violent mood swings, suicidal, loss of vision, constant falling, unable to walk unassisted, explosive diarrhea, abdominal cramps that coused him to role into a ball and cry, hair loss on all of torso, gva rash, difficulty breathing, serotonin syndrome... just to name a few. Many of those symptoms are graft vs host... Little to No pain control. My husband still suffers from cognitive issues he did not have before trying these medications and problems with pulmonary function.

We were forced to look for a different provider, our onicoligy team that had provided all fallow up care related to cancer tx wanted to turn this care over to pain management... They are overwhelmed with unnecessary appointments for stable servivers.

This lead to being forced to try the alternative medication mentioned above. We were also subject to mental abuse and lies. I had a copy of our referrals that stated my husband had been stable for years on his opioid medication with NO adverse effects.. Yet every pain management Dr we saw told us he was referred for addiction, that NO one can have chronic pain after chemo, that my husband was discharged from Onicoligy and was NEVER TO CONTACT ONICOLIGY AGAIN. That he was being taken of all pain medication. THAT HE HAD TO GET A SPINAL CORD STIMULATOR.. even thoe onicoligy specifically said that wasn't a good option do to his gva... he might never heal and could couse more tissue damage. These Dr told us that didn't matter... that it wasn't their problem that uncontrolled pain flares his gva... that it is ILLEGAL for my husband to be prescribed pain medication NO MATTER THE CONSEQUENCES. We were told that because he was on opioid medication he was not allowed any say in his medical care. That I was never to come to his appointments, nor was anyone else allowed to come with him. This hits the main points.

Do to the mental abuse my husband and myself have PTSD... every month we go through the anxiety of "is this the month he will lose his effective medication and be given the choice of a extremely painful death or suicide". I would also like to state neather of us had any problems with Depression, through all our previous years of dealing with mantil cell. Sents 2000. But, going through this abusive treatment by Drs and while they tried to replace his effective medications with those listed above... we became suicidal. Who wouldn't when told statements such as: Learn to live with it, you need to figure out how to take care of him off his medication or what to do with him, he doesn't qualify for pain control, he's an addict and never has had pain. I was accused by Pain management of making up his cancer and that he has never had a stem cell transplant. . Even thoe all of this is in his medication history.

Our onicoligy clinic has started a continuation of care clinic for their cancer servivers because of this type of treatment. My husband is the longest living serviver of mantil cell lymphoma that they know of. He should be studied, not abused.

I would also like to tell you about my husband tring neropathy theropy, this did help with some of his pain and returned part of the feeling in his leg and feet. He cut his opioid medication by 135 mg of morphine a day and says his reduced dose works every better now. He did this reduction in 1 month, with absolutely no withdrawals or adverse effects. He still requires over 90mg a day. We were called liers by pain management and that "No One " can self taper. They refused to call our provider to verify our statement. We have tried many treatments, this was the only effective one.

In closing I ask that you take into consideration patients like my husband. Our quality of life and his survival depends on pain control. I didn't even hit on all the consequences of uncontrolled pain, I'm sure you will read more in other letters.

Remember children are seeing their parents suffer and die from these consequences. Cancer patients are stopping their treatment because they cannot get pain medication. If we would of known this was going to happen to us over a decade after my husband's 2nd transplant we very well may have chosen death. Even thoe our children were in 9th and 7th grade.

Please look at the what is happening to Chronic Pain Patients...

Thank you for your time
Debra Winterroth

From: Dora Winters-Ruijs
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:42:08 PM

Dear Board of Scientific Advisors,

Greetings, my name is Dora Winters,
I live in Orange County, CA. Almost two decades ago, I endured a car wreck where I was violently rear ended. For years following this accident, my symptoms slowly and progressively got worse. I initially managed my pain through chiropractic adjustments, massage therapy, acupuncture and hiking. I suffer terrible pain flares from severe spinal stenosis, cervical spondylotic myelopathy and other injuries to my neck. After sitting long I can feel the discs in my neck compress and pinch. I tend to lay down rather then sit down. So I work from home these days. After sitting long I also feel pain in my lumbar and tailbone. It's getting worse as I get older and the weather gets colder. I also have neuropathy pain in my arms. Migraines lasting days. In addition to herniated disks in my lumbar area.

I suffered horrifically in late 2017 - 2019 when my doctor of nearly 10 years arbitrarily began tapering me. I was stable on 50 MME for 7 years. His hands were tied and he knew this would harm me but he had no choice but to taper me down to 20MME. That big of a dose cut left me in severe under treated pain. In addition to the taper, new policies were implemented I was no longer allowed refills. Previously, I saw my Pain Dr every 3 months. Once taper began I was expected to come in every single month for Rx and for Urine Drug Testing. I'd go from 4 times a year to now 12 times x year.

At the time, I was so troubled by these new arbitrary mandates that I wanted to just quit this new Pain Management Circus it had come to be. It felt like addictprotocsls were spilling over into pain management. I told my doctor I was going to try and stop on my own. He understood why I wanted to stop the 20MME. I left and I was was gone altogether for 15 months. In which time the unbearable chronic pain nearly killed me. I could no longer sleep. My blood pressure skyrocketed and I was living a nightmare in a continuous pain crisis. I missed much of my son's life and school during that time. Including family events. I spent many days in bed. I kept thinking maybe tomorrow the pain will subside. Maybe next month I will feel better. Maybe in a year it will finally go away. It never went away.

Meanwhile my primary care doctor took over klonopin for my anxiety that my pain doctor had been treating. But I still could not sleep and was constantly exhausted. It got to the point where I had thoughts of suicide due to ongoing pain. I believe the Clonazapam combined with the blood pressure medication prevented me from having a heart attack and ongoing panic attacks that may have resulted in a worse outcome. I also sought out a pain psychologist. She taught me how to distract myself as much as possible with art. She helped calm my daily crying spells. Also helped me get the courage to not give up hope. Months went by, a year went by, I was deteriorating mentally, physically, emotionally and spiritually.

I returned to my pain doctor 15 months later a broken woman. A shell of the woman I used to be. I never completely recovered. My doctor said he wanted to help me but he couldn't due to new arbitrary policies. I begged him, I pleaded with the doctor I once knew. We had a solid relationship for many years and he was clearly distraught to see me suffering he made a decision to honor is Hippocratic Oath and would try to alleviate my suffering. He prescribed me a new MRI. When he handed me that MRI request, I finally saw HOPE. I wanted to see why I was in so much pain too. Surprisingly, Aetna denied prior authorization. They had always covered everything previous, but apparently not anymore. I paid $1200 out of pocket and returned with a new MRI. After we reviewed it my doctor restored my medication back to my original dose 50MME. I told him my primary care doctor would not continue the klonopin if I was back in pain management due to his interpretation of the CDC GL's. So my pain doctor also took back over the Klonopin prescribing for me. He knew I was more anxiety ridden than ever and revised his professional diagnosis with my updated MRI and stabilized my life with pain medication.

Next step was the pharmacy, I couldn't believe I was able to get back into pain care. Once I got to the pharmacy, again surprised Aetna denied paying for more than one weeks worth of pain meds. It was a slap in the face. It was in the system I was deemed a new patient. I've talked to Aetna many times and just get the run around. They denied paying for the exact same medication they paid for 8 years previous. I did nothing to deserve this. Now I pay upwards of $100 a month for meds I used to pay $10 copay. My pain specialist has always been out of network so I pay $170 a visit which is now mandated monthly. The combined monthly amount of $270 plus migraine medication is killing me financially. I feel guilty spending this much money, taken away from my family, when my insurance should cover it. Yet they are all misapplying the 2016 CDC GL's. I filled my prescription and that night I was finally able to sleep again. I was able to function again. I cried in joy that my life was going to drastically improve but I also cried from loss of time and guilt knowing so many other patients were still suffering without a doctor to treat them. And the financial burden it would be to continue Pain Management for so many including myself.

It's important that we make sure doctors must be protected to freely prescribe based on his/her professional medical discretion. Of course caution and risk-benefit analysis must be assessed but the doctor is the only person with a medical degree that has evaluated the patient.

This journey has lead me to becoming a pain activist who has been studying trends following outcomes of forced tapers. I've witnessed more death and disability you can imagine. Chronic pain patients are marginalized, stigmatized, often not believed. Forced to writhe in pain because of the "fear of addiction". I have seen the damage of the "fear of addiction" mindset. The doctor will initiate a force taper to a legitimate chronic pain patient citing and often times misapplying the CDC GL As the patient loses more more medication:

The patient becomes destabilized.
The patient exhibits loss of function.
The patient is forced into disability.
The patient is suddenly treated like the patient has a drug disorder or a criminal when trying to seek help.
The patient's social life begins eroding as patient can no longer function since medicine has been arbitrarily cut.
The patient is filled with distress, anxiety, pain, despair.

We see a medical collapse, heart attack or some other major illness attributed to the taper that puts patient in the hospital. Many hospitals will not treat chronic pain.

The patients who can retain a doctor are treated like parolees who have broken the law and are now on lifetime probation. And are paying lifetime restitution for our crimes of being in pain and chronically ill.

its pertinent we make a clear distinction between people who have an addiction disorder and people who suffer from chronic pain. There must be a separation of Addiction and Dependence if we are ever going bring medicine back to compassionate, individualized patient-centered treatment. For both chronic pain and OUD. This will help stem the overdose crises. Many suffering pain patients are going to the streets out of desperation. I often wonder what percentage of street illicit fentanyl overdose deaths are abandoned pain patients desperate, dying to alleviate their pain and suffering?

The CDC claims they did not push tapering. But the GL seem to cause a hysteria in pain care as it contains implied suggestions. One example is CDC used word "taper" 42 times and "overdose death" 140 times in the 2016 guideline for opioid prescribing.
With this kind of language and the constant media hysteria around pharma litigation - How could it not be misinterpreted?

Since the GL implementation the relationship I once had with my Doctor has been compromised. His actions now are mostly fear based if he prescribes too high or too much due to the CDC's 50 - 90MME. My doctor told me he was visited by the DEA. He says there are different interpretations of the MME and he plays it safe. He will only prescribe up to around 50MME. Keep in mind, he is the last generation of doctors that were taught treating pain was a human right.

Threshold recommendations of MME's continue to be used against patients with pain to deny care often from fearful doctors. Please remove arbitrary thresholds, restore balance and support comprehensive, compassionate care. Arbitrary MME's do not factor in the science with regard to genetics, weight, tolerance, metabolism. The FDA understands this - The CDC should clearly understand as well, given the CDC is now in the business of regulating medicine.

Thank you for reading my comment and I leave you with one final quote:

“Just say no is not a treatment plan, it’s abandonment without an effective alternative.”

~Dr. Stephen Ziegler

Dora Winters

From: Donna Zucker
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:22:47 PM

Sent from my iPad. Hello. My name is Donna and I am a disabled nurse of 34 yrs with IP…intractable pain. I have a laundry list of incurable disorders and I do massage, chiro, epsom salt baths, heating pads and opiates….until you wrote your guidelines which you were not qualified to do. You do not treat pain. We live with it on a constant basis. It's not easy nor fun and we loss friends and family along the way bc they don't understand and also get angry with us for always "having something wrong" or as said often complaining and we are discriminated against by many…..and you are one government agency that's caused us to go without medical care and some have killed themselves and you are responsible and you don't care which is shameful. I am angry as you can tell bc I am in need so 3 very painful repair surgeries and one I just had done in 2017 and your insisting all wear useless masks caused my lungs to become infected bc I have emphysema from unnecessary chemo and I now need another repair done. Then a redo of foot surgery and a breast surgery that will be very painful. Why am I telling you this you ask? It's bc I can't not even get an appointment at ANY pain clinic in network here in NJ for the opiates I need everyday…..and now I am being denied necessary surgeries..plural…bc of YOU. I will never allow anyone Dr to cut me without adequate opiate meds that I NEED and not what any DR or the CDC says I am ONLY ALLOWED TO HAVE and you have based all your theories on none facts and made up info to suit your agenda and you do have one and we all know it. Several of the nurses at the clinics I've called state the Dr is afraid of loosing his license and one said they are afraid to be sued….so they won't give me an appointment. That's against the law to deny a patient care if you have the means to treat. I said I'm afraid to continue to go without needed medical care so we are at an impasse. I am throughly disgusted with YOU and all drs that are to afraid to challenge you! So to put it on the record here and to let you know these last several weeks I have called the CDC multiple times to alert them to my situation and I asked the phone workers to relay my message of this: I am in need of daily opiate pain medication that I've always been afforded and now I have none. Zero. My days are long and hard. I need surgeries. So tell your CDC people that I have made calls to people to try to find illegal opiates from anyone that will sell them to me so that I may stop my suffering if I survive bc chances are the are laced with poison and if I don't die I'll be able to book at least the 1st of 3 surgeries and I'll go from there. Is that what you want? Bc that's what you are getting. How dare you cause this level of harm to come to 50,000,000 pain patients across America when we have done nothing wrong and are now being denied medical care…and then you sit back and laugh at us! If you do care about the citizens of this county that pays your salaries then you never would have wrote such a piece of garbage in the 1st place and you would have retracted the entire thing at first mention of anyone suffering and being denied care. You do not care! You are causing children to be suicidal bc they too have chronic and intractable pain and mostly from vaccine injuries which I know well bc my son is one of them….MMR got him. I know many others and animals too that have died or have suffered from poison jabs. We are all requesting loudly…LOUDLY that you retract and INSIST all medical professionals to go back to treating all pain with opiates that are safe and necessary in all medical tool box's. Anything less then this act will prove you care only about your agenda and you are in violation of the Nuremberg code. I would hope the CDC is dismantled and all personal is without jobs. You deserve nothing less for your criminal acts of encouraging drs to deny us comfort care and threatening drs with losing their licenses bc they treat people with pain….which include surgeons, cancer Drs., palliative care Drs and primary care Drs. I have more to say and I'm from New Jersey…..so I'll stop myself bc it could get ugly for you. Sincerely, Donna Zucker
IP patient with multiple disorders and scoliosis who's never been addicted in 34 yrs and has done nothing wrong. Being denied proper necessary medical care bc of CDC interference when they have an agenda to harm us all. CDC is not qualify to comment on proper medical management of anything. The addicts are living on the streets and use illegal opiates…not prescribed. Get your facts straight! Of I die from illegal pain meds it's on you. And you won't care. How lovely is that……

From: petunia418@aol.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline CDC Opioid Prescribing Guidelinefor Chronic Pain and 2021Updated Draft CDC Guideline for Prescribing Opioids
Date: Friday, July 23, 2021 1:44:58 PM

Friday July 23 2021
RE: CDC Opioid Prescribing Guideline for Chronic Pain and 2021Updated Draft CDC Guideline for Prescribing Opioids

To The CDC,
I am writing to ask you **Please do NOT LIMIT DOSING OF OPIOIDS FOR PEOPLE WITH CHRONIC SEVERE PAIN.**
Please Allow the Physician and patient to decide the best dosing, timing and type of opioids.
Please do NOT Require Constant Insurance Over-rides and special permission.
Allow and TRUST THE DR - PATIENT - RELATIONSHIP.
Abuse of opioids is very rare among the thousands of people who require opioids for quality of life and functionality.
Most of the addiction and deaths from opioids are from ILLEGAL USE AND COMBINATIONS OF ILLEGALLY purchased drugs. Addiction is a separate issue from Pain and Chronic pain and opioid therapy.

I am one of the many thousands of people, patients, who's life has been extremely affected by severe chronic non malignant pain since 1984. More than half my life I have lived with daily unremitting blinding sharp low back pain when I sit or stand for more than 10 minutes. I went for 10 - TEN years with NO opioid therapy, living my life LYING DOWN, because sitting and standing were/are so painful, I had to go on disability - SSDI, had to give up a professional career, lost friends, my home and became suicidal due to the lack of quality of life. I have been trapped in a body wracked with pain. High doses of opioids - in my case Oxycontin and breakthrough dose oxyIR is the key to not being **A prisoner of war, A prisoner of pain** since I was just a young woman of 31 in 1984 it is now 2021.... .

In 1997 I began to see a Physician who prescribed Oxycontin, I have reasonable pain management now with daily HIGH DOSES of OXYCONTIN. And Immediate release oxycodone. This medication was and is incredible, with no side effects and no need to increase the high dose after many many years of careful daily use:
I was finally able to go back to work part time (I have a Masters degree in Occupational therapy and a BFA in Studio Art), GO TO AND SIT THROUGH CHURCH, raise a family, sit at the table to eat dinner, become an active community member, leading Scouts, both Boy and Girl Scouts. a member of the PTA and local Art Associations and Dance, hike, kayak and bicycle.
I had and have continued to try everything to reduce pain. Non opioids do NOTHING to help this pain. I am fortunate that I can afford to go to a gym, yoga classes and swimming which in conjunction with Oxycontin and Oxycodone ARE very helpful in reducing the spasms that cause the severe mechanical pain.

If my medication of Oxycontin/ oxycodone is lowered, there is much less that I can do, much more pain and a poor to horrible quality of life.

My medication does not take away all of my pain, *but about 50-65 percent, the rest is pain and life management as stated, adaptive positioning and exercise which I can not do when in exhausting severe pain .* I need the medication levels to fully use pain management techniques in life.

Lets please go back to Kindness and How it used to be. Do not put limits on time, type, amounts and make hours of picky paperwork necessary for patients to get the medication they need for quality of life.

Believe me I have wished I had cancer! Malignant sources of pain, would be so much easier, So we would not be second quessed!!

*I am **69 years old now,** I unfortunately have increasing OsteoArthritis pain in all of my joints, (I have had major Cervical surgery and have a 2 level fusion with fixation) and if after ALL these years of successful pain management with oxycontin - if my pain meds are made difficult to get and I am forced to lower, that would increase the pain I've had for so long, this will take away the ability to be a productive citizen and experience joy...* if that is the case Ladies and Gentlemen - my life will *not* be worth living.
Thank you
Sincerely
Deborah
from Massachusetts

From: Dennis W Ewing Sr
To: NCIPCBSC (CDC)
Subject: Opiate report
Date: Thursday, July 22, 2021 5:33:26 PM

Please get more feedback from pain patients before you publish another recommendation containing mme limits. This is just bad science. There is proof that some genetic types don't process these medications the same as others. In some cases a smaller dose is all their body can handle in others it takes q larger dose for the same effect. I fall into the later group.

I had a doctor that decided he didn't want to deal with the DEA and their second guessing of his practice that cut me off. I had to see several doctors to find one that would treat me. I have been in treatment for over 30 years and have tried every modality possible to get out of pain to no avail. I have spent thousands of dollars trying to get better. The only thing that helps at all is opiate class medications. I cannot take NSAIDS due to blood clotting issues and a family propensity to kidney damage from them. To continue trying to force all patients into a box for treatment is wrong medically and scientifically. If we were playing under the rules I started treatment under I would have no issues continuing treatment. I take more than the limit you are attempting to force all patients into would leave me bedridden and possibly dead from other complications. Undertreated pain increases blood pressure and stresses the body in other ways. To fail to treat pain is causing deaths and misery. I am now at the point that I am undertreated. As I age my condition gets worse and until about 10 years ago I would have had a dose increase to cover the increase in pain. I have not had a dose increase since I was put on morphine in 2013 when I had a DVT along with my other issues. I feel I am no less worthy of treatment of my pain than I am of treatment of my diabetes. The current guidelines have caused me pain and problems keeping a physician that works in pain management. Many pin management doctors are going back to anesthesiology and stopping the practice of pain management due to excess scrutiny going back to these guidelines. Please remove the arbitrary limits on dose from the next guideline. Tens of thousands of pain patients will heave a sigh of relief if you remove them.

--
Dennis W Ewing Sr

From: dkbonafede BONAFEDE
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:29:17 PM

I have had a chronic pain condition for 45 years that it took doctors 13 years to accurately diagnose as atypical trigeminal neuralgia. TN is recognized as one of the most severe pain conditions known to man, and unlike typical TN, I have CONSTANT PAIN instead of episodic pain. I had a 12 1/2 major brain surgery (micro vascular decompression) in 1989 to escape the pain. It did not work. Next I had balloon compression surgery to try to stop the trigeminal nerve from constantly firing. That did not work. A year later I had gamma knife brain surgery at Scripps—again with no relief.

Prior to these surgeries I had numerous root canals, teeth removed, the roots of teeth cut away from the sinus nerve, and took numerous medications for relief including Tegretol, Atenolol, Prozac, Neorontin, Lyrica, etc. I attended the Annual Trigeminal Neuralgia Conference in Pittsburgh and met a doctor who had some success with the use of morphine for my atypical type of TN. I gathered literature from him to share with my neurologist and primary care physician. After careful review by a team of doctors, I was put on a trial of morphine.
After taking the morphine orally twice a day in an extended release tablet, I never had to visit an ER for pain injections like Dilaudid again. I was able to teach full-time and get some enjoyment out of life. I no longer needed therapy for depression. I took 100mg. tablet twice a day with no significant side effects except occasional constipation.
Then the “war on opioids “ was called, and I became one of the chronic pain victims of your legislation.
I now am limited to the maximum dose of morphine arbitrarily mandated which is less than half of my therapeutic dose which was carefully determined over a couple of years by doctors who had treated me for decades. Strangers who have no knowledge of my medical history or of me personally control my doctors’ treatment of my condition. My blood pressure has been out of control due to the extreme highs of pain, and I have developed heart problems. (As a result of the unmanaged pain? I could not say for certain, but I never had heart problems before.)
Several times a year my pharmacy does not have enough morphine to fill my prescription. They will not give me part of my prescription and fill the rest later. They say the shortage is due to the limited supply of morphine now. I have to go to the pain clinic to withdraw the prescription and have others sent to other pharmacies who might have it. As a result, the pharmacists at my pharmacy have treated me with suspicion as though I were a drug seeker. Drug seekers don’t go to the same doctor and same pharmacy for decades without incident. I go to the pain clinic every month and give regular urine samples to “prove” I am using my prescribed pain medicine and nothing else even though I have NEVER abused my meds. Patients are treated as though they are guilty of misuse and need to be watched when they are entirely innocent.
If you have no members of your team making these decisions who have my condition, how do you know better than my doctor of 40 years what my therapeutic dose of morphine is? The deaths from opioid misuse are typically from use of street drugs and mixing alcohol with them. I have never heard of a chronic pain patient dying of opioid misuse nor have my doctors. We use our meds and do not sell them because we need them to function! Government should not be in the medical business. If a few doctors are prescribing opioids indiscriminately, there are or should be other ways to discipline or monitor them without arbitrarily setting a limit to the dose they can prescribe.
Many of us chronic pain patients are suffering unnecessarily because of your legislation or “guidelines”. Many chronic pain patients commit suicide—many of them have my pain condition. There is a huge difference between dependence and addiction. Dependence on opioids enables the patient to function and overcome their condition. Addiction does the opposite; the person seeks more and functions less. I am dependent on morphine not addicted—just like a diabetic is dependent on insulin. You cannot stop deaths from overdose of and mixing of street drugs by controlling/limiting the use of opioids by chronic pain patients. You need to go after the drug czars, not the doctors and their patients.
Thank you for hearing me out,
Debra K. Bonafede

Sent from my iPhone

From: Pam Deiter-Sands
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:35:20 PM

I am a clinical psychologist who works with people who have disabilities and acute or chronic health problems. In the past years, as pain medications have been restricted in many ways, I have witnessed steep decline in quality of life for people with severe pain. These patients DO NOT abuse medication, sell or share medication, or struggle with addiction. In spite of this, they already suffer increasing pain-related problems with sleep, mobility, productive work and resulting mental health challenges due to restriction and unavailability of opioid medication for pain. Opioid medications are effective in pain management, and they are an important resource for people living, moving and working in pain.

Please privilege and prioritize the lives of those who carefully and correctly use prescribed opioid pain medication to effectively manage pain.

Thank you,
Dr. Pamela Deiter-Sands
Connecticut

Sent from my iPhone

From: churn3@maine.rr.com
To: NCIPCBSC (CDC)
Cc: Nicole Hemmenway; "Cindy Steinberg"; "Tom Norris"; Ernest A Merritt III; "Noah Nesin, MD"; Nananda Col
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 6:38:49 AM

To CDC:
I have major concerns with the New Guidelines.

I am a person that has been living with Chronic Pain for over 20 years now. These CDC Guidelines have affected the way my Healthcare Team can make, my Tailored Treatment Plan. I live in the State of Maine and I have been seeing change from my Providers the are on my healthcare team.
Why is it each State is not up to the task of "Patient Centered Healthcare?" What happen to Treating the needs of the Patient, to help maintain a better quality of Life.

I feel that each Person/ Patient living with Chronic Pain should be able to use what Tools work for their condition. This needs to be Implemented by the Patient working with the Healthcare Team. Each time these CDC Guidelines are " updated " They are not inline with the needs a person that has been living with Chronic Pain like me. Because of these Guidelines there are many times I am not able to find a Healthcare Provider, that will continue providing my Treatments that have been working for me.

Also I have a major concern with the "serious problems identified" the CDC has stated for Exclusions of MME Dose Limits. Why isn't Chronic Pain included?

Chronic Pain verses Cancer Pain. These Two Chronic Conditions do not go away.
But the CDC is stating that because I live with a Chronic Condition, I can't get the same treatment that others do when living chronic condition like Cancer!
To me the "Pain is a Serious identified Chronic Condition."

I hope the CDC takes these comments from Patients like me and others that are living with Chronic Pain more Serious and put the Healthcare back to "Patient Centered Care" With the Patient involved with the Healthcare Team. I feel the Individuated Treatment Plans do work if the right Tools are available. In each State.
Thank you for your time,
Ernie Merritt

Patient Advocate:
Facilitator of " The Southern Maine Chronic Pain Support Group. www.painsupportgroup.org
US Pain Ambassador:

Person Living with Chronic Pain.

Ernest A Merritt III
3 Parker Cir.
Saco, ME. 04072
Email: churn3@maine.rr.com
Cell # 207-423-8189

From: Emily Brereton
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:34:09 PM

I am the caretaker of someone with chronic pain.

Due to forced tapering, he went from active and functional, a professional ballroom dancer with a satisfying career, to someone barely able to ambulate around the house, unemployed and suffering.

He is 48 with osteoarthritis.

In addition, since losing his prescription, his blood pressure has increased and he’s lost muscle mass. He lost his job and cannot find work he is able to do. He cannot play outside with our children, exercise, or enjoy the many hobbies he used to have. He cannot get a full night’s rest because he wakes up in pain. And he’s entertained suicidal thoughts, seeing no end to the daily suffering.

We have sought treatment from every other angle, we have tried every other drug or physical therapy offered to us. He was successful with opiates for over 15 years. He never needed to raise his prescription, double dip from different pharmacies, or resort to anything harder. He was perfectly fine.

Without opiates, he will never regain his full functuality, and my family will remain hovering at or below the poverty line. We have tried to tackle his pain from every other angle.

Acknowledge the good that opiates can do when properly monitored and taken. Adjust the guidelines to reflect this reality.

The current reality is not trauma-informed, it does not match the harm reduction model we use to treat addiction. Instead, the current reality is forcing millions of families like my own into poverty and suffering, and it’s not allieviating the overdose deaths we seem so keen to stop.

Stop punishing chronic pain patients for this unrelated public health issue.

Sent from my iPhone

GSK Consumer Healthcare
184 Liberty Corner Road
Suite 200
Warren, New Jersey 07059

do more
feel better
live longer

Board of Scientific Counselors
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
c/o Gwendolyn H. Cattledge, Ph.D., M.S.E.H.
Deputy Associate Director for Science
4770 Buford Highway NE, Mailstop S-1069
Atlanta, GA 30341-3717

Re: Updating the CDC Guideline for Prescribing Opioids and the Board of Scientific Counselors (BSC) Opioid Workgroup's Report of the Draft Guideline

To Whom It May Concern:

On behalf of GSK Consumer Healthcare and the millions of consumers who utilize our over-the-counter pain management products, I am writing to provide comment on the update to the CDC Guideline for Prescribing Opioids and the BSC Opioid Workgroup's Report on the Draft Guideline. GSK Consumer Healthcare urges the BSC Workgroup to consider the benefits and role of non-steroidal anti-inflammatory drugs (NSAIDs) as a first-line treatment for pain, as an alternate to opioids in pain conditions where they are appropriate. GSK Consumer Healthcare also asks that the BSC Workgroup take into consideration the recommendations of the medical experts (in medical society guidelines) regarding NSAID use, and the results of clinical studies demonstrating that NSAIDs are equally effective as, or possibly more effective than, opioids.

About GSK Consumer Healthcare

As you may know, GSK Consumer Healthcare is one of the world's leading over-the-counter (OTC) health care companies with number one positions in a number of markets, including the US, India, and Germany. We combine science and consumer insights to create innovative everyday healthcare brands that consumers trust, and experts recommend for pain relief, oral health, cold, flu and allergy, digestive health and vitamins, minerals and supplements. Some of our best-known products include Advil, Advil Dual Action, Excedrin, and Voltaren, which are all indicated for the treatment of pain related to multiple medical conditions. Our investment in scientific and technical excellence supports the development of a pipeline of new products that meet the needs of patients, payers, and consumers.

Opioids, NSAIDs, and Federal Public Policy on Pain Management

As far too many Americans know, either from firsthand experience or the experience of a loved one, the misuse of opioids can have tragic consequences. That is why GSK Consumer Healthcare is working to make it easier for Americans to access non-habit-forming pain management products over-the-counter, both through streamlining the OTC regulatory process and by collaborating with our governmental and medical partners to make it clear to consumers that there are as, if not better, effective and safer alternatives to opioids.

There is a strong evidence base, supported by both recommendations from medical experts (in medical society guidelines) and clinical study data, that NSAIDs are as effective as or more effective than opioids in a number of pain models. These guidelines and data lend support to an approach in which NSAIDs should be considered a first-line option as an alternative to opioids to deliver effective pain relief, especially given their well-defined and preferred safety profile in regards to habit formation. We highlight in this document some of the key pain states where NSAIDs are a primary treatment option for pain management. These include dental pain, osteoarthritis, migraine, and back pain for which data are available to support the use of NSAIDs, including as an alternative to opioids.

Dental procedures are frequently associated with acute and intense pain during the post-procedure period, which often leads to the prescribing of oral opioid products. However, the American Dental Association (ADA) notes that NSAIDs have been shown to be more effective at reducing pain than opioid analgesics, and are therefore recommended as a first-line therapy for acute pain management [Ref 1]. Ibuprofen and the fixed dose combination of ibuprofen and acetaminophen products are recommended by the ADA as oral analgesic treatment options. This approach is supported by a recent systematic review and meta-analysis by Choi M et al., which compared codeine-based oral products to NSAIDs for pain in post-surgery models (a high percentage of which were dental pain models) [Ref 2]. The researchers found that the subjects reported better pain score improvements, better global assessments, and fewer adverse effects when treated with NSAIDs compared with codeine-based products.

Osteoarthritis is characterized by flares of symptoms, which include pain that is generally managed by an oral or topical analgesic. The most current American College of Rheumatology (ACR) Osteoarthritis Guidelines strongly recommend topical NSAIDs (knee) and oral NSAIDs (knee, hand, and hip) as first line options for treating osteoarthritis pain [Ref 3]. Opioids are identified in the ACR Osteoarthritis Guidelines as an option conditionally recommended ‘against’ for treating osteoarthritis pain. A systematic review and meta-analysis by Fuggle N et al. evaluated the safety of opioids for osteoarthritis, and concluded that there are considerable safety and tolerability issues surrounding their use, and that they should be used after other analgesic options, and for short time periods [Ref 3]. The oral NSAIDs are a long-established option for osteoarthritis with their anti-inflammatory effect, while topical NSAIDs are also a proven option, with low systemic exposure [Ref 4].

Migraine is a chronic condition characterized by migraine attacks with symptoms including mild to severe pain that can last from 4 to 72 hours. The American Headache Society (AHS) recommends the use of nonopioid analgesics NSAIDs, acetaminophen, or caffeinated analgesic combinations (eg, aspirin + acetaminophen + caffeine) for mild-to-moderate attacks [Ref 5]. Opioids are often used in the emergency and urgent care settings when migraine specific medications are not readily available. A recent systematic review and meta-analysis by Vanderpluym JH et al. had findings in line with the AHS recommendations that included (1) NSAIDs as a first line treatment with evidence of high credibility; (2) the evidence for the use of opioids was considered to be low or insufficient, and (3) opioids were associated with higher rates of adverse effects compared with other treatment options or placebo [Ref 6]. The authors noted that despite not being recommended for acute treatment of migraine, opioids are frequently prescribed for this use in this setting.

Low back pain as a condition can be acute, subacute, and chronic with pain being debilitating, leading to the use of opioids as a common treatment option. The low back pain guidelines of the American College of Physicians, North American Spine Society, and Veterans Affairs/Department of Defense endorse the same recommendation; all recommend NSAIDs as a first line option, generally after considering non-medicated options. [Ref 7, Ref 8, Ref 9]. They also recommend opioid use, particularly in chronic low back pain, ‘only’ after other options have failed.

In addition to the evidence supporting the use of NSAIDs for pain management, OTC NSAIDs offer the added benefits of broader access, potential cost savings, and a reduction in the burden on the healthcare system. Access to OTC NSAIDs can remove the delay in obtaining an effective prescription pain relief option. However, it is important that product users are aware of the benefit/risk profile of the products, which is clearly communicated on the label. Additional support is readily available from pharmacists in the pharmacy setting, as well as through discussions with a doctor or other appropriate healthcare professionals. Further education materials for healthcare professionals regarding the available treatment options for pain management, their benefit/risk profiles, and key considerations in selecting a product may be worth consideration.

Recommended Educational Efforts

Given the data discussed above, GSK Consumer Healthcare recommends an educational program to raise awareness of the effectiveness and relative safety of NSAIDs *vis-à-vis* opioids. While GSK Consumer Health's OTC NSAIDs are available without a prescription, we encourage collaboration and discussion with healthcare professionals (HCPs) to ensure consumers/patients are aware of the full spectrum of pain relief options available to them and select the option with the most appropriate benefit/risk profile for their specific form and severity of pain, with consideration of their medical history. GSK Consumer Healthcare would gladly aid in this effort. Such an educational program should, one, raise awareness of NSAIDs among primary care practitioners, and two, provide support to pharmacists and offer them educational materials to share with consumers to aid consumers in choosing the best option to manage their pain. These materials would make clear that NSAIDs are a viable alternative to opioids in the right setting.

GSK Consumer Healthcare will continue its work to make OTC pain management products available to the American public. We stand ready to work with the CDC and its partner agencies on any efforts that provide Americans with alternatives to opioids.

For further information or if you have any questions, please do not hesitate to contact me at elizabeth.8.brewer@gsk.com. We thank you for this opportunity to provide comments and for your consideration of our views.

Sincerely,

Elizabeth Brewer, MS. MPH

Elizabeth Brewer
Global Lead, Government Affairs – Americas

References:

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5) The acute treatment of migraine in adults: the american headache society evidence assessment of migraine pharmacotherapies. Headache. 2015 Jan;55(1):3-20.
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10) Martell BA, O'Connor PG, Kerns RD, et al. Systematic review: opioid . treatment for chronic back pain: prevalence, efficacy, and association with addiction. Ann Intern Med. 2007 Jan 16;146(2):116-27.

From: Emily Cahan
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:34:10 PM

Please do not punish patients in pain.

Emily

From: Elaine Campbell
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 8:37:29 AM

I'm 67 years old. I have multiple sclerosis, lupus, rheumatoid arthritis, and right-sided hemiplegic migraines. Every day I get up with pain in my legs, joints, and sometimes my back hurts so much I feel like I'm breaking in half. I could use something for pain, but I have to stay in this state. I don't have addictions. I don't drink, I gave up smoking, and I have a regimen of exercise that has to be done every day despite the pain. Thank you.

From: EILEEN LYNCH STEVENS
To: NCIPCBSC (CDC)
Subject: Public comment on CDC hearting 7/16/2021: CDC guidelines
Date: Sunday, July 18, 2021 12:16:07 PM

To whom it may concern:
Regarding: CDC hearting 7/16/2021 on CDC guidelines.

I write in support of rescinding the 2016 CDC guidelines concerning opiate prescribing. These guidelines, as I understand it, have been grossly misinterpreted: Patients are being hurt by being denied pain control Doctors are being persecuted and being imprisoned.

I am personally affected by this.
A family member has had their medical license suspended and is in fear of prosecution.

The absurdity of this is that they were mostly treating opiate dependent people with buprenorphine.

I personally know people suffering daily from being denied treatment for their pain.

Thank you,

Eileen Lynch

From: Ellen Leonard
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline - chronic pain sufferer
Date: Thursday, July 22, 2021 3:26:33 PM

I am 70 year old suffering with chronic pain since my breast cancer diagnosis in 1996. Fast forward to 2021 my health conditions as follows; knee replacement 1998, gall bladder surgery, parathyroid disease, hip replacement, lumbar surgery, cervical surgery, soon to have arthroplasty on both hands. My rheumatologist oversees my care of osteoarthritis. I'm in pain and it radiates through my body and relocates every day. 10 years treating my pain with oxycodone 10 mg 2x daily. I manage my pain with that dose and function without medical aids. I walk 2+ miles daily. My body has been through a lot, I don't see an end until I age out, I drive 90 miles to see my rheumatologist; necessary as my county does not prescribe opioids; opiate patients are treated like criminals when picking up script(often times pharmacist does not have product) waiting times is excessive, unable to travel when script is due as can't transfer to other states; I am not an abuser I'm a sufferer. Due to opiate control my body has suffered through numerous spinal epidurals, excessive physical therapy and nume surgeries. Do not take our dignity and reduce access to pain medication particularly at end of life. Release the control for those whom have demonstrated the need for immediate pain relief.

Ellen Leonard
310.529.9855

From: Emily Peters
To: NCIPCBSC (CDC)
Subject: OWG report comment
Date: Monday, July 19, 2021 2:56:18 PM

MME guidelines have been drastically detrimental to I am at 4 10mg methadone tablets for pain a day and have been for a few years and had to beg to get that much yet because pain. My blood pressure often reaches hypertensive emergency levels. Due to the narrative that all pain patience are drug seekers it is very hard for me to get any help in ER's for this issue often waiting multiple hour to get 10mg of Percocet to add to my methadone to serve as a literal lifeline. I have asked my doctor for increases based on thes issues but I am shot down everytime and with very few doctors providing opiods anymore and dropping patients at the drop of a hat I cannot change providers. I have also been subjected to multiple failed less proven procedures over and over again. My primary care thinks it is crazy and agrees I should be on mire but can do nothing. I have even have a spinal cord stim unit from Medtronic but it has had already been replaced once and is failing again and it is nearly impossible to get service on it has been in me almost 4 years and really only worked 18 months and only as supplementary pain relief. So now I have a worse than useless implant in me as it is causing problems. Some have tried to push me into a pain pump but with my psych meds that is a bad idea plus I have concerns about getting service on it and infection. I have also gained massive amounts weight(200lbs) due to not having enough meds to allow me to even get a minimal level of activity, and often need a power chair. I am on disability mostly due to inadequate treatment, This needs to be corrected now I am only 36 and short of pain and the comorbidities it is causing relatively health, health that could be drastically by proper pain treatment. I take 4000mg of acetomphine a day, 3200mg of advil a day, 15mg of flexiril a day, wake up at 4 am for pain meds and suffer drastic insomnia, I am slowly destroying my body just to maintain pain lvls, because my doctor cant subscribe me more opioids which be safer, with out risking his practice. I am also transgender and this problem makes impossible for me to get gcs a need for my mental and physical because I cant physical take care of the needs of recovery in my condition.

I am a prisoner to pain and thus my body due to these ridiculous guidelines and state laws. All while addiction centers make million and pharmaceutical dynasties make billions off of unjustified treatments.
Please fix this.
Sincerely
Emily Peters
Adella.peters2013@gmail.com
9045342265
Jacksonville, Fl, 32211

Sent from Mail for Windows 10

From: Emi K. Wellness
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:49:38 PM

Hello,

I am living with chronic illnesses (fibromyalgia, Chronic Fatigue Syndrome, Degenerative Disc Disease, chronic atypical migraine, disc tear, bulging/herniated discs, etc.) that leave me with intractible, 24/7 chronic pain throughout my body. I am a young woman in my 30's. I recently moved from NJ to AZ and found that it is nearly impossible to receive opioid painkillers here, and I have been turned away by doctors and pain clinics alike. No one wanted to treat me.

The only clinic I found willing to do medication management is far away and doesn't take insurance. It's strict and it requires many things of me, including expensive drug tests and telemedicine appointments, medication counts, phone calls to my mom in NJ to ask her if I am abusing or selling my medication, etc. It has been hell here trying to compete with drug dealers and drug addicts.

The CVS pharmacy across the street from me (I don't drive and I am physically limited) refuses to ever fill my prescription because every pharmacy here has limits on monthly opioid medications. It makes no sense to me. Since I am new to the area I am simply tossed aside. I am not given the right to get my medication from my nearest pharmacy.

I cannot function without my painkillers. I can't go out and see people, enjoy my hobbies, sleep, work or relax. It is far from what I want but that is my life now, as someone with a disability that robbed me of my past life in 2015. I spend so much on medical bills, and still I cannot get the medication I took for years without paying hundreds of dollars a month.

It took months to find this clinic and I seriously considered taking my life after realizing that I would be forced to go through withdrawal before dealing with horrific, debilitating pain, with nothing to help me. I wanted to die, because my quality of life is seriously stunted. I try to enjoy life every single day, and I appreciate everything in it. But if I have to live in much more pain than this, then it is hard to say if it's worth living.

Please change the rules. I understand addiction and drug abuse are serious things and that people are dying as a result. I also understand that many pain patients are being denied the medication that allows them to have any life at all, and many are turning to suicide as their only alternative. I take this medication to survive and to thrive. I have no desire to get high on my meds, to take more than prescribed, or anything along those lines. I never have. I simply want my pain to be at least slightly manageable so I can get out of bed and live. That is all. And that is all that most pain patients want.

Do not forget the millions of us who are suffering. Do not cut us off of our painkillers just because others choose to abuse or sell them. Most people with chronic pain take their pain meds as prescribed and do not become addicted. Tolerance is not addiction. Pain relief should not be so difficult and stressful to achieve. There are always two sides that must be taken into account.

I am not dying of cancer, but when I was bedridden and crawling on my floor trying to get to the bathroom, I couldn't really tell the difference and neither could anyone else. I suffer at a near intolerable level ON my medication. Please allow pain patients to take the level of medication they need to relieve their pain. Please open your minds to holistic methods as well. Do not forget about those who are suffering with chronic pain disorders! Life is already difficult enough for us. Please don't shut more doors in our faces. We are begging you to see our perspective and to see our suffering. Please.

Thank You,

Emi

Mental Health/Wellness Advocate & Mentor, U.S. Pain Foundation Ambassador, Chronic Pain/Illness Warrior

From: Fred Bonsmann
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:34:49 PM

What is a pancreas transplant patient so pose to do.theay took out my pancreas and then I never got a transplant now I have sivear adhesions tyeing off my internal My Colin and kidneys I have had six surgeries and more to come and I sopose to go with out pain meds I would like to see one of those politian go through this they have no idea what they are talking about.

In the early 2000's when this alleged opiate crisis started, I like many others bought into this opiate crisis propaganda. Then they started criminally prosecuting doctors. Eventually I was prosecuted, merely for not kicking very ill patients out of my practice due to slight improprieties in their urine drugs screens, something that was not the governments business and was between my patients and myself. Although I won my appeal, and my convictions was reversed, the lies, deception by the DEA and FBI, including harassing patients into speaking against me even if it wasn't true, made me question the validity of this so called opiate crisis. My patients and their families started to complain to authorities about the rise in drug sales by local dealers, only to fall on deaf ears. Yet, every day we read about some Physician, midlevel such as Nurse practitioners and even nurses being prosecuted. Patients who suffering from chronic pain due to various conditions are being told that they are lying and being labeled as addicts., and the Doctors who were helping them are going to jail. The government, FBI and DEA have taken on the role of Doctor, with absolutely no medical training. Anyone else doing what they are doing would be accused of practicing medicine without a license, and facing legal action even being accused of murder. But someone has given these entities, FBI, DEA and even medical boards immunity to make whatever accusations they want no matter who it hurts. 60,000,000 people in the USA suffer from chronic pain. That is over ten times the people who suffer from addiction. I have been a Physician for 28 years. Addicts can take control and I stand behind this 100%, but chronic pain patients cannot since they suffer from debilitating medical conditions, many of which have no treatment other than symptomatic, which are life compromising and threatening. Yet addicts are getting a pass, while patients with chronic diseases are left to suffer. That I know of, 62 of my patients with chronic diseases like lupus, MS, RA, chronic lyme and now post covid syndrome due to government complacency, have committed suicide. Why should addicts control the pleasure they get from opiates, stimulants and benzodiazepams like Ativan and valium since the government has giving them a pass by passing on the blame of their selfishness to someone else. Despite the fact that those in need of opiates due to chronic medical conditions far outnumber people with chemical dependency. Addiction is not a disease, it is a choice based on biological needs that can be controlled, like child pornography.

The data from the 1990s absolutely without a doubt show that there was never a rise in prescription drug abuse. Modern day analysis shows that less than 3% of drugs abused have involved prescription drugs. Data from the 1990's, when the government told us that we must address pain and suffering, calling it the 5th vital sign is lacking. Then sometime between 1998-1999, you chose to criminalize opiates. Starting about 2000, there was a sharp rise in heroine, synthetic heroine but prescription opiate use remained no different that in the previous decades. This abuse of illegal street opiates has now reached biblical proportions, up to 1040%. Yet they continue to prosecute Doctors. 80% or so are of color. The remaining 20% predominantly take care of people of color. They tried misleading us into believing that this rise in illegal drug use from 2000's on was due to an increase in prescribing of prescription opiates in the 90's. They know this is a bold face lie. This happened because legitimate patients had to reach to illegal street drugs due to inappropriate government collusion. I had an 88 yo cancer patient die of synthetic fentanyl after only one use. And what are they doing about street fentanyl? All we are seeing is an increase in doctors prosecuted through lies and deception.

This is clearly not a war on drugs, but a flagrant war on doctors and chronically ill patients. Why is the federal government is doing this is? I hate to speculate, but they are causing harm to people with chronic medical conditions, which one day will be all of us with post covid syndrome will now join the party. We ask that this unlawful attack cease immediately.

From: cppadvocate2831
To: NCIPCBSC (CDC)
Subject: Guidelines
Date: Friday, July 23, 2021 10:58:57 AM

Agency: FOOD AND DRUG ADMINISTRATION (FDA)
Document Type: Notice
Title: Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; Public Workshop; Request for Comments
Document ID: FDA-2021-N-0275-0001

Comment:
To the OWG Members: I'd like to begin with the obvious: this was never a CDC issue to begin with. This is the FDA's business.

I personally find the guidelines INSULTING to patients and their providers-particularly pertaining to the issue of co-prescribing benzodiazepines and muscle relaxers concurrent with opiate pain medication. One of the biggest struggles that goes along with chronic pain is anxiety and depression.

Our providers have obviously considered the risk versus benefit aspect. As patients, we are familiar with the risks and benefits, as not only our providers and pharmacists review such information; but we know how these medications work (or don't work) for us. In addition, benzodiazepines are often very helpful with neuropathy and problems like tarlovs cysts. Most of the patients affected by these guidelines are "Legacy Patients", such as myself.

I've been in pain management since 2006 for severe, intractable, debilitating chronic spinal pain, multiple herniated discs, DDD, severe fibromyalgia, spinal stenosis, nerve damage, spasticity and several other related conditions.

Each one of them is extremely painful on its own...together, they make life a living HELL. Simple tasks are exhausting. Completely exhausting.

Fortunately, I have an intrathecal pump that literally keeps me alive. The medication delivered directly to my spine keeps me comfortable enough to sleep for a few hours at a time. In addition, I take anxiety medication...and without it, I would have constant heart palpatations and other problems. I use it responsibly, as most legacy patients do.

Because of the guidelines, my doctor took away my break through medication. Though the pump does a fairly decent "job" controlling my spinal/nerve pain, I still have neck and all-over fibromyalgia pain that affects me quite considerably.

The dose in my pump has been lowered too, as my doctor is afraid to be "flagged" and targeted-as are most these days. (PLEASE remove the MME limits!!!)

Since when does DEA equal M.D.? It seems as though doctors are being targeted because they have addresses and assets and much easier to find and indict than cartels and drug dealers. The biggest problem we face is the illicit abuse. Many will "blame" doctors and rx opiates, but this has been proven to be false over and over again.

What have we come to when a child with bone cancer is only offered Tylenol for pain???

I am not only fighting for my own rights to adequate and proper healthcare, but for future generations as well. I worry that one of my children will end up with my condition(s). That scares me so much, it's indescribable. Without my children, I would have given up years ago when the entire healthcare system started to fail us.

I have a 16 yr old neice with severe spina bifida whom I also fight for. She is not currently on daily pain medication, but what happens when she ends up needing something? She cannot take NSAIDS and we all know that Tylenol is pretty much only good for a fever.

I have friends and family who are Veterans-they've either been forced to an addiction clinic for minimal pain relief (which only flags them as having OUD, and interferes with their healthcare across the board) or left with no options. These folks have or are fighting for YOUR FREEDOM!!! Why are you supporting a document that harms them?!

This has become such a tangled mess and only you can begin to untangle it. We are dealing with so many issues, including insurance companies denying payment and/or requiring pre-authorization for opiates, surgeons being paid more to NOT prescribe, pharmacies not wanting to get in trouble with the DEA, therefore claiming to be "out of stock".

Now with the enormous settlements by the manufacturers, we are worried the "well will be run dry" and it will be even more difficult to receive treatment.

Addiction, though very serious, is a separate issue. So many addicts go to rehab and are told it's "not their fault" for the choices they made. They blame a doctor who did surgery years prior to them choosing to seek out and use heroin or other illicit substances. We do not divert our medications because we need them!!! We are [partially] being punished because of others' bad choices.

PLEASE end the war on our healthcare!!! We are real human beings, please treat us as such-see the harm that has been done!) I could write on and on as this is multi-faceted, but I will spare you. Again, please understand the incredible harm that this one document is doing to millions of people, not just here in the states but globally.

I know that it is hard for others to understand what we go through, so I ask that you please consider all of the comments with compassion and understanding. Thank you.

Sent from my Galaxy

From: Calise, Gian
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 10:27:58 AM

Thank you for your attention and for your ongoing efforts to keep the public safe.

I urge you to draw a line in the sand regarding the well-intentioned steps we must take to manage the harmful impact of opiate abuse to the public. Specifically, that those in need of chronic pain management NOT BE DENIED access to appropriate pain medication.

I was romantically involved with a person who had chronic pain following hip replacement surgery. I am closely connected to a sufferer of EDH Ehlers-Danlos syndrome. When this person awakens to dislocated bones because of her body's inability to make collagen, an essential component in connective tissue, she is in profound unrelenting pain.

The only thing worse than seeing my loved ones in such discomfort is that they are frequently denied treatment, coverage and empathy from our well-intentioned health care system.

Deny the drug abusers access. protect them and us from the consequences of improper opioid access. But do so knowing full well that your highest mandate is to ensure those who legitimately depend on these drugs have access. First do no harm to these chronic pain sufferers.

I have seen the damage pain can cause when untreated... do better than that by representing this minority's valid needs.

I've never taken an opioid pain killer. I have zero financial incentive to oppose or promote them. I write out of experience and compassion. Thank you for your time.

Gian Calise
20 Scenic Dr.
West Warwick, R.I. 02893
drawman623@aol.com

From: Gerard
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:23:28 PM

I suffer from RSDS/CRPS; severe Rheumatoid Arthritis throughout my body; and advanced Spinal scoliosis, stenosis, and multiple herniated discs. I need opioids in order to live a full and normal live because of my extreme pain. I still volunteer to teach art at The Fleisher Art School in Philadelphia; moreover, I continue to produce award winning artworks in my studio. But my pain conditions are limiting my life now.

People abuse what they will abuse, including whiskey, television, and adopting laws that interfere with the personal good of others! I should not be punished because of my physical disabilities. It makes me angry that Puritanical views on pain treatment prevent people like me from experiencing life to the fullest.

Sincerely, Gerard Di Falco
2201 Cherry Street
Philadelphia, PA 19103

Board of Scientific Counselors
Meeting Re 2022 CDC draft Opioid Guidelines

Dear Chair, Ladies and Gentlemen,

I am Gary Franklin, Medical Director of the Washington State Department of Labor and Industries, and Research Professor at the University of Washington. It is my honor to represent the public agencies in Washington State in support of the updated 2022 CDC draft opioid guideline as discussed in a report by the Opioid Workgroup (OWG) at the July 16, 2021 meeting of the Board of Scientific Counselors. In 2005, we reported the first deaths in the US in a peer reviewed journal related to prescribed opioids-these were 32 injured workers who received prescribed opioids through worker's compensation. None had any illicit drugs or alcohol on board. We also found a huge increase in opioid doses starting in 1999 with the so called intractable pain regulations, that made opioid prescribing inappropriately permissive based on false information on opioid safety. This was the start of the flood of opioids in Washington and in the nation. The US is still far ahead of all other developed nations in prescribing opioids. So even today, even with all the terrible fentanyl associated mortality, 28% of deaths are still associated with prescribed opioids. In addition to the morbidity and mortality, we and others have found a sharp increase in work disability among those prescribed opioids early on following a routine injury. In a Class I prospective cohort study, we found that just 2 prescriptions or more than 7 days of an opioid in the first 6 weeks after injury doubled the risk of disability one year later.[1] Thus, the heightened emphasis in the draft 2022 CDC guidelines (as discussed in the OWG report) on acute and subacute prescribing is totally appropriate. The opportunity to prevent inappropriate, or simply inadvertent, transition from short-term to long-term opioid use, both after acute injuries and post-operatively, is perhaps the most important component of both the 2016, and draft 2022 guidelines as reported in the OWG report. Finally there's been a lot of discussion about the dosing thresholds and a strong suggestion to remove these threshholds from the recommendations by the OWG. We have reported huge odds of mortality in our Medicaid population from combinations of opioids and benzos and sedatives even between 50-100 mg MED/day.[2] In one particularly vulnerable group, older adults, in whom mortality has increased, overdose events were 60% more likely with opioid doses at 20-50 mg/day MED, and nearly double with doses >50 mg/day MED compared to the average dose of <20 mg/day MED.[3] We would keep the thresholds in the recommendations, or make them guiding principles, not just contextual notes. Our survey work indicates that most primary care providers want and need such guidance on opioid dosing.[4]

Thank you for the opportunity to comment on the BSC proceedings and the OWG report.

Gary M Franklin, MD, MPH
Research Professor
Departments of Environmental and Occupational Health Sciences, Neurology, and Health Services
University of Washington

Medical Director
Washington State Department of Labor and Industries

References

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4. Franklin GM, Fulton-Kehoe D, Turner JA, Sullivan MD, Wickizer TM. Changes in opioid prescribing for chronic pain in Washington State. J Am Board Fam Medicine 2013; 26: 394-400.

From: gwenn@uspainfoundation.org
To: NCIPCBSC (CDC)
Subject: Crucial Comments on Updated Draft Guideline for Prescribing Opioids
Date: Thursday, July 22, 2021 9:24:20 PM

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control
Board of Scientific Counselors

- The majority of the changes in the Updated Guidelines are almost identical to the original guidelines and not beneficial to people with any type of chronic pain.
- There is no scientific evidence supporting the arbitrary use of MME dose limits. The FDA has even called this into question.
- There is bias in the evidence. A biased focus on risks and harms of opioids with no discussion of the benefits of opioids for pain relief when used appropriately.
- Many physicians have either ceased treating chronic pain patients or fired patients because of the deterrent effect of the guidelines and fear of losing their licenses due to witch hunts.
- The guidelines fail to rectify or even acknowledge the numerous problems identified by identified by researchers, clinicians, pain management experts, patient advocates, and patients.
- The guidelines fail to recognize that best practice in pain management is a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options.
- Drug overdose deaths in the United States rose 29.4% in 2020 to an estimated 93,331, which proves the failure of the CDC approach to drug overdoses. Arbitrarily restricting prescriptions by physicians has clearly failed to solve this crisis.
- The guidelines penalize chronic pain patients and criminalize physicians, but without a concerted effort to confront recreational drug use, substance abuse in general (including alcohol), the seemingly unchecked flow of fentanyl into this country, the CDC is fulfilling a populist political role but abandoning its medical duties.
- The exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!
- **Basing decisions on pain and function shows a lack of understanding that some people may never be able to regain functions and opioids are the only treatment that can lower their pain levels and provide them a quality of life. Take that away and suicide is their only answer.**

I am hoping that these “comments” are not disregarded but will be incorporated into the new changes, it will save lives.

Sincerely,

Gwenn Herman, LCSW, DCSW, and person with over 25 years of pain

From: Gayle Miller
To: NCIPCBSC (CDC)
Subject: CDC guidlines causing injury and unnecessary deaths.
Date: Wednesday, July 21, 2021 3:56:51 PM

I was an RN for nearly 30 years working in Rehab Facilitys...
I began as a Nurse back in 1990. And worked as a nursing assistant for 10 years prior to that.
I was in management as an RN.
I worked closely with Rehab much of the time.
I specialized in Assessment.
I was also brought into one of Seattle's largest Nursing Homes to do a total re do of their nursing restorative program which state officials told me it was one of best they had ever seen.
I have worked as a staff nurse early in my career , treatment nurse, assistant Director of Nursing, turned down Director of Nursing services many times.
RN rehab Nurse... But was involved in or was head of The Assessment Process thru much of my career.
I was sought out and recommended for the assessment position thru out my career.
I am not blowing my own horn, but simply saying I have years of first hand knowledge and education in this area...
Front line experience!!!!
Let me tell u a story that repeated itself over and over again for years!!!!
A fully independent and cognitively fully intact little old lady brings cupcakes to church for the church social. She gets out of her car and trips on the curb. She breaks her hip.
Pre mid 1990's she goes to the hospital and get a new hip. She is sent to the rehab center for a few days of therapy so she can go home and be independant again. She comes in on IV pain med line still in her arm from the hospital and with orders for a low dose opiate on a taper for a week so she can get up and participate in therapy, get up to the bathroom, ect... Have reduced pain after the surgery just because its the Humane thing to do!!!!!
She does very well and gets to go home in a few day or by end of the week. She did not get addicted nor have any adverse side effects to the meds. She returned to independent living and lived on..... Great Outcome!!!!! Saw this over and over again!!!!!!
Then comes medicare making these nursing home doctors write out pages of justifications for using pain meds in any serino, which he does not have the time to do in the first place.
Pages of justifications to state the obvious. He can't do it. He crys and decides to retire because he can not in all good conscience practice medicine any longer and see his patients suffer, not get well, and die a unnecessary ugly death.
Yes this is true!!!! Absolutely true!!! He like so many nurses who watched these people suffer immeasurably and die because of this... just found it insane and inexcusable!!!!!
The new serinos then begin.
Little ol lady independant and cognizant trips on curb. Breaks hip. Has hip repair. Goes to rehab facility , is alert and oriented fully when she arrives and is motivated to get her therapy and go home and return to independant life. See her worried kids and grand kids, her aged sister. Her husband.
But when the IV meds from the hospital wear off she is in horrific building pain. She begs for pain med. She knows she came with an order for one.
But yet she does not get any. At best she might get a tylenol that does not help the pain of this fresh surgury at all!!!!!
She crys out in pain!!! She screams and weeps in pain!!! She begs for something for pain!!!!
You can hear her crys thruout the hallways.
She can't eat, she can't sleep, she can't be moved so she can be toileted so she soils her bed

over and over. When staff go to clean her she cant tolerate being touched. She begs for the nurse to come. Staff insist on cleaning her and when they try she strikes out in pain.
Staff tell nurse she is combative and Dr is called. He orders antipsychotic meds. The does just kept getting increased. She is out of it now.
Still not eating. Not alert and oriented. Still in pain but not crying out as much cause she is doped.
She still can't participate in therapy. Therapy says she refuses therapy rather than she cant participate ...
Family's come in the next day and their loved one is not the same. They are told it's the effects of surgery and anesthesia often times.
This is a lie!!!!!
This lady then eventually dies. She gets pneumonia from being bed bound, starves to death because she cant eat. Has a stroke because of the psyc meds, She has a dx now of failure to thrive and she is left to die!!!! Absolute truth!!!!!
Over and over again!!!!!!!this happened!!!!!!
If a nurse tried to intervene she could loose her job.
Some family's who were not so gullible took their loved one home right away AMA, and to their PCP for pain meds. Those ladys got well and returned to independence.
But most were not that lucky.
It's so sickening!!! It was so wide spread!!! So started the assessment of Pain. Specifically of pain to prove what we already knew.!!!!! Effective treatment of pain produced good patient outcomes!!! Lack of adequate pain controll produced misery and needless suffering and deaths!!!!!!!
Under treatment of any kind of pain just leads to greater pain and poor to no quality of life and suicide or unintentional deaths!!!!
So we proved it and pain became the 5th vital sign!!! Pain was vastly overlooked !! We already knew this!!! Quality of life was suffering greatly!!!
People in pain don't get addicted to pain meds normally. That's a rare occurence and most likely genetically linked. Less than 1% have the gene for addiction to opiates and there are even Gene's to prevent this addiction.
Then we did the most stupidest thing ever... we gave highly deadly benzodiazepines to people taking opiates and the deaths skyrocketed!!! The mix was deadly!!! Benzodiazepines already per CDC'S OWN FIGURES shown a high death rate from benzos alone!!!!!!
OMG what genus thought that one up!!!! But then the benzodiazepines deaths got counted as opiate deaths!!!! SHAME ON YOU !!!!!!!!!!! The public did not hear about this of course and benzos started being quietly discouraged.
Shame on you!!!!!!!!!
Opiates are save and effective for pain if taken as directed and stored properly says the FDA and have no upper limits!!! More mg's does not increase deaths or adverse events in opiate tolerant people and tolerance is to be expected!!!!
WHY IS CDC EVEN INVOLVED IN THIS??? THEY SHOULD NOT BE!!!!!
THE cost $$$$ of opiates is low. But yes if you make pain the 5th vital sign the overall cost estimates are probably very high....
Inchurance companys making record profits but delivering the worse care ever in the USA have given us the worse medical system ever!!!!!
People don't matter, just costs!!!! Doctors can not and are forbidden from practicing medicine anymore!!!!!
This is Genocide plain and simple.
I was disabled in 2016 after a failed carpel tunnel surgery!
I ended up with CRPS, Fibromyalgia, Spinal Stenosis, Chronic Pain Pain that is severe and

unrelenting!!!!
I have been undertreated for pain and mostly very limited functioning at best.
I normally have a high pain tolerance. Was very active in life... But this pain issue has destroyed my life and abilities and caused other problems due to lack of mobility... I am healthy otherwise and 62 years old.
The pain I have been living with these past 5 years or so is undesirable and not tolerable much of the time. It's insane and so unnecessary.
I am not addicted to the meds!!!! I have never felt a high from them.
I tried multiple types of injections over and over again monthly in the beginning. None helped and I am sure between them and epidural for pain that more nerve damage was done!!! Now I think I have Central Pain syndrome as well or some other syndrome. I have tried Tens, OT/ PT/ Palm Therapy, Calmare Therapy, other electrical stimulation therapy's, but they always agravated or cause increased flares in CRPS or my other Conditions.
I have not been allowed adequate pain management!!!
As mme's increased due to tolerance the med increases stopped....
The Dr's have falsified medical visit paperwork, saying things I never said or things they never said. Left off important assessment info.
All I guess to try to cover themselves from liability issues with DEA as that fear Grew.
I have lost my Dr. Now and can't find a new one. DR'S Acknowledge my Dx but they say their hands are tied!!! They acknowledge my pain verbally in person but are afraid of DEA or don't understand fully what's going on but don't want to be involved in it. They are told by their hospitals and clinics not to prescribe.
They want to help but feel they can't.
I have not had any adverse side effects to my medication. It works well if I can get an appropriate dose.... I can even live with a certain amount of pain..But when I can no longer preform even my basic ADL's it's too much!!!!!!
I can not preform my basic ADL's !!!!! The pain is just so bad!!!!!
I have written for help. Begged for help. Wrote the CDC for help, the Congressmen, the Governor , office of President Medicare... pain groups and organizations!!!! I wrote the AMA for help.
I want to live out my life !!!!
I keep struggling but have little quality of life. Now without a Dr. And life saving meds due to run out, I don't know what my fate will be...
This is all so senseless!!!! Its truly so insane it has to be deliberate!!!! Has to be about the $$$$ there just is no other rational explanation!!!!
Many things like the steroid injections we have known forever that they cause tissue damage and can lead to chronic long term pain!!! The very invasive and dangerious last resort treatments that mostly don't work are being pushed like spinal cord stimulators!!!!!
Therapy is great for short term after surgery but its horrid for chronic pain in many instances. It causes more pain.
We have known these things for forever.
What about AT121? Why is it not being used!!! It was suppose to be already released!!! Cost I would think is the problem.
New med = high cost!!!!
This is all about the money!!!
And it just can't be!!!!!
Look the baby boomers will be all dead in another 10 years or so!!!! Their cost will be gone!!!!
For Gods sake the opiates are the cheepest and most effective problem free effective meds or treatment for pain!!!!!!

We know this already!!!
People with actual pain are not abusing them!!! Not getting addicted!!!!! We know this!!!! We have known this forever!!!!!
There can not be mme limits, nor can DEA be involved!!!!!!
CDC should not even be involved and they should be providing free training now mandatory training in conjunction with AMA and FDA of all doctors encouraging Doctors to treat pain effectively. Dispelling all the lies being told!!!!!
This must happen before any more lives are lost unnecessary.
I can find No Doctor anywhere willing to help me!!! I have flown to different states even looking but can not find one. And I don't even need above the 90mme thing!!!!!!!
I have needed a back surgery since last fall for my spinal stenosis. Can't barely walk now. Loosing control of bowel and bladder.... surgeon won't do this next surgery unless my pain is better controlled before he does the surgery!!!
Says only a 50/50 chance the surgery will help and pain could be worse after surgery!!!!
I can loose ability to walk altogether while waiting. Could die from syndrome associated with this.
Who ever you are reading this I need immediate help!!!!! You may be a Dr. Yourself. You may know a Dr who would help!!! Do peoples lives not mean anything to you??? Because they are dieing all over everywhere around you!!!! Because of these 2016 guidelines you put out!!!!!
The ones you have not corrected!!!!
Should it not be up to the patient to decide what treatment they feel most comfortable with??? What they feel is safest for them?!?!?
Since they are the ones who suffer the actual conquences of treatments, can't they be the only ones who should decide what they feel is best for them?!?!?!?
For Gods sake that's just basic common sense and basic human rights!!!!
You all need to do the Right thing!!!!!
This war on drugs started as a way to controll blacks. Our own government started all the drugs in this country.
It's a war that can't be won. People can only be helped that want help!!!
We know this!!!!!!
Chronic pain and acute pain patients have never been part of the problem. Not in any significant numbers.
Unhealthy younger people not physically fit are having pain issues and other medical problems earlier in life. They are!!! They are not healthy!!! Baby boomers over all got a good start. Their immune systems got s good start.
But our whole society has gotten unhealthy. And with that medical conditions are sky rocketing. Pain issues are impacting younger people.
The pain is real. Many neurological conditions poorly understood are arising. No test for them. No cures
We need to treat pain with what we know works until a time comes we have just as effective meds or treatments that are as safe of safer....
Until we actually discover all the pain pathways and how they work... because we don't now!!!!!
You can't cut off what we have based on theory or oppinion in the meantime, especially when we have tons of data that proves these meds are safe and effective for years!!!!!
We have to rely on patients to tell us about their pain!!! There just is not a machine that can give us and verify this info!!!!
From my own work and personal experience I can tell you that pain meds are safe and effective for those that need them!! They prevent declines in health across the board!! They

maintain quality of life better than anything we have. They prevent other illness and further damage in people!!!!

Inactivity causes so many other diseases and conditions to occur very rapidly. !!!!!!

The lack of adequate pain control causes not only pain and needless suffering, but increases cost exponentially across the board because of the illnesses and injurys and conditions that occur when pain is not treated adequately!!!

This is a fact I can not stress enough!

Now I know some people in CDC have a sense of morality. They rushed to redo the guidelines at the end of 2020 and get them out because of the horrific harm the 2016 guidelines did. But then that release was stalled!!!!

We need CDC Whistle Blowers Now!!!!!

Tell who is stopping this release!!!! Tell the real story!!!

Tell it loud and far!!! Expose the corruption behind the scene!!!

What about you? Yes You!!! You, a daughter a son, a grandchild a brother or sister or mother or father a spouse or girlfriend or boy friend or husband, A loved one!!!!!

What will happen to them! To you???

Sooner or later Pain will enter your life!!! A car accident, any accident, a surgery gone bad a medical condition... you will suffer in terrible pain as they will at some point.

Will you become a causality of your own inaction at this point!!!!??? Your loved ones????!!!!!

If pain is treated effectively as soon as possible after any injury the injury will heal better and without as many complications as it would if pain is not treated effectively asap!!!!! This is a fact!!!!! It really is!!!!! We do know this!!!! Or we did know this!!! Doctors that practiced medicine knew this. Nurses that actually cared for patients knew this.

Newer Doctors got training in pain and they never were allowed to practice medicine. Potential mentors who could have taught them retired before these new doctors got out of school.

Nurses well their quality has also fallen dramatically . Saw this starting in late 80's and early 90's.

Shortages and other factors pushed Nurses thru schools of Nursing at exponential rates. People who would have never been allowed to graduate due to incompetence and general lack of needed knowledge!!! This is true. So many entering the work forse with No Skills!! Not able to do basic assessments!!!! This is a fact!!!!

The quality of Dr's has also suffered horribly!!!!!

What will you do when you are turned away from treatment of your pain????

Action is needed Now!!! Not next year, not next week! Its needed now!!!!!

Share this letter with all at the CDC.. think about this!!!!

What you do and how fast you do it to correct this insane situation will determine the future... it will determine the future of humanity itself.

It Is That Important!!!!!

It's been that important!!!!

Actual Drug addicts are unaffected by the 2016 guidelines!!! They still get their drugs!!!! It is only the people in real pain that had been getting it treated at least partially and had some quality of life without addictions or other adverse side effects that are being impacted by those guidelines!!!

They targeted legit pain patients!!!!!

Besides the suicides of people wanting desperately to live , some very religious! Some fearing Going to Hell , agonizing over just not their pain but the decision to commit suicide because their pain is that intollerable, they fear they are being forced to go to Hell!!!!!

Can you even begin to understand the anguish that is causing!!!! Even people who are not overly religious, but have that thought in the back of their heads!!!!!! Can you even begin to

understand that!!!! Seriously!!!!
Their are those honest people all their lives that would never take illeagle drugs now forced to consider that option. They don't know anything about where to obtain them or how unsafe they are. Fearing getting caught up in ileagle activitys and going to jail....
What about them???
More unintended deaths!!!
The only options here seem to be death one way or another!!!
People do have very severe totally disabling pain!!!
It comes out of the blue. Life is going along they are working and planning for the future then it strikes.
I bought a home near my home town. I was remodeling it on vacations every summer preparing it for my semi retirement. I had a 5 year plan when it struck me.
I would have house paid off. Money in the bank and I would move back home from the west coast to be closer to family in my and their remaining years. I was very healthy at the time.
I applied for and got a Michigan RN license so that was ready to go. Keeping up my continuing education hours for 2 states.
I would work part time in home care in Michigan. Have my garden, and animals and spend time with family and loved ones.
But then it started. Carple Tunnel symptoms. We had changed our software and fine motor movements got problematic. I tried ignoring it like I did most of my life. It would go away on it's own like most other stuff had all my life.
We did not run to the Doctor for every little thing when I grew up. That worked for us as it did many family's of that era.
But it did not go away! It got severe and the pain stretched all the way up into my left armpit shoulder and breast. I had to go see the Dr finally. Then specialist. Sure enough severe Carple tunnel. Therapy made it worse. The injection only partially helped for a couple months. The only way I could keep working was to have the surgury. But guess what... the pain had gotton so bad during all that My Doctor also started me on a low dose opiate. Had no issues with it and it did recieve the symptoms at first.
The surgeon discovered I had an extra mussel in each wrist when he did the surgery. He had never seen that before but he looked it up and only 2% of the population have that.
I guess he did not figure in where there were extra muscles there were also extra nerves.
Anyways I have never been a weenie so to speak so during the surgery, I watched the whole thing. Refused all meds except the nerve block itself. Talked to the Dr. During the surgery.
Thought it went well until I went back to work and suffered extreme pain upon using my hand again.
It was a holiday weekend so Dr. Couldn't see me right away. Said wear the brace over the weekend and come in Tuesday.
The same brace that I tried before the surgery that created pain!!!
Saw the Dr. He put me back in therapy which just created increased pain and swelling and awful spasms if my hand in the hours after the therapy and woak me up during those nights.
On weekends when I had no therapy this did not happen and the pain calmed down but after every therapy session this occured and got alot worse!!!!!
I kept telling them this at therapy. They didn't know why this was occurring I guess so they ignored it.
Finally after 6 or 8 months of therapy it got so bad that the symptoms were there all the time and they couldn't help but see the symptoms themselves.
Still they nor the surgeon seem to understand what the problem was and all they did was reduce therapy on the right until they said no more therapy on the right... instead they turned their focus to the left that i had surgery on 4 months after the surgery on the right hand. I

ended up with the surgeon saying i was disabled.

The pain had gotten so severe so quickly I was having epidurals and pain blocking injections done all the time it seemed. Trigger point injections, all kinds. After the first epidural attempt in my neck the pain got worse even moreso.

Injections don't usually bother me. I barely feel them normally. But with the epidural in my neck the Dr was having so much trouble even under xray guidance that he could not find a space to inject. He was actually grinding the needle into areas of arthritis tring to grind his way thru. The procedure went on 20 extra minutes tring many places in my neck but the pain got so unbearable for me and he was not getting anywhere that he stopped and said I hope some of the med got into where it was meant to go.

But after that all injections into my neck were intolerable. And I had many. None of them helped but Dr said if I don't say they help inchursnce won't pay.

It was not until I moved back to Michigan in 2016 because I could not work anymore that I got my Dx of CRPS.

I had many of the symptoms and it explained what I was going thru.

It began to make sense that therapy in Washington contributed to this. By ignoring the pain and symptoms I was having at therapy they kept the CRPS flared up until they did not go away... they became permanent!!!!

Then the epidural and many other injections being insisted on in my neck for what was actually CRPS sx. Made it worse and riled up and in constant flare plus I swear they hit nerves and caused central pain syndrome or something simular.

The pain had spread from my arm pit breast area across my shoulders , up my neck and down to my mid spine. The symptoms were just like someone slicing open my back with a knife, pouring in gas, and lighting it on fire... along with my whole upper body being crushed in the back of like a garbage truck all at the same time. These became my symptoms 24/7 and why I needed the pain med.

I had burnt my hand when fire works blew up in it when I was around 15 years old. I had 1st 2nd and 3rd degree burns out of that so I know what being on fire and burned feels like! Also when I was 8 or 9 years old I was playing and ran thru a fire pit by our cabin that I thought was dead coals but turned out to be hot coals and burnt the bottom of both feet pretty bad.

I know what being burned feels like!!!!!

No I was never crushed in the back of a fire truck but I did get my hands stuck in a wringer washer a few times washing my cloths when young. Got caught between cement blocks and bricks . Smashed hands in car doors and between logs.

We had wood heat growing up.

Cut our own trees and put up the wood. Also got old used cement blocks and bricks and cleaned them for use.

Did lots of stuff. I was always very good with fine motor movements though and and very flexible. I think I might have lots of extra mussels and nerves thru out my body actually. More nerves to get damaged by Dr's who don't know they are there.

When I left Washington The full opiate crisis had not really hit everywhere yet. I had had a few increases in my meds but I built a tolleracе to the meds or pain just got worse maybe. Then every fall I had built up a new tollerance to the meds.

But the increases needed were not being given and fear of DEA was growing.

I had a very hard time finding a Dr in Michigan. They had all signed pledges not to give pain meds all over michigan.

I found one. 100 miles away that I had to go to every month and get drug tested every month. He was abit odd but he didnt believe in a million years that pain meds could be taken away. He was arrested for a sex crime and put in prison. I could not find anyone else here. I flew back and forth to Washington to pain clinic there where I had got all the injections. They

insisted I get more injections everytime I came.
They did give me a minimal amount of meds but no where near enough to make it possible for me to do my normal ADL's regularly. I needed Wheel chair transport in airports. Taking a shower was a huge task. Flying even more difficult.
After 8 months I found a doctor here. He seemed unaware of the opiate crisis at first.
He gave me a little better pain coverage for awhile but then after a pharmacy refused to fill a half a pill increase just exceeding the 90mme and gave trouble over it... he all of a sudden woak up to it all. His charting changed. He wrote stuff never discussed and wrote stuff that was not said.
He just moved to Maine and now I have no Dr.
The pharmacist lady said, yelled at me. Why do u need these meds!!! I am not going to fill this.
I had asked to do a trial of long acting vicoden to see if it worked better for me and Dr agreed. But it was not at a high enough dose and sent me into a flare up upon my constant flared condition right away.
We had also recently tried another med at night but it didn't work either.
I was tring to turn those back into the pharmacy when I went to pick up my new increases half a pill a day but she refused to take them back and she flagged me as having them on MAPPS along with the Rx she would not Fill !!!! She said to me and I quote, " you will not be able to fill any pain med prescription anywhere , not even at Costco, when I get done with you."....!!!!!!!
That's a fact. When i went to find out if my old pharmancy would fill they said they would but when they saw the flags they called her and she told them stuff that was not true at all. Not sure if she had me confused with someone else or not???? But then they said she was threatening to turn anyone that filled and Dr to Dea they could get involved.
Then Dr freaked out and got weird. I asked him to call and get it straightened out but he never did. He was convinced my old pharmacy would fill my scripts but they kept telling me No. I told him but he said they would. I ended up having to travel 90 miles to get rx filled and at old amount not increased one half a pill. Dr to afraid to increase it.
Then I found out Dr. Hadcnot increased that rx by one half pill but by one half pill q 4 hours.... Omg what a mess.
But , this has been a problem since 2016 really. A nightmare!!!
I have fibromyalgia also. Arthritis really got worse with inactivity because I could not tolerate my normal more active lifestyle with this pain...
In 1986 I was injured. My mid back. Lifting injury caused by another person who dropped their end of things. Drs thought it was just a strain but I think tendons or ligaments got ripped near my spine in mid back. It was not getting better and I had to stop working and went back to college and got my RN had to stop more physical types of work. I was very physically fit back then. Very active.
It took 5 or 6 years of struggling with pain when I found a Dr who said I had fibromyalgia. He gave me injections into all my trigger points every 3 months ,normally around 27 injections with a steroid that numbed my back . He did 4 or 5vrounds of these and it finally settled down it saved my life. I couldn't be as active as I was but still I eas not in terrible pain all the time either. I saw chiropractor who said my neck curve went away because of this injury and eventually my L4 and 5 would wear out in a very bad way.
It did. In 2011 I had to start driving. Until then I walked or biked unless I had a partner and they drove. I needed handy cap plaquard because of trouble walking but that too settled down when I stopped walking everywhere. I took a bus to work most of those years prior to that. But it settled down with some life style changes. Just used motrin if it acted up.
I don't drink or take other drugs by the way.

But then in 2017 or 18 I blew a dics and had surgery. It was a mess in there surgeon said.
After that my low back started bothering me all the time....
Now I can barely walk.
Need a surgery that i don't know of it will help. And can't get because pain is not controlled.
Can't even find a new Doctor to help me.
I don't know what my choices are at this point....
I started smoking again. Alot.
I am tring to find a Dr. But not getting anything positive there so far. Time running out.
Maybe I will get lucky again i hope.
But this is my story!!!!
I was a Good Nurse.. I advocated for all my patients!!! Patients liked me. Trusted me fully.
But still I write this because I want to be a part of the change again that contributes to making a better world and correct injustices.
If it's the last thing I do I want to try to do that.
Not just for me but for You!!! Your loved ones, all people who needlessly suffer and die!!!
It's not Right this is happening!!!
You know i had very good disc height and excellent spinal alignment all my early life until that 1986 injury. Then things deteriorated from there. One thing impacts another ....
But to even imagine a world where we don't effectively treat pain and tru to end suffering when it's so easy to do, is just so insane!!!!
It doesn't seem real or possible this could even be happening!!!
Yet it is.... how can that be?????
You, I am writing this and hopefully someone is reading it. Someone who is not a mindless person who just goes along as they are told to.
Even typing this into my phone is going to cause me all kinds of pain in abit from now. I am not suppose to type at all but there is no way around it. I use my thumb. My whole hand has been numb for awhile now. Just sitting here to do this has my shoulders all cramped up.
I can just can't sit too long. Can't stand or walk briefly. Can't lay down long.
Please be someone who is able to see this madness occurring.
Please be someone decent who wants to and will be a part of stopping this madness.
And if you know a Dr. who will help me please email me asap
Thankyou for your time. G. Miller someone who very much wants to survive this maddness.

From: Arachnoiditis Sufferer
To: NCIPCBSC (CDC)
Subject: Docket No. CDC-2020-0029
Date: Thursday, July 22, 2021 4:25:04 PM

I am writing to say the 2016 CDC Guideline should be rescinded in its entirety because of the harm it has caused in the pain patient community and the doctors that treat us.
I suffer from a spinal cord inflammatory disease called adhesive arachnoiditis which makes pain worse than metastasized bone cancer as well as I have a genetic difference called CYP4502C9 defect whick unfortunately makes me a rapid metabolizer so the opioid pain medications which are a small but vital part of my treatment plan are several times higher that the CDC limit 90MME.The guideline has made it almost impossible for me to find a doctor to treat me and I have watched as my fellow patients who were also medically documented rapid metabolizers have lost care and then committed suicide. When my own doctor Dr Forest Tennant was raided and forced into retirement with no charges ever made my fellow pain patient Jennifer Adams a rapid metabolizer killer herself with her service revolver she used as a decorated police officer. It is so bad for pain patients I cannot find a local doctor to treat the part of me that is not sick after being abandoned by my doctor.
Please do not let even a sentence of the anti opioid special interest groups Chow represents remain. Remove the 2016 guideline and get the government and DEA out of the doctors office killing patients where they do not belong.
Gary Snook
Pain Patient

Statement to CDC
OPIOID prescribing Guidelines
Work Group Report
July 16, 2021

I am Gena Struna, a chronic pain patient of 6 years. I represent the “real world” as referenced earlier in this meeting. My access to compassionate care and pain management has fluctuated over time. I’ve gone from being the one who held our family’s daily functioning together, to becoming a burden when pain control is inadequate.

Thank you, as a group, for acknowledging that pain, specifically chronic pain, is a significant issue in our society. However, unfortunately, the scope, definition, and application of these guidelines overall are highly problematic. The writing itself is full of implicit bias against pain medication. Each one of you should know that college students learn to avoid implicit bias in first writing courses!
Doctor Cunningham alluded to the dynamic of “ideal world” versus “real world”as opposing goals in formulating the guidelines; in the real world, they are a huge problem. It makes no difference what the text says, the very definition used and assumed in the larger narrative of “opioid epidemic” lumps two very distinct populations together: 1) Chronic pain patients, who require prescription pain medication in order to function at a basic level, and 2) people with addiction illness, whose primary substances are primarily illicit Fentanyl and heroin. The overriding assumption by the general public and even misinformed providers is that “all opioids are always bad”. Pain patients AND their families are senselessly suffering because of this flawed belief. We are asking for these groups to be addressed separately to overcome the many problems of the present approach.

In practice, the guidelines have become as law, or literal law or policy, at all levels of involvement: The Federal Drug Enforcement Agency (DEA), state laws, state boards of medicine, health insurance companies, pharmacies, drug production companies, individual provider offices. Patients have an extremely difficult time finding a provider willing to prescribe any, hardly sufficient amounts, of pain medication as they are fearful of DEA overreach and frivolous legal action and/or are misinformed. Some patients have suddenly been force tapered off a dose that had worked well for them for many years, causing severe injury or death. Patients living with moderate to severe chronic pain are forced to make long trips from home to access any care they can find, or suffer from their beds as their lives are wasted away. Talk in numerous patient support and advocacy groups has evolved from discussing types of treatment for certain conditions and symptoms, to how to find and interact with a provider, to sharing suicide plans. Almost daily we lose people we know and love who were literally ignored to death by the American health medical system. The situation is DIRE.

We appeal to Dr. Walensky (Director of the CDC); we know you have a reputation of fidelity to scientific data and that you pledge to keep political influence out of the CDC. We are relying on your leadership priorities to bring back a level of quality and functioning, and to save lies of people living in intractable pain! With your help we wish to again find trust and compassion in medical care.

Thank you for your time.

-Gena Struna, Master of Science
Family and Consumer Sciences

From: Glenn Wilkinson
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:10:51 PM

I have multiple myeloma. I was diagnosed in June of 2013, and have been taking oral chemotherapy for a little over 8 years. One of the symptoms of multiple myeloma is severe leg and joint pain. It feels like someone is hitting my legs with a hammer. I get considerable relief by taking Norco, an opioid containing pain medication. At present, I can only get a 30 day supply of 120 tablets which limits me to taking 4 Norco tablets daily (2 in the day and 2 at night). My oncologist can only prescribe 120 tablets even though the instructions are to take 1 tp 2 tablets every 4 to 6 hours as needed for breakthrough cancer pain. If I had the correct supply and could take as needed the correct amount would be a maximum of 8 tablets a day. Times 30 days supply would be 240 tablets the prescription should be written for. Current regulations limit us cancer patients who are in need of valid pain medication to 1/2 of the potentially needed quantity. Why limit us to 120 tablets per 30 days? We should be allowed 240 tablets every 30 days. We cancer patients experience extreme pain and because of the current and planned regulations on opioids must ration our prescribed pain medication to try and get through each day/night the best we can.

Please do not overlook us (cancer patients). We need to be allowed to use the valid opioid containing pain medications to the fullest extent of treatment. Do no limit us to 1/2 of the quantity simply because there are other people out there who may abuse it. It an oncologist needs to prescribe 240 tablets so their cancer patient can take the allowed 2 tablets every 6 hours (8 per day) for each 30 day prescription. Put yourself in our place and see how it feels to have severe pain but only enough pain medication to take 2 tablets every 12 hours (4 per day). Please do not limit the oncologist to prescribing 120 tablets every 30 days.

I am aware your major concern is limiting the abuse of medications. However, limiting the quantity the oncologist can prescribe is not the answer. Please, at least allow ONCOLOGISTS who prescribe for their cancer patients to write prescriptions for 240 tablets. We are the ones made to suffer even more than just having cancer!

I hope this makes sense and have not rambled too much.

Kindest regards,

Jerome G. Wilkinson, Jr.
HMCS (E-8), USNavy Retired

From: Hylah Clemans
To: NCIPCBSC (CDC)
Subject: Opiods commentary
Date: Friday, July 23, 2021 4:29:47 AM

My mother, my daughters, and I were born with a collagen disease called Ehlers-Danlos Syndrome. It causes widespread pain. As such, I am one of the many millions who rely on opiate medication to control my chronic intractable pain. I am also considered a "rapid metabolizer" of this class of medicine.

When I first started opioid therapy, I was able to work, take care of my children and my home. I was stable on my medication for years. There was never any addiction, never any hint of addiction, no desire to get "high". I kept my medication away from anyone who might divert it, having no desire to suffer in agony. There was never any issue.

Then policies meant for monitoring addicts going through parole seeped into the clinical process. Though I have never failed a urine screening, I was forced to taper. I have been called "drug seeker" and refused services in an ER even though I had broken my back. I have been forced to endure procedures in the name of "pain relief", some of which have left me worse off because of my Ehlers-Danlos; others left me in screaming agony, but there was no relief given.

I use - and abuse - OTC medications daily to try to cope. I am slowly killing myself this way, but I have no choice.

I have attempted suicide to escape my pain; millions of my compatriots have succeeded. I have considered turning to street drugs; hundreds of thousands of my fellow patients are pain refugees using heroin.

I am not longer a productive member of society. I am absolutely disabled by my pain, which is absolutely unacceptable. It is also notably illegal.

I see two glaring points of hypocrisy regarding the current prescribing guidelines.

On one hand, most Rx medications have no prescribing maximum. There are dosing guidelines based on lab values, but no maximums. Each doctor choose doses tailored to best meet the needs of each individual patient with statins, beta blockers, insulin, thyroid replacement, et al. No one would ever tell a doctor that they cannot prescribe more than 15ml of insulin to a diabetic; yet this is standard practice for controlled substances, specifically sleep medications and opioids.

On the other hand, Americans are told that they are free to damage their bodies as they wish, as long as it does harm anyone else. As such, alcohol and tobacco are available for purchase everywhere. Tobacco companies are known to have spent BILLIONS making their products more addictive, and still are allowed to sell those products. However, the ingestion of narcotics is illegal-- whether because of pain, recreation, or addiction-- and is tracked by the government. Arguably, any individual ingesting heroin, fentanyl, or oxycodone is only affecting themselves.

With alcohol or tobacco addiction, the nation is reminded that the the individuals caught in the addiction cycle will do anything to get their vice substances; similarly, the nation is reminded that each individual is personally responsible for the quantities of their vice substances ingested, even when it turns deadly. None of this is considered relevant or truth when the vice substance is a narcotic, though. Why is that?

It is also essential to note that the production of prescription grade opiates has fallen 40 in recent years. IF opiate addictions were truly fueled by Rx medications, the deaths would too. Instead, opiate related deaths have risen. There is no correlation between pain medication and street drug deaths.

My physical dependence upon opiates for pain is no different than my physical dependence upon thyroid replacement hormones. I just want to have my life back. I want to be able to work, to clean my house, to take care of my children, and to be intimate with my husband. I am being robbed of that through these rules.

It is time to stop PROP, stop conflating pain patients & pain medications with addicts & street drugs. Stop the propaganda and let doctors make decisions *for their patients* with the patients, not with the CDC or the DEA. Abolish the prescribing guidelines.

From: Holly Clowers
To: NCIPCBSC (CDC)
Cc: Holly Clowers
Subject: Opioid guidelines
Date: Friday, July 23, 2021 3:14:20 PM

Thank you for the opportunity to comment anonymously. I will try to stick to a few key points. I am a physician married to a physician. We are both rare disease patients and can no longer practice. We both suffer severe pain in addition to many other life limiting symptoms, and we both have uncertain life expectancy. We should be able to access palliative care.

When I was still able to practice, prior to the 2016 guidelines, I was shocked to discover I could not find suitable physicians to refer patients to for pain management when they required opioids (skin conditions equivalent to large surface area deep burns). Access to opioid care became exponentially worse just prior to 2016 and has continued to worsen since then.

My spouse was still able to practice until he had an interruption in access to treatment. Among other issues, he has had two autoimmune diseases for decades, he is developing bamboo spine (auto fusion), and to avoid quadriplegia he was forced to undergo a complex 3 level cervical fusion after which he was given nothing for post operative pain relief on top of not receiving his baseline low dose opioid. He has never suffered from addiction.

I was stunned when my mother died in 2017 of cancer and RA with severely undertreated pain in another state. I did what I could to help her find care.

My father had a below knee amputation and received nothing for pain post operatively. I was able to advocate for him to receive 500mg of gabapentin. He subsequently died.

I lost another family member and expect to lose a 4th.

I suffer spontaneous dislocations, subluxations, and fractures among other issues, routinely. I know better than to seek care acutely because I will be accused of drug seeking though I’ve never misused any substance. I have references for reducing injuries at home. This situation doesn’t remotely resemble US medicine for a 2 physician family.

Attorneys General and DEA seem focused on going after prescribers “at the top of the list” even after massive reductions in prescribing. Pill mills are gone. CDC is facilitating the exodus of the last pain treatment physicians. Those of us suffering will be left only with providers willing to subject us to inappropriate or harmful procedures and medications that don’t help much if changes aren’t made immediately such as withdrawing the current guidelines. It is clear that there were undeclared conflicts of interest in authors for both versions. This is common knowledge.

I believe in government agencies such as CDC. You play a vital role in fighting diseases such as COVID. You are destroying your reputation as well as demonstrably making overdoses worse and destroying pain care. Please stop. Withdraw the guidelines.

Thank you again.

Sent from my iPhone

From: RockGoddess
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 9:46:41 PM

My pain is under treated.
I am no longer able, nor do I have the desire to do anything.
A few years ago I was exercising, singing in a band, and doing pretty much all the things that a" normal person" who is not in chronic pain does.
Since my medication has been cut in half, the pain has increased to the point where I am constantly tired and have no desire to do much of anything other than sit or lay down.
I am 64. I have a lot of life to live. But due to being abandoned by the medical profession, who no longer seem to care about the chronic pain community, I feel that I am destined to live my life in severe pain and unable to do any of the things that brought me joy in the past.
It is very disconcerting that this is the way the government has chosen to treat its most vulnerable. Instead of taking care of us, you choose to torture us.
I understand that there is an addiction problem in this country.
But targeting doctors who are only trying to alleviate their patients pain is not the way to attack the problem. It pretty much has been proven that the problem is illicit fentanyl and street drugs.
And the addicts that you are trying to help are being treated better than we are. We have become collateral damage.
So addicts get treated with respect,
And we chronic pain patients who are not responsible for the drug problem in this country are left writhing in pain without a life.
Is there something wrong with this picture?
I read the so-called revisions to the 2016 opioid prescribing guideline for chronic pain. And I have to say it's just more of the same. So I imagine we are going to be treated the same as we have been treated for the last 5 years, which is deplorably.
I imagine it doesn't matter to you that people are in so much pain that they're committing suicide.
For the record, Andrew Kolodny has no business making these rules.
It is clear that he is anti opioid and that he makes a ton of money as an expert witness. It is not in his interest to care one iota about chronic pain patients. In my opinion he is a monster, and I would compare him to the likes of Mengela. He and prop should be denied opiates. Let's see what happens when they are in excruciating pain. They should be prescribed a Tylenol.
If I sound angry, it is because I am. My life has been taken away from me. There is a solution to me getting my life back. But it seems the government in all its wisdom has decided that that solution should not be available to me. So congratulations on continuing to treat us like we matter not at all.
You continue to condemn responsible patients, and the doctors who want to help them.
I wonder how many more people have to commit suicide because they can't stand the pain anymore before you will open your eyes and see that opiates, prescribed responsibly will help us live our lives the way we are meant to.

Helene DiPonzio

From: Heather Green
To: NCIPCBSC (CDC)
Subject: CDC Guideline for Prescribing Opioids
Date: Friday, July 23, 2021 1:35:11 PM

I’m going to make mine as short as possible. I know you’ve been contacted by many patients AND doctors asking you to reconsider.

The simplest fact is this: overdoses keep rising. What you’re doing isn’t working because you are torturing us. Pain & addiction patients alike need careful access. Neither of us have it. Deaths will continue to rise until you recognize this fact.

We all live in fear of an early death, be it by our disorders, side effects from non-opioid options, fentanyl in illicit drugs or suicide. You are driving this with your actions.

Heather Green

903-268-4546

Sent from my iPhone

From: Hayden Hamby
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:38:37 AM

WHY is that I along with some 15 to 20 million other patients who have pain management physicians, continue to suffer and struggle with pain as per the 2016 CDC "guideline" for opioid prescribing physicians when our only "sin" is having lifetime pain issues that only a personally prescribed, tailored to need dosage of opiate or synthetic opiate medication is THE LAST way to make life a Little more tolerable, better?
I have had two very invasive spine surgeries about 25 years ago as my doctor advised, been through ALL alternative pain reducing therapies advised to me by my doctors only to find that opiate medication was and is, the LAST effective means to manage severe lifetime pain from surgeries due to back issues?
I continued to own and operate my small home building business for 23 years after two very difficult failed spine surgeries WITH a personally tailored dosage of opiate medication UNTIL force "tapered" in dosage by 80 percent (daily dosage) at the start of 2017
I was on the same dosage for about 20 years with ZERO increase prior to the publishing of the 2016 CDC "guideline".
I lost my business within 6 months of forced tapering, we lost our home, ability to go to church, all most all social function and all hope of any kind of even near normalcy for the rest of my life.
What crime have I and 15 million other pain management patients committed?
I understand that a VERY FEW patients that used/use opiate medication was the LAST effective means to dampen pain "diverted", abused or did anything "wrong" with their personally prescribed medication. I realize that there were VERY FEW licensed prescribers/providers that did "wrong " prior to the "guideline", so WHY do ALL patients nationwide need be force "tapered"? Why are ALL physicians commanded to follow a "guideline" as it is "voluntary"? Why are physicians being taken before state medical boards and stripped of their hard earned license IF not following the "guideline"?
I understand that there are always bad actors both on the patient side AND prescriber side of opiate medication but, CDC, DEA. And state medical boards took the easy way out with a maximum daily dosage for one and all patients suffering with lifetime pain, no "cure" !
This is WRONG!
People are losing their physical health, emotional/psychologic health, and taking the last resort of suicide and I believe it will........ get WORSE.
It is published (by CDC) that the covid-19 lockdown caused and is still causing great emotional strain and difficulty
due to job loss, home loss and just getting FAR behind on monthly monetary obligation. ADD......... lifetime severe pain with little to no effective means to manage the pain to covid suppression!!!.
The 2016 CDC "guideline" IS, in fact responsible for failing health among the millions of people that "live" with lifetime pain with the last, effective means of management being..........opiate medication prescribed at an effective dosage, not one maximum dosage for one and all!
Hayden Hamby Jr- 25 year pain management patient

Dueto job loss, constructive

Sent from Mail for Windows 10

From: Heather Middleton
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:50:41 PM

To whom it may concern at CDC;

While I appreciate the July 16, 2021 recommendations for opioid use, I feel you failed to consider a few things.

First, palliative care patients are not being cared for with appropriate medication because of your guidelines. They're suffering and they should not have to as they are dying.

Additionally, patients such as myself who have had chronic pain for the last 25 years and have tried everything non medicinally and have truthfully taken opioids as they are the only thing that help take the edge off my pain. I say take the edge off because I've had to cut down my dosage because of your recommendations. So I live my life in pain 24/7.

I'm more concerned however, about The hundreds of patients who are committing suicide because they can't take the pain anymore. This is never being addressed when you talk about guidelines and it should be.

Please take these things into consideration. We've waited for years for a new guideline and nothing has changed.

Sincerely,

Heather Archer

Sent from Yahoo Mail for iPhone

From: Holly Micheletto
To: NCIPCBSC (CDC)
Subject: CDC Opioid Guideline
Date: Tuesday, July 20, 2021 11:04:18 PM

To whom It May Concern:

I have been living with Chronic Pain for 28 Years. I've been working with a Chronic Pain Physician since 1999. It has been a long hard road full of twists and turns. I have tried every narcotic you can imagine, had an intrathecal pain pump, neurostimulators, injections and so much more. In 2007 my quality of life had decreased and I was experiencing an immense amount of Pain. I chose to be weaned down and off the pain pump and down on my oral breakthrough narcotics. I went from being on Disability to an active participant in life.

Until I had to move, last year, I was taking 8mg of Dilaudid up to 6 times a day, as needed. I had been selling Real Estate since 2010, Volunteering in My Community and living a pretty good life with Chronic pain, managed with my Dilaudid, physical therapy, cold laser, myofacial trigger point release, chiropractor, exercise and a Chronic Pain Management Coach. Since I moved to North Dakota my new Chronic Pain Provider wanted to titrate my dose down. I have tried and am not doing well. My pain has increased from a manageable 4 to an 8. I understand she is trying to follow the guidelines of the CDC, but it is making me less productive. I don't understand and I am now a Chronic Pain Management Coach, myself. I have added Meditation to my care, but due to my increase in pain, I'm having a hard time concentrating and working. I've never abused my narcotics and just want to live my best life. I hope you'll "hear" my story.

Sincerely

Holly Micheletto
406-939-3302 (cell)
wtsupholly@gmail.com (email)

From: Heidi Morris
To: NCIPCBSC (CDC)
Subject: Recind the 2016 guidelines
Date: Wednesday, July 21, 2021 5:37:45 AM

I have chronic pain from a dvt aprox 17 years ago. I have documents supporting pain as well as things I've tried to treat the pain. From non narcotics to a spinal cord stimulator, treatments I have sought out myself. My pain has been so bad I was literally unable to use my leg. Pain has kept me from family functions and missing out on my children's childhood. I was prescribed an opiate and took it for many years. Then suddenly was told they were no longer able to prescribe them to me. I struggled! I was then prescribed them again when a doctor saw the pain I was in. Then recently that doctor left his practice. I went back to my primary who said she would help me with pain "until I could find someone to treat me" she gave me literally 1 pain killer to last me an undetermined amount of time. There are no pain management doctors in the town I live, leaving me yet again barely hanging on. I have been on painkillers for a good portion of 17 years I have never called to get extra medication never taken more than what was prescribed to me, I have never misused them in any way! When trying to find an alternative I was told that there is nothing on the market to treat long term pain (I have been on Cymbalta and several other medications with some serious adverse reactions) The medical professionals that prescribe have to weigh treating a patient vs getting in trouble. I plead to you to change the way you look at opiates to those using them in the proper way. To some of us they are the only chance we have at a quality of live. If you have ever had chronic pain you know how much it incompasses your whole life and dictates what each day will be like. Understanding that there are people who misuse that shouldn't be taken out on us who do not! A doctor should never be in fear of losing his/her license for making a medical decision best for each patient.
Thank you for your time,
Heidi Morris

From: smf53@aol.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated CDC Opioid Guideline
Date: Thursday, July 22, 2021 10:41:49 PM
Attachments: PBM AND PAIN MANAGEMENT IN SPORTS.pdf

CDC BSC REMARKS
JULY 16, 2021

I am Scot Faulkner with the Photobiomodulation (PBM) Foundation.

We applaud the CDC's newly revamped **Opioid** and **Drug Overdose Websites**, and your recent publication:

Safely and Effectively Managing Pain Without Opioids | Drug Overdose | CDC Injury Center

We enthusiastically support the CDC's policy of encouraging Non-pharmacologic therapies to manage pain.

The PBM Foundation recommends that the CDC add Photobiomodulation (PBM) to your list of options for pain management and consider this therapy as ADJUNCTIVE to existing treatments, as well as helping patients scale back their opioid use.

Photobiomodulation is red and near-infrared light, directed at the body with the right intensity, to stimulate mitochondria repair, restore cell function, and reduce inflammation. PBM is noninvasive, and a natural process aiding a natural process.

PBM is a FDA cleared medical technology that successfully manages pain. It is widely used in Veterans' Hospitals, and leading medical centers, including Harvard, MD Anderson, and St. Jude.

PBM has been used in over 100 million patient treatments without any documented side effects.

There is an overwhelming body of evidence proving PBM Therapy's efficacy.

This is supported by over 750 Randomized Clinical Trials (RCTs) and 8,000 research studies, many published in leading scientific journals, including the Lancet.

All those suffering from acute and chronic pain should be made aware of PBM's effectiveness, and cost effectiveness.

PBM's ease of use, lack of side effects, and low cost, will save lives, improve lives, and help achieve clinical equity throughout our health care system.

Thank you.

Hon. Scot Faulkner
PBM Foundation
304-716-6235
smf53@aol.com

https://pbmfoundation.org/

PBM BACKGROUND
Photobiomodulation (PBM) is a FDA cleared medical technology that successfully manages pain and reduces opioid use. PBM has been used in over 100 million patient treatments without any documented side effects.

PBM Therapy is successfully helping Veterans with managing pain and reducing opioid use throughout the Veterans Integrated Services Networks (VISNs), including the Martinsburg VA Medical Center, the Boston Veterans Healthcare System, and the Jesse Brown VA Medical Center in Chicago.

PBM prevents the painful side effects of cancer chemotherapy and radiotherapy. The Multinational Association for Supportive Care in Cancer (MASCC) recommends PBM as the standard of care for preventing oral mucositis. PBM is now preventing cancer therapy side-effects at leading Cancer Centers, including St Jude, MD Anderson, and the Dana-Farber Cancer Institute at Harvard.

PBM Therapy's efficacy is supported by over 750 Randomized Clinical Trials (RCTs) and 8,000 research studies, many published in leading scientific journals, including the Lancet.

Here is the list of 189 active PBM clinical trials.
Search of: Photobiomodulation - List Results - ClinicalTrials.gov

Photobiomodulation (PBM) Therapy was the topic of a Congressional Briefing on October 11, 2018, a Senate Demonstration on April 2, 2019, a White House Briefing on April 9, 2019, and the focus of meetings with the Office of National Drug Control Policy (ONDCP), the Center for Disease Control's (CDC) Scientific Board of Counselors, and the Center for Clinical Standards and Quality at the Centers for Medicare & Medicaid Services (CMS).

PBM as a viable pain management and regenerative technology was presented to:
- Federal Pain Management Best Practices Inter-Agency Task Force on May 9, 2019,
- Action Planning Meeting to Prevent and Manage Opioid Use on September 20, 2019,
- CDC's Board of Scientific Counselors meetings on Opioid Prescription Guidelines on July 22, 2020 and July 16, 2021.
- The NFL-NFLPA Pain Management Committee reviewed details on PBM's mechanism of action relating to pain management.

[ATTACHED]

The CDC featured PBM treatments as part of its stakeholder engagement on acute and chronic pain.

Photobiomodulation PBM was discovered in 1967. Red and near-infrared light, when directed at the body with the right intensity, stimulates mitochondria to repair and restore cell functions and reduce inflammation. It is a natural process aiding a natural process.

CLINICAL DESCRIPTION

Photobiomodulation Therapy (PBM Therapy), previously known as Low-Level Laser Therapy (LLLT), is a low intensity visible and near-infrared light therapy which is applied to joints, injuries and the nerves that supply them [1]. The effects are analgesic, anti-inflammatory and regenerative (the light improves the rate of tissue healing) [2]. PBM Therapy is usually applied multiple times a week for several weeks, which leads to substantial relief. There is significant evidence from over 750 RCTs, and systematic reviews that show benefits of PBM Therapy is effective for musculoskeletal [3-5], neuropathic [6], and traumatic pain [7]. The treatments are safe [8] and noninvasive [9].

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THOR
THE FUTURE OF MEDICINE

CONTENTS

WHAT IS PBM THERAPY?

Application of monochromatic light to

- ⬆Tissue Repair
- ⬇Inflammation
- ⬇Edema
- ⬇Pain

PUBLISHED CLINICAL EVIDENCE

- Tendinopathies
- Joint Pain
- Sprains
- Neck & back pain
- Post-surgical pain
- Neuropathic pain
- Wound Healing
- TBI PTSD CTE

THOR RESEARCH PARTNERS

MGH 1811
MASSACHUSETTS GENERAL HOSPITAL

EINSTEIN
Albert Einstein College of Medicine

VE RI TAS
HARVARD
SCHOOL OF PUBLIC HEALTH

St. Jude Children's Research Hospital

BRIGHAM AND WOMEN'S HOSPITAL

VE RI TAS
HARVARD MEDICAL SCHOOL

UPMC
LIFE CHANGING MEDICINE

NYU School of Medicine
NYU LANGONE MEDICAL CENTER

CORNELL UNIVERSITY FOUNDED A.D. 1865
Cornell University

BOSTON UNIVERSITY

USU
Uniformed Services University

1884
Memorial Sloan Kettering Cancer Center

Tufts
UNIVERSITY

GEORGIA SOUTHERN UNIVERSITY

THE UNIVERSITY OF TENNESSEE
KNOXVILLE

WVU Cancer Institute

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LA Clippers

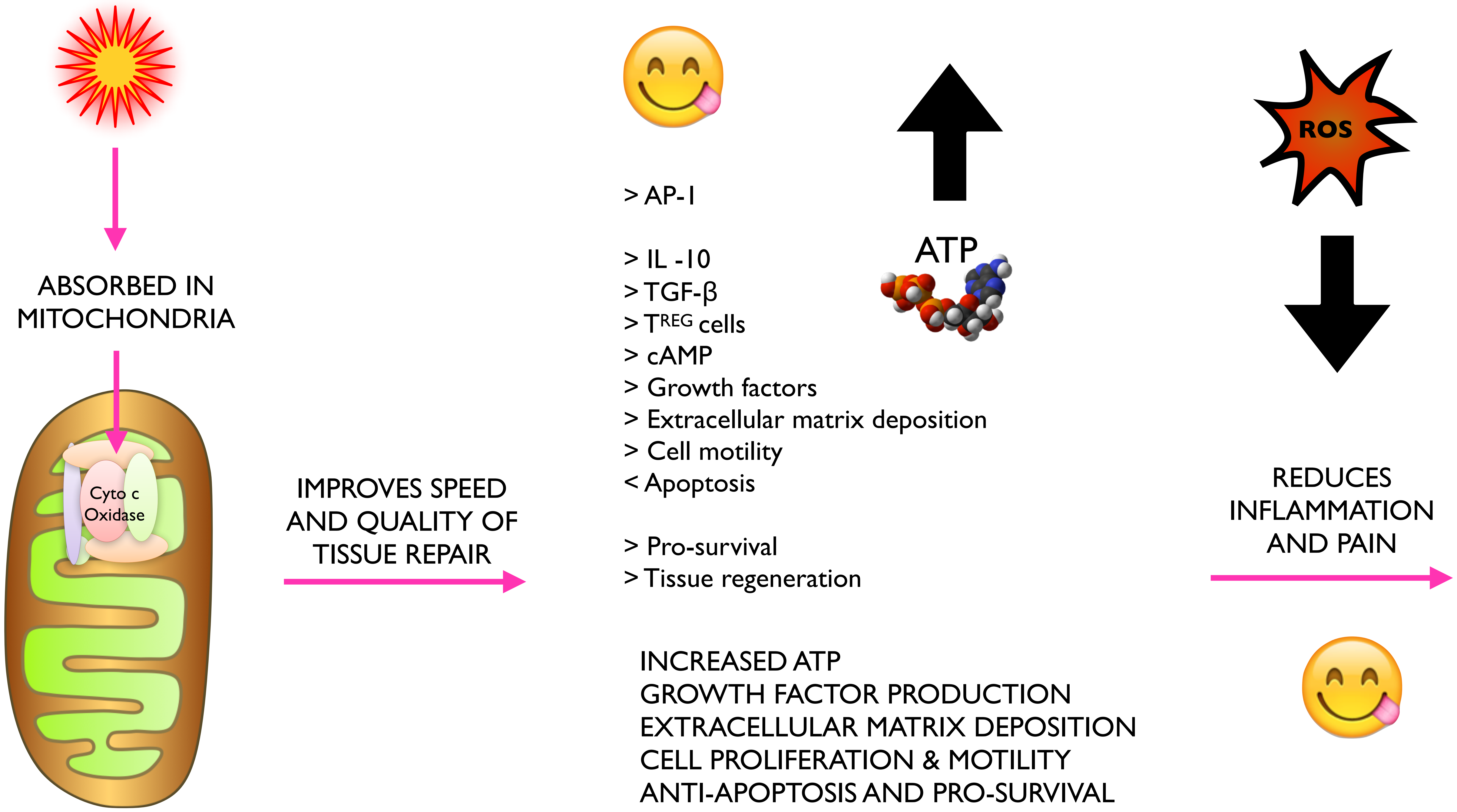
Ultimate Fighting Championship

USA Track and Field

Phoenix Suns

OREGON PROJECT

HOW IT WORKS IN THE CELL



PBM LIGHT

ABSORBED IN MITOCHONDRIA

IMPROVES SPEED AND QUALITY OF TISSUE REPAIR

> AP-1

> IL -10
> TGF-β
> T^{REG} cells
> cAMP
> Growth factors
> Extracellular matrix deposition
> Cell motility
< Apoptosis

> Pro-survival
> Tissue regeneration

INCREASED ATP
GROWTH FACTOR PRODUCTION
EXTRACELLULAR MATRIX DEPOSITION
CELL PROLIFERATION & MOTILITY
ANTI-APOPTOSIS AND PRO-SURVIVAL

REDUCES INFLAMMATION AND PAIN

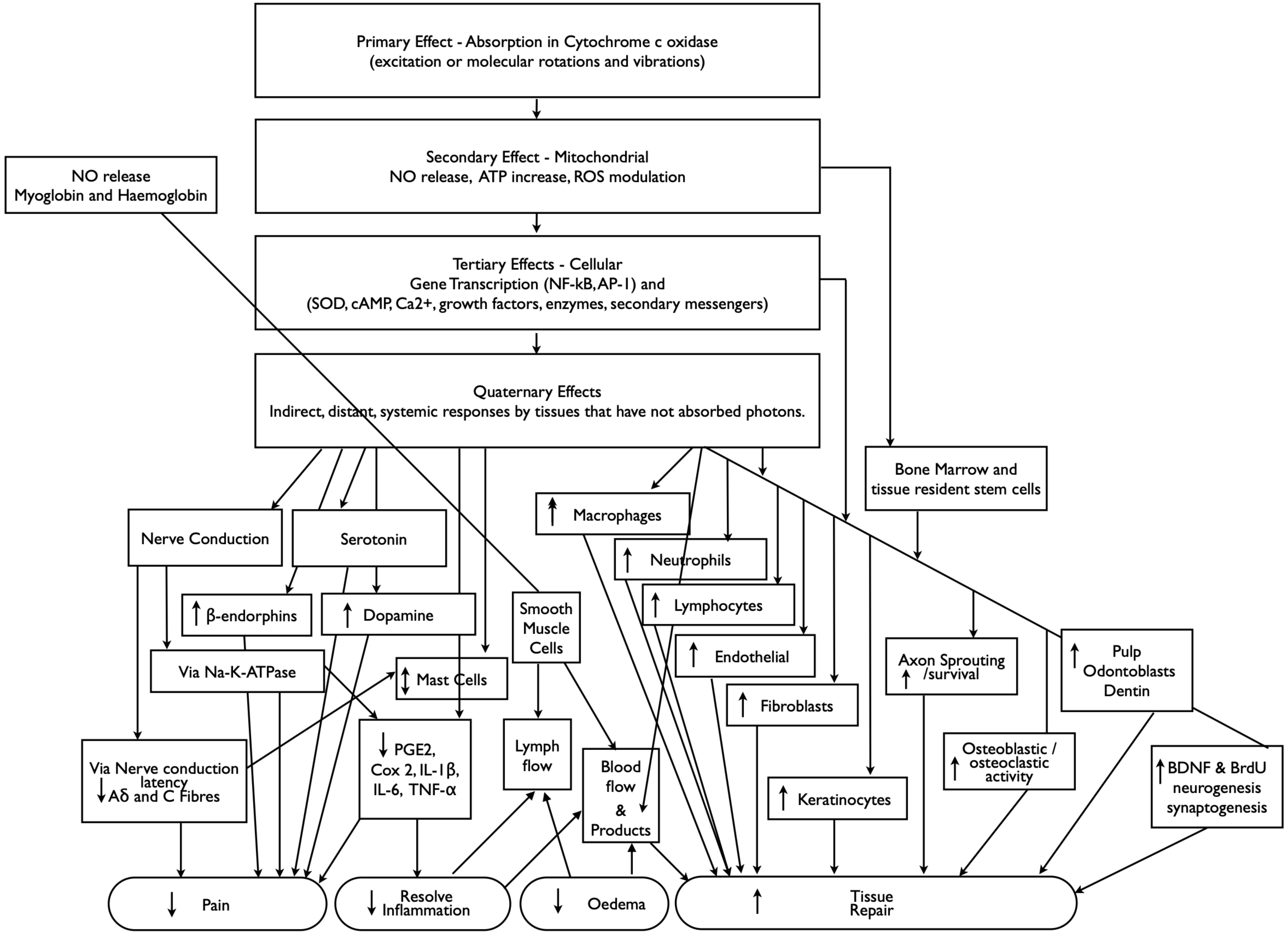
OXIDATIVE STRESS

< NF-kB activity

< TNF-α
< IL-6
< CRP
< Cox 2
< PGE2
< IL-1β
< IL-2
< IL-7
< IL-8
< PGE2
< MCP-1

< Inflammation
< Necrosis

HOW IT HEALS AND RELIEVES PAIN



Primary Effect - Absorption in Cytochrome c oxidase
(excitation or molecular rotations and vibrations)

Secondary Effect - Mitochondrial
NO release, ATP increase, ROS modulation

NO release
Myoglobin and Haemoglobin

Tertiary Effects - Cellular
Gene Transcription (NF-kB, AP-1) and
(SOD, cAMP, Ca2+, growth factors, enzymes, secondary messengers)

Quaternary Effects
Indirect, distant, systemic responses by tissues that have not absorbed photons.

Bone Marrow and tissue resident stem cells

Nerve Conduction

Serotonin

↑ Macrophages

↑ Neutrophils

↑ Lymphocytes

↑ Endothelial

↑ Fibroblasts

↑ Keratinocytes

↑ β-endorphins

↑ Dopamine

Smooth Muscle Cells

Via Na-K-ATPase

↕ Mast Cells

Axon Sprouting ↑ /survival

↑ Pulp Odontoblasts Dentin

↑ Osteoblastic / osteoclastic activity

↑ BDNF & BrdU neurogenesis synaptogenesis

Via Nerve conduction latency
↓ Aδ and C Fibres

↓ PGE2, Cox 2, IL-1β, IL-6, TNF-α

Lymph flow

Blood flow & Products

↓ Pain

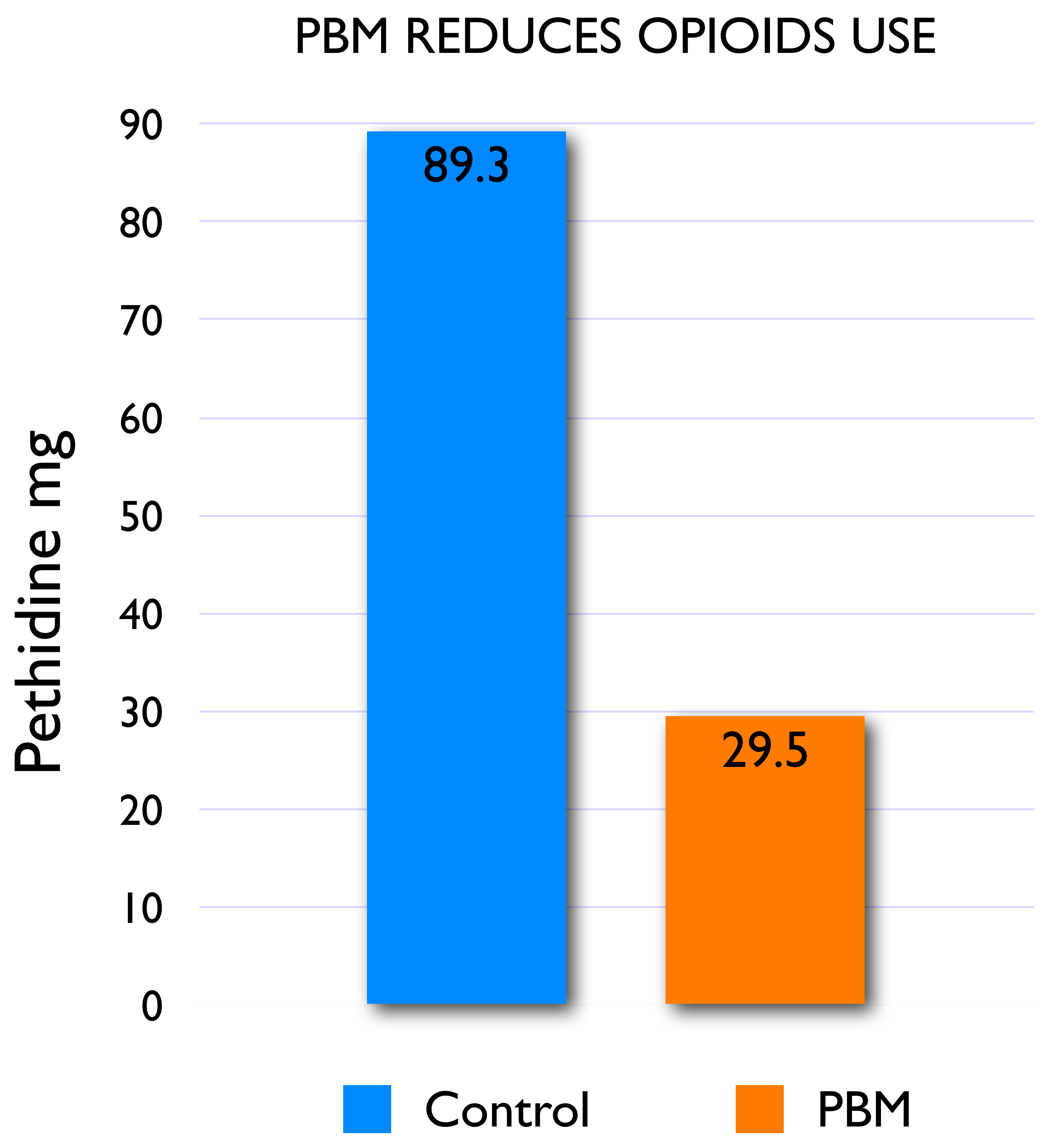
↓ Resolve Inflammation

↓ Oedema

↑ Tissue Repair

PBM REDUCES OPIOID USE IN TIBIAL FRACTURE SURGERY PATIENTS

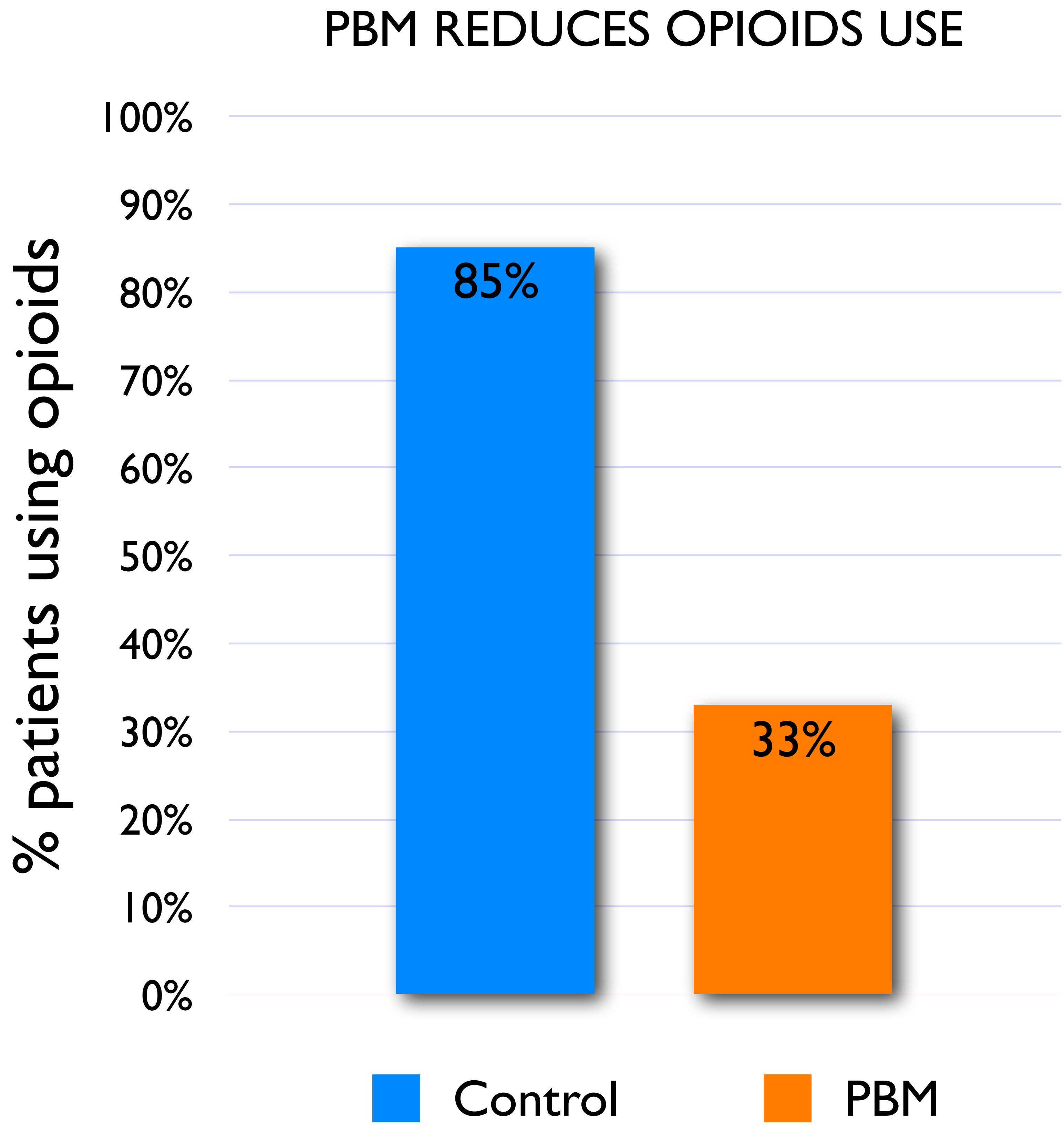
- Orthopedic surgery induces severe pain
- Double-Blind Controlled Randomized Clinical Trial
- 54 patients
- Tibial fracture surgery
- One treatment post-op
- 808 nm
- 300mW
- 20 sec
- Four points
- 1 cm^2
- 6 J/cm2



Nesioonpour S, Mokmeli S, Vojdani S, Mohtadi A, Akhondzadeh R, Behaeen K, Moosavi S, Hojjati S
The effect of low-level laser on postoperative pain after tibial fracture surgery: a double-blind controlled randomized clinical trial.
Anesth Pain Med 2014 Aug 4(3) e17350

PBM REDUCES OPIOID USE IN HEAD AND NECK CANCER PATIENTS RECEIVING CONCURRENT CHEMORADIATION (CRT)

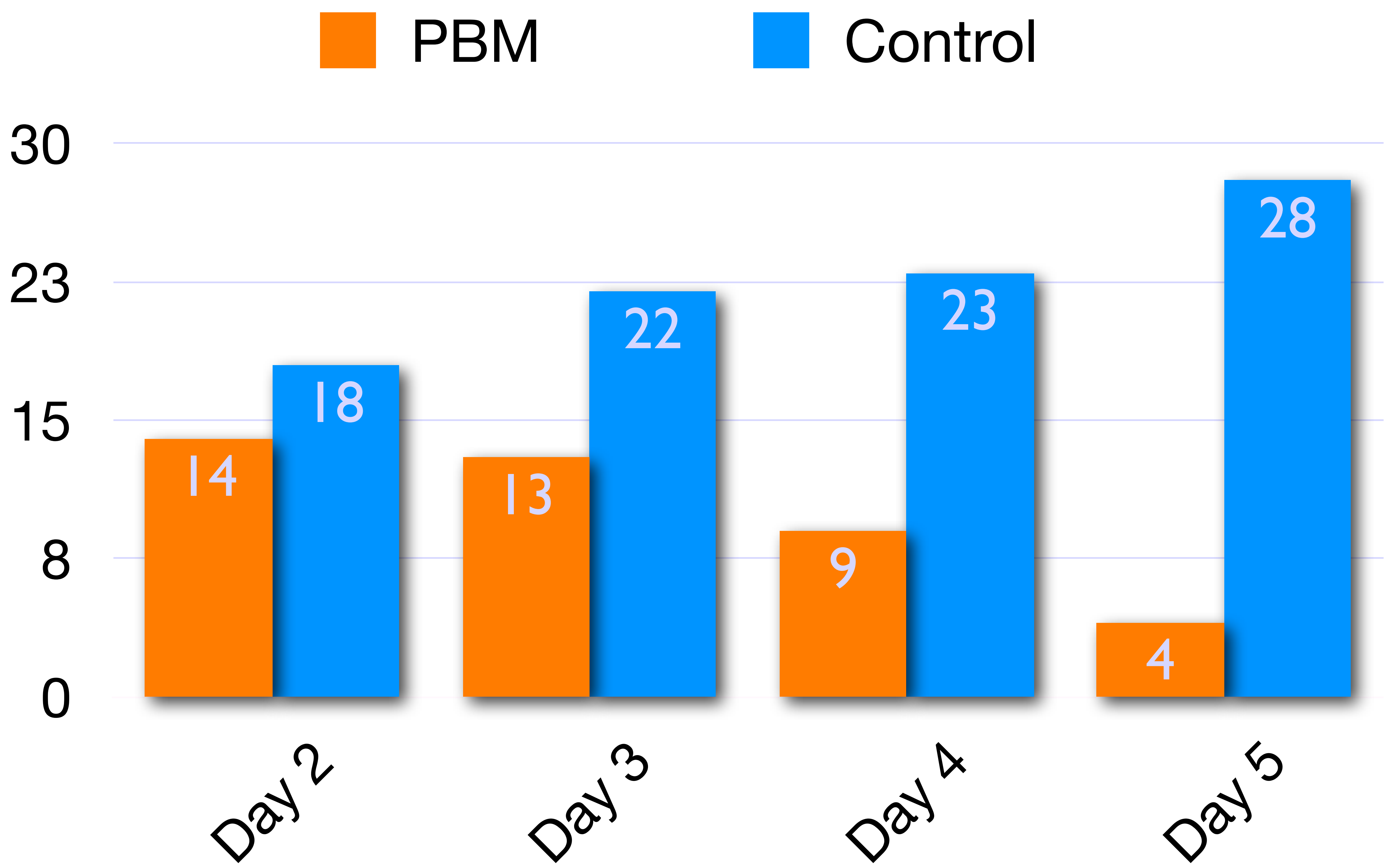
- Oral Mucositis a debilitating side effect of CRT for head and neck cancer patients
- Prospective, randomized, double blind, placebo-controlled, phase III trial
- 94 patients
- Head and neck squamous cell carcinoma
- Treated with CRT 5 x week for 3 weeks
- PBM treatment to prevent Oral Mucositis
- 5 x week for 3 weeks
- 660 nm
- 100mW
- 10 sec per point (9 points in oral cavity)
- 0.24 cm^2
- 1 J
- 4 J/cm2



Antunes HS, Schluckebier LF, Herchenhorn D, Small IA, Araujo CM, Viegas CM, Rampini MP, Ferreira EM, Dias FL, Teich V, Teich N, Ferreira CG Cost-effectiveness of low-level laser therapy (LLLT) in head and neck cancer patients receiving concurrent chemoradiation. Oral Oncol 2015 Nov 7

PBM REDUCES OPIOID USE IN POST-OPERATIVE PAIN

- Randomized, double blind, clinical trial
- 20 patients
- Open Cholecystectomy
- 1 x treatment post operatively
- 830 nm
- 60 mW
- Contact laser irradiation was applied in two concentric circles at 1 cm intervals
- 8 s per point using moderate pressure and below the subcostal margin over the gall bladder bed for a similar period of time using firm pressure.
- 24 J/cm^2
- 6 - 8 mins total

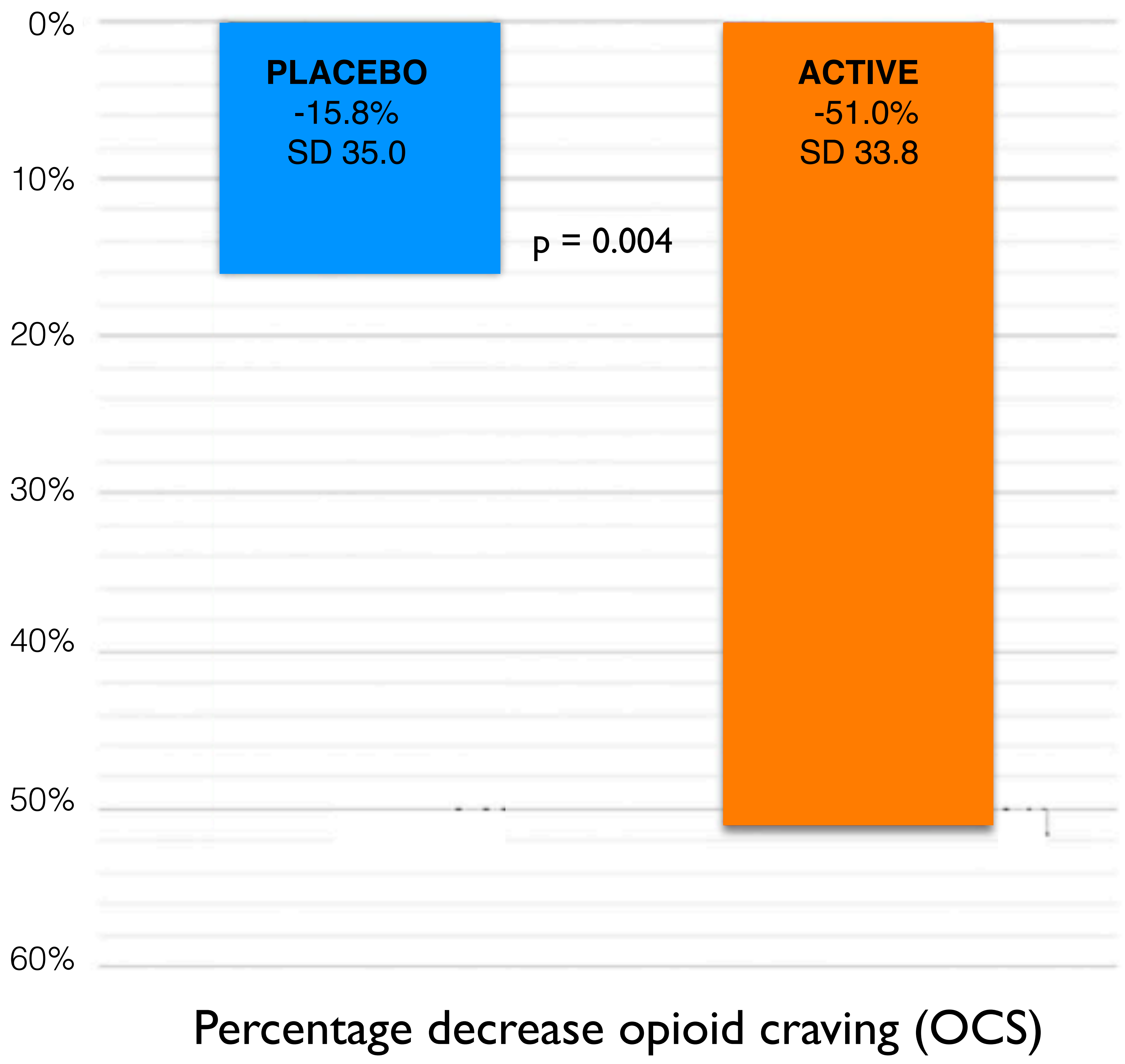


Kevin C. Moore, Naru Hira, Ian J. Broome* and John A. Cruikshank
The Effect of Infrared Laser Irradiation (LLLI) on the Duration and Severity of Postoperative Pain: A Double Blind Trial
Laser Therapy, 4: 145-150. 1992

PBM REDUCES OPIOID CRAVINGS IN OPIOID USE DISORDER PATIENTS

- 17 patients
- RCT crossover study
- History of recent or current OUD
- Opioid Craving Scale (OCS)
- Hamilton Depression Rating Scale (HDRS)
- Hamilton Anxiety Rating Scale (HDRS)
- Urine drug test
- One PBM session

- Four mins of PBM (active or placebo) to EEG sites F3 and F4
- 810 nm CW LED 4 min
- 250 mW/cm2 60 J/cm^2



p = 0.004 Wilcoxon Sign Rank Test
p = 0.0071 mixed model

**p = 0.004. Cohen's ∂ was 0.73 for the active treatment over sham

Fredric Schiffer, William Reichmann, Edward Flynn, Michael R. Hamblin and Hannah McCormack
A Novel Treatment of Opioid Cravings With an Effect Size of .73 for Unilateral Transcranial Photobiomodulation Over Sham
Front. Psychiatry 11:827.

THOR PREVIOUS OPIOID CRISIS GOVERNMENT ENGAGEMENT


Congressional briefing

James Carroll
Founder CEO
THOR Photomedicine Inc
WWW.THORLASER.COM

James.Carroll@thorlaser.com

Video recording of congressional briefing


White House meeting

Policy briefing

CONCLUSION

- PBM is a safe, non-invasive, non-toxic, non-addictive treatment
- No known side-effects
- Longer lasting relief than drugs
- Reduces cravings after a single treatment in OUD patients
- PBM is unique because because it helps patients heal
- FDA cleared products available now
- Intended use: For temporary relief of muscle & joint pain
- Available through GSA Advantage (Federal Supply Schedule)

From: Hope c
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:22:09 PM

Hello, I have fibromyalgia. I am repeatingly told that opioids don't help with fibro pain. They help with my pain. I only use them sparingly, less than a dozen a year. It's so incredibly hard to get my doctor to write a prescription because they fear of the repercussions on them. If there has to be some way to let responsible people have access to these meds. Thanks, Hope Opoka

Sent from Yahoo Mail on Android

From: Ina Fishman
To: NCIPCBSC (CDC)
Cc: Mia Erickson; Mandy Merkel; Cheryl Pecaut
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:52:25 PM

To him it May Concern,

I am very unhappy to see that the guidelines for pain management have not been
Improved to provide care for & support of pain patients. Please consider accessing the experiences of pain patients& their limited quality of & ability to participate in their own lives& those of their family& friends.

My life is one of daily struggle just to survive since my world is so constricted by chronic pain. I have many medical diagnoses which limit my ability to recover function
of this wounded body. I have inoperable spinal conditions as well as other health
problems that leave me in intolerable pain much of most days. I have used narcotics judiciously only as prescribed& tried all other available treatments from acupuncture to Ayurveda, many trials of physical& occupational therapy, Gabapentin,Neurontin,& many other medications without benefit of pain management . I have been declined treatment for my pain by several doctors & pain clinics because of the guidelines under which they operate & fear for reprisals if they medicate appropriate pain patients with narcotics which are helpful when administered in some situations.

Also medical marijuana is not legal in my state which may be beneficial in my case,
But I am Unable to utilize this natural herbal treatment.

Care for people, not numbers, compassionate care for those who are suffering should be part of your agenda. Pray that you or someone you love does not suffer the
Torture of unrelenting pain because of restrictions put on availability of pain relieving medications because of lack of appropriate information utilized in decision making in this situation.

Yours truly,
Ina Fishman
Sent from my iPad

From: janbagwell@charter.net
To: NCIPCBSC (CDC)
Subject: My pain...
Date: Thursday, July 22, 2021 2:04:27 PM

Please be careful of how you treat pain patients through your guidelines.

I live in pain. 24/7. Have you ever lived with pain? It chews up your mind and spits it out. It tears up your nerves. I also live with major depression due to the pain. I have no live. I leave my house to get groceries and sit with my 90 year old father once a week.

I live in pain. I used to have all kinds of animals. I used to have a wonderful garden. I used to be able to concentrate to read books. I used to keep a spotless house. I used to keep my grandchildren all the time.

I live in pain. My pain isn't in your list of acceptable pain issues. It is still pain. I was injured at work. They got out of paying for my care. I NEVER missed a day of work due to my pain in 10 years. I'm not a lazy person.

I had to change drug stores because of sill rules about pain meds. I just had to promise our NEW drug store that we would move all of our prescriptions from a CHEAPER drug store to them or they would not fill our pain prescriptions any longer. I have to give urine tests because I LIVE IN PAIN.

People who live in PAIN are treated as subhuman. Every other medical ailments can be treated why not pain??? My hypertension, (which is exacerbated by MY PAIN), is treated. My depression, (which is caused by constant pain), is treated. I can no longer have meds for my severe anxiety because I AM TREATED FOR PAIN.

PLEASE, please think about us instead of the IDIOTS out there who die from heroin and illegale use of APPROVED pain medications. WE should NOT be punished because of THEM.

Jan W. Bagwell

From: John Bear Premier Opioid Research
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:35:53 PM

YES I have no access to opiates withDraw for OUD no Bupe or methadOne Please >He;P
T

From: Judi
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 2:02:01 PM

To Whom it may Concern:

I am gravely disappointed by the continued complete lack of concern at all for those living with severe chronic pain who are on opiates and have been forced down or off completely seriously impacting our lives in a very negative and severely damaging way. Some of us have many other complicating serious health issues so that we can't even have potential surgeries or tolerate any other medications at all and have already tried all the alternatives available (after a lifetime/decades of severe chronic pain). It was many years after I was told opiates were my next step that I finally had to give in. I am completely disabled due to all my pain issues and was in horrible shape BEFORE losing the appropriate dose to give me help. I also suffer from very severe Restless Legs Syndrome and the opiates are the only thing that ever helped with that horrific condition as well. This level of excruciating pain and RLS are both conditions far worse than death to those who have to live with them. No CPPs asked for or deserve to have to cope with all this chronic pain. And none of us ever wanted to have to live our lives taking opiates around the clock!

What this guideline has done to already horrific lives is a travesty. No one should have to suffer so horrifically due to pain when taking opiates as directed gives SOME quality of life to those who otherwise have none. Those living with severe pain causing conditions are punished enough just having to live with them. Many pray to die every single day. So many are now completely dependent on others for many basic needs that they could handle before. We are literally being tortured and/or killed (many have died already) as a result of this enforcement. Many of us have lost great pain management doctors due to them retiring/leaving/being forced out of their practices due to all this. Chronic Pain Patients/CPPs have done NOTHING wrong yet are being penalized due to the actions of addicts – and the number of overdose deaths has continued to rise since CPPs were never the problem. It is the illegal street drugs that are the problem. Why anyone thought that taking away the only means of legal opiates for pain relief would in any way help the problem is beyond me when this action could only make it worse as you take away the only safe legal means of obtaining pain relief, some will become desperate enough to do anything for pain relief … which could drive some to the use of illegal street drugs making the problem far worse, not better.

My first husband was an addict so I know first-hand the stark differences between addicts and those dependent on pain meds. Nothing you do will EVER stop an addict from using until the addict chooses to get help. Why are you torturing and punishing those who are unfortunate enough to have to live with crippling pain?? This is insanity. No one who hasn’t had to live with such severe pain on a daily basis should ever be allowed to make these decisions. It is like you think it is mild to moderate pain but that is not what people who are placed on long-term opiates are living with. This is severe debilitating pain … and for me it is all over my body at all times including muscle, bone, nerve and joint pain. Those with severe pain do NOT get high from opiates and the pills don’t take away all our pain. They just bring it down to a more tolerable level then the pain builds back up until the next dose. I have gone from getting around mostly with a cane and at times a walker before the forced taper to having to use a rollator and get qualified for and use a very elaborate mobile wheelchair – which also required us to purchase a home to accommodate the mobile wheelchair. I fall all the time and fear serious injury constantly. I can never sleep and I am still being forced farther down even though my blood pressure has been sky high and I have been unable to tolerate any of the meds to bring it down as I have such severe reactions to almost all medications. My body is going downhill so fast due to all this. I had sought constant weekly treatment for DECADES due to all my pain! My genetic testing even shows that pain will be an issue for me. When you are allergic to practically everything and have no other options, just finding the one narcotic I could tolerate was beyond difficult. All the treatments I sought for decades were unable to help me either; many made me worse. I was stopped from therapy more times than I can count due to lack of progress or worsening of conditions.

Anyone can become a victim of severe chronic pain. Next it could be you … a tragic car accident for instance. I have so many allergies and other health issues that this forced taper has caused me to lose 50lbs. Every day I spend time screaming and crying. This is not life, this is a horrific existence that I wouldn’t wish on anyone. PLEASE consider the nightmare many with severe chronic pain are living with and make the new guidelines so that they help us. Addicts can get help anywhere. Most of us lost all access to our doctors when this forced taper began. You would care if it was you or a loved one living this nightmare. It honestly feels like the plan is simply to torture and kill all of us off. There has been no concern at all given to any other serious and complicating medical conditions any of us have either.

Our lives are your hands. Please try to put yourselves in our shoes and imagine how you would feel.

Sincerely,

Judi Beardsley

From: Jennifer Brown
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:26:22 PM

Dear BSC,

I am writing to you because I am a 39 year old well documented Chronic pain patient, who has had my life destroyed from the 2016 CDC opioid guidelines. They should have never been written in the first place! They were written by a biased group of people that did not have any education on Chronic or Acute pain patients. State legislators were quick to make laws to fit the false narrative. Which in turn weaponized the CDC guidelines. The only people they have hurt/tortured are the already law abiding citizens (Good Doctors, family members, veterans, and contributing members of society that happen to be chronic pain patients and acute pain patients). Addicts do not follow laws. You need to finds ways of helping addicts thru mental health programs that look at why they choose to use illicit drugs in the first place. Illicit drug use is a symptom/effect of their problems, not the cause. Pain patients are very different than addicts! We have a very different effect from using opioid pain medication. We use our pain medication to join the living! We use it to work, spend time with family, charity work, walking/exercises, physical therapy, possibly traveling, gardening, to actually sleep thru the night, to sit for more than 5 mins due to pain. Putting pain patients and addicts in the same group does not make any sense at all! These updated guidelines pretty much sound the same as the biased 2016 CDC guidelines. They will continue to ruin wonderful peoples lives. More will turn to suicide to end our suffering. Addicts will move on to a different drug that has no quality control. DEA will continue to terrorize good Doctors and pain patients by ruining their lives. They have done nothing but cast people into a wasteland of suffering behind closed doors. I am in the process of selling off half of my business as I cannot do the work that I could while on opioid therapy. I believe that the guidelines should be retracted completely! Pain patients and Doctors should not have to jump though all of these impossible rules and requirements. Also we are not guinea pigs that deserve to be cut on and poked just to receive proper pain management. Doctors should be able to have patient centered care again without the DEA breathing down their necks and waiting for their livelihoods to be destroyed. Law makers need to exit out of our Doctors offices. They do not practice medicine. Our healthcare should be decided by Doctors and us! After the guidelines were implemented, going to the Doctors is like going to a criminal probation meeting. (I know because people on probation in the past told me so.) Almost worse, 24hour random pill counts, urinary analysis, monthly appointments, treated like an addict for even mentioning pain, judged, cannot even talk about health problems because whole appointments are dedicated to talking about addiction, being treated as a pin cushion, having to try endless medications that don't work, endless appointments. That's even if your lucky enough to find a Doctor that will try to

help you. Still people are cut off due to no fault of their own, like me. I now have PTSD about going to a Doctor appointment even if I just have a sinus infection. People with chronic pain are likely to have anxiety also, but are forced to choose between anxiety medication or pain medication even if for years it worked for us. Or are left with nothing like me. These guidelines have stolen my body, my peace of mind, my dreams of a future, my work, my time with friends. I don't want to just exist in agony, I want to live! The updated version sounds like more of the same biased torture! Pain patients are dying from suicide due to untreated pain. Addicts are dying from illicit unregulated drugs from the streets. I want my pain controlled again. I know what works for me! These lifesaving pain medications gave me 20 years as a contributing member of society. I had a fantastic life worth living! Now that has been taken away from me at no fault of my own and against my will. All for some lame attempt at saving people from themselves. We have a right to choose what we put in our bodies. We should only be explained the risks and given a wavier to sign absolving anyone of our decision to take opioid pain medication. It's our constitutional right to have "Life, liberty, and the pursuit of happiness!" I want my rights as an individual back!

Thank you for your time.
Jennifer

From: Jenn
To: NCIPCBSC (CDC)
Subject: Chronic pain
Date: Friday, July 23, 2021 1:28:21 PM

To whom it may concern,
I'm a 44 year old with a back injury. I had two back surgeries in 2014 and was good until 2018 when things got worse. All the docs Over the last year that I have seen are scared and will not prescribe meds for relief even though I have all the tests to prove they are needed. I have lived my life is pain and have thought about suicide because it's so overwhelming. It's not a good quality of life for anyone. It's depressing. I have tried all other meds and even have tried medical marijuana and nothing works. Please keep us chronic pain patients in mind when doing reports and suggestions. There has to be a better way.

Jennifer Cianciulli
484-325-0647

Sent from my iPhone

From: jim@jamesdoulgeris.com
To: NCIPCBSC (CDC)
Subject: Public comment on revised guidelines for pain management
Date: Friday, July 16, 2021 1:13:46 PM

I am writing you to bring a serious unintended consequence to present guidelines for pain management. I recognize that they are aimed for the public good, however, as with any public policy, they can do harm to those with special circumstances if not exempted.

With opioids, for example, uses for obvious short term applications such as surgery, trauma, cancer and end of life care are common sense and humanitarian. The debate for long term use for chronic conditions from amputations to rare conditions, notably complex neurological conditions such as Complex Regional Pain Syndrome, also known as Reflex Sympathetic Dystrophy, are lumped in with small studies of common conditions. That means researchers and clinicians alike are ignoring rare conditions that are more severe and passed over by the economics of small populations and the vast expense in time and money for FDA approval even for old drugs with long history of safe and effective use. While even those small studies show conclusive evidence that opioids do more good than harm, best practices are almost universally subsumed by politics and hyperbole at the state level.

As a medically retired hospital and accountable care organization CEO with nearly 50 years' experience, now a patient with three rare diseases, the worst of which is called Complex Regional Pain Syndrome ,or CRPS, I am acutely aware of the consequences of unintended gaps in public policy, particularly with opioids. While opioids are addictive and abused by a much larger, unrelated population, they are one of the only options to manage and maintain a tolerable quality of life for complex and severe conditions such as CRPS. As its name implies, CRPS is a painful, complex neurological condition. It causes the sensory response from a light touch to a fall to register as pain. It causes intense pain spasms for no seeming cause at all, and much, much worse. CRPS ranks a 42 on the McGill Pain Index that ends with 50 with the most unbearable pain. It is ranked as more painful than cancer or amputation or even childbirth. It is generally recognized as the most painful condition known to medical science. For more information, please visit https://rsds.org.

It is simple common sense that broader abuse does not make legitimate users abusers. In fact, they are responsibly managed by pain management physicians and responsibly used by people with few if any options, yet there is debate on their efficacy despite overwhelming evidence that they are effective and used responsibly. Moreover, federal and state regulations, with only a few exceptions like New Hampshire, which passed legislation to protect people in legitimate need, lump chronic conditions in with regulations aimed at stopping abusers, exempting only short term applications. This is not only cruel, it defies logic and common sense. Attempting to correct these gaps in sloppy legislation are met with tone deaf resistance if they are responded to at all. I know, I am as active an advocate for rare disease including passage of the STAT Act of 2021 as my condition allows.

Depending on how long one has had this incurable condition, and it strikes children the most, we are all doomed to a lifetime of escalating misery. There are no alternatives because, as with most rare diseases, there is no money for research, no new drug on the horizon. The condition remains uncurable and relentlessly gets worse over time. Opiates along with other therapies allow those of us with advanced cases to function. Without them, we are totally disabled by intense, acute pain. These circumstances combined with doctors denying patients proper pain relief for well-founded fear of regulatory zeal, no coordination in treatment to identify best practices and even denial that the condition exists in the face of overwhelming clinical evidence combine to earn the sad distinction for CRPS as “the suicide disease.” For people to elect death over unbearable, unrelenting pain because they are denied pain relief is a cruel, tragic and irresponsible failure of public policy. CDC guidelines that bring common sense and compassion will be a powerful counterbalance and instrumental in helping those of us with relevant rare disease the tools to maintain the optimum quality of life available to us. I, on behalf of the CRPS and broader rare disease community urge the CDC to use its position and influence to help us to a better life.

Sincerely,

James Doulgeris LinkedIn
727-512-3138
jim@jamesdoulgeris.com
@jdoulgeris

From: Jeffrey Doyle
To: NCIPCBSC (CDC)
Subject: CRPS and opiate guidelines
Date: Thursday, July 22, 2021 1:01:35 PM

Hello,
I'm writing because I live with a serious condition called CRPS also known as complex regional pain syndrome as well as mast cell activation syndrome. I've never abused my medicine not should I be treated like a criminal. Having a rare chronic illness makes for a hard life as it is. I have all the odds stacked against me already and please I pray that my medicine won't be taken away . It's a mater if life and death for me.

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:
A biased focus on risks and harms of opioids with no discussion of the benefits of opioids for pain relief when used appropriately
Arbitrary use of MME dose limits with no basis in science
And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

We hope that in drafting the final Guideline, the CDC takes these views into consideration.

We urge you to write the CDC today to tell them your thoughts on the Updated Draft Guideline. If the 2016 Guideline has affected your care, tell them how it has affected you. Ask them to make changes in this draft that would improve your pain care. It is crucial for people with pain to go on record with the CDC about a document that is certain to affect the future of pain care!

Sincerely,
Jeffrey Doyle

From: Jessica Ericksen
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 6:18:58 PM

Hello,

I am a person who lives with progressive issues that, when combined with past poorly done surgeries, have led to significant pain that severely affects my day to day life. I have metal implants that are digging into my body because of the way the bone healed around them, a cyst that is eating away at part of my spine (bone erosion) and causes CSF issues that lead to extreme daily headaches, significant degeneration in my spine from past surgeries, and other problems.

I was left without appropriate medical care for years because no doctors wanted to treat someone dealing with pain. This led to my medical issues deteriorating even more and left me in pain so bad I could not leave my room for up to a month at a time. That is a bleak existence and contributed to severe depression. Pain clinics only wanted to implant devices that were contraindicated by my underlying medical issues and could have paralyzed me. Fortunately, I was able to find a primary care doctor who works with me to manage my pain. With a moderate dose of narcotic pain medication, I am able to have quality of life. I still need a lot of help and have to carefully manage my activities but I can leave my home most days. I'm working on getting myself well enough to have a career.

I'm in multiple support groups for my various conditions. For the most part the people who are able to be functional are the ones who are able to access pain medication. The ones who can't are often completely unable to work and miserable. Some of them have turned to suicide because they are offered no relief or treatments that just don't work for complex issues (counseling is not enough in any way to handle severe, daily pain and physical therapy can help in some cases but in others we end up harmed by inappropriate exercises). Some who were very functional with appropriate pain medication have been taken off of it and lost their jobs and homes. Some have no primary care because doctors refuse to see them due to them being pain patients so they miss out on life saving preventative medicine that non pain patients easily access such as breast cancer screenings. I myself have to travel 1.5 hours round trip to be able to access a pharmacy that will fill a narcotic pain prescription and that is only doable because I am fortunate enough to have family with the time to drive me out there.

Your guidelines so not protect people living with pain. We can live. We can have full, happy lives but sometimes we need medical care to do so. The updated guidelines do not help us. They also don't stop addiction in any way. All you've done is pit people living with pain against people dealing with addiction. While occasionally this group overlaps, most of the time these are two separate populations who both deserve appropriate care. You are killing pain patients and people are still dying of addiction that is not connected to appropriately prescribed narcotic pain meds. I sat and sobbed the other day after learning of yet another pain patient who had progressive medical issues and died by suicide because she was unable to access pain medication despite years of trying. She was a well educated woman with a career that equipped her better than most to access resources and advocate for herself. After years of trying to get help she lost her business and ability to function and saw no hope that she would ever receive treatment that actually worked for her pain despite years of documented, painful, complex medical conditions. This is a direct result of what has become a war against pain patients. Focusing on us is easy because we are often too tired and too sick to fight back but actions like making evidenced based addition treatment widely and affordable available would be a much better way to help people dealing with addiction.

I know I would not be alive if I had not found a doctor who was willing to take the time to help me. It took me years to start to recover from being left in the physical and metal agony of severe, daily uncontrolled pain with no help. I can never get those years back but you can ensure your guidelines don’t contribute to people missing out on more years of life.

Thank you,

-J.M.E

From: Jenny Falcon
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:28:31 PM

Dear CDC,

As a chronic pain patient since 1998, I am well versed in pain management and have taken a 6 week intensive Pain Rehabilitation program. What I am most concerned about is the lack of pain management for post-op patients. I believe the pendulum has swung in the wrong direction and many patients are not receiving short term post-op pain control. I prefer not to take opioids and am currently managing my pain with Low Dose Naltrexone, but I do expect better pain management after surgery. A patient should no have to fight for this or end up at the ER due to uncontrolled post-op pain.

In my case 3 years ago I was given 15 low mg opioids after head and neck cancer surgery, when I got home from the hospital something popped in my neck that caused tremendous pain. If I hadn't had leftover pain meds from a previous surgery I would have had to go the ER.

I constantly see desperate posts from other patients in my cancer group who's post-op pain is not addressed, often they are told to take ibuprofen or tylenol, which is inadequate. This is medical malpractice in my opinion and surgeons should not be afraid to treat their patient's pain.

Thank you for your consideration,

Jennifer Falcon
4068 Everett Ave
Oakland CA 94602

From: navymom02155@aol.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:02:26 PM

Dear CDC members,

I am writing as a patient who has mutiple autoimmune problems. The worse one is fibromyalgia which is relentless. I don't think enough research has been done on fibromyalgia. It is the worse kind of pain and nobody can imagine what I'm talking about unless you experience it.

I was once on a fentanyl patch which made me feel like my old self. I am now taking tramadol only as needed. There was a time before my diagnosis that I would not take an aspirin. My life has changed drastically and I have no social life as I need to be home due to the fatigue and pain.

Please, try to get funding and do not stop the opiods which patients need so badly. I have been suffering since age 42 and I'm now 65 years old.

Kindly consider my request.

Sincerely,
Josephine Ann Finnegan
66 Elm Street
Medford, MA 02155

From: Julie Glatczak
To: NCIPCBSC (CDC)
Subject: OWG from July 16, 2021
Date: Friday, July 23, 2021 4:37:43 PM

I am commenting on the harm the 2016 Opioid Prescribing Guidelines caused me. For one thing we all know the harm was foreseeable for chronic pain patients who have been on LTOT for decades and yet these "guidelines" were made "laws" by most states. Didn't you think that those that are on LTOT have been through all the alternative therapies and modalities throughout the years? Yes, we have. I've even tried experimental treatments by anesthesiologists without success. Actually, I had a Lidocaine pump placed in my upper right arm for CRPS and the anesthesiologist had to take me in to emergency surgery to remove the pump because I was allergic to the metal the pump was made out of. My dream job was being a nurse but because of my disabilities I had to give it up but as I was feeling I might be able to try obtaining employment again because my LTOT was at a dose where I could function and could probably sustain employment but then my forced tapering began and my health and quality of life went downhill from then on. I developed several more health problems because of the lack of pain control. My blood pressure is at a critical level where I was scheduled for a thyroidectomy and the surgeon and anesthesiologist both backed out on me and cancelled my surgery because of my uncontrolled HTN. My PCP and cardiologist just don't know what to do for me anymore because I am on several blood pressure meds and at the max doses of these meds and my blood pressure will not come down. I also have hyperthyroidism which I just received RAI 131 treatment on June 18 in lieu of the thyroidectomy. My PCP, endocrinologist, cardiologist, and urologist were all hoping the RAI 131 would bring the blood pressure down but as of today it is still critically high. I was told by my endocrinologist that I am in the 1% that the RAI 131 is not effective as my TSH level has not changed. I am so frustrated with healthcare in America today. Never would I have thought during my time as a nurse that it would ever come to this!! I have other comorbidities that I won't even go into detail. Have any of you ever been in so much pain where it actually has you contemplating if your life is even worth living? I do. I feel like a useless Mom and grandmother. I used to be able to spend time with my young grandchildren and play an active role and now they look at me with "that look of sadness" and it just breaks my heart. I know that my story is not any different from all the other stories you will hear but to me and my loved ones, it is special. My last comment to you is that I surely hope that in America today that you take the lives of many with chronic pain into your thoughts and please have some compassion when proceeding forward. Thank you.

From: Janet Groth
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:59:39 PM

I don't believe that they are going to be much help unless we are allowed to get back to where our meds were, returned to the original dosage before you decided to go after someone to blame for all the drugs on the streets and internet.How you can blame pain patients for this mess? Why don't you have the DEA do there jobs and go after the drug dealers and all the drugs coming in from Mexico? We all know what is going on when are you going to have drug testing in Congress and all politicians,like they do to most other people in big companies.Now all the DEA does is flip through papers and pick out doctors to harass.They are so afraid of losing their jobs or are going to jail.Do we all know who the minority is now.

We can't go out and protests like all the other groups do to be recognized because we are in too much pain to do these little things,we are lucky enough to get out of bed we're in so much pain.After over 33 years of pain l can't wait until it is all over.Before they change the guidelines l had a life now all l have is pain.At least now they are going to help the pediatric patients to get rid of their pain,imagine if it was your child screaming in pain and all they say is we won't lose our license over you or you child.Give them a tylenol or an advil,or take 2 aspirin and call me in the morning. The only ones treated like that are the Veterans that got hurt saving our lives and now you take away their lives by taking away their medicine that let them go places and do things.Now the people who are not children or veterans are out of luck we will never get our meds back we will suffer forever,and you pray every night that you won't wake up in the morning but before you know it the pain is waking you up,and you look at the clock and it has only been a half hour and you say to yourself another goodnight of sleep.PLEASE LEAVE PATIENTS AND DOCTORS ALONE.WE TALK TO OUR DOCTORS NOT TO YOU GIVEN THEM ORDERS YOU ARE NOT MY DOCTOR BUT YOU THINK YOU ARE BECAUSE YOU ARE CONTROLLING OUR MEDICINE NOT THE DOCTORS.AND YOU ARE ALL RESPONSIBLE FOR ALL THE SUICIDES WHICH IS GETTING REAL HIGH.IT WAS 14000 THE FIRST YEAR YOU TOOK OVER TELLING WHAT WE CAN TAKE FOR PAIN.NOW I WOULD BET IT IS THAT HIGH EVERY YEAR,SO IT MUST BEAT LEAST 70,000 BY NOW .Keep up the good work.Find the dealers and jail them,leave the doctors alone and let them help us.And have the DEA do their jobs and get rid of all the illegal drugs.But l would like to see all Dea Agents and all the members of Congress and all elected officials be drug tested and if positive they lose their jobs immediately no 2nd chances.
No excuses just like us with to much pain to do anything.

From: pooleman@aol.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:06:53 PM

I have been a chronic pain victim for 15 years, due to debilitating, chronic, (NON-STOP) intractable pain. I have a folder that is 5 inches thick of all the surgeries (7) and all the modalities I have tried with no success. After 7 years of suffering with every step I take, my internist, (upon finding out I was taking 24 200 mg motrins everyday) said you cannot keep doing that you will cause life threatening consequences. Linda Yau Foxhall Internists is you care to call, 202-362-4467.

I went to suburban hospital because without motrin in large non-stop quantities, I could not function. I told them I lost the will to live. I spent the night in the psychiatric ward. The next day I met with a shrink, and after a one hour conversation, he said I was the most normal person he has ever met, and that I needed pain pills. I could not function on my job, and had no life worth living, until I started taking percocet. I can only come the the simple conclusion that the people that are writing these pre-historic policies are NOT chronic pain victims.

I am 68 years old, so the pedestrian, garden variety arthritis, that all my friends complain about, TO ME are NOTHING, yet for my friends they act as though they are really suffering. They have no idea what chronic intractable pain is. They have pain that comes and goes, and only acts up at certain times, and they get relief because of the lack of severity or the infrequency, or the casual use of motrin resolves. Motrin to me at even normal dosages is woefully inadequate. I have a simple choice I can live in a wheelchair, be bedridden or take percocet to achieve some relief and some semblance of a life worth living. I wonder what those on the committee would do if confronted with perpetual torture, with no end in sight, for the next say 50 years. I wonder if they would choose that quality of life, and if they could afford it. Imagine waking up every morning, facing yet another day non-stop pain.

To my friends that simply cannot understand, I take duct tape, and tape marbles to the metatarsal bones, on the bottom of their feet (as this is the equivalence of my pain 24/7) and see how long they last. In fact I tell them if they can make it through one day, doing all the walking and getting up and down I would give them a thousand dollars, no one has lasted more than a 1/2 and hour, and ALL STATE " they would rather die then live like that ". Interesting comments for JUST PAIN!

Those that are making these arcane decisions, I will offer you the same $1,000.00 dollars. Now add to that a career in retail sales in a 20,000 sq. ft. store with concrete base and a thin glue down carpet. Now imagine walking up and down stairs and being on your feet ALL DAY 6 and 7 days a week, that is retail. You wouldn't last long and would break your metatarsal bones, in less than a day.

The other avenue you are leaving patients, besides taking there own lives, is to go on the street and become a hard core junkie, risking their lives in so many other ways. Needles in their arms, robbery to pay for the drugs, shootings, beatings, robbing, air bubbles in their needles, overdosing due to no regulation, etc etc.

I would suggest you actually sit down with REAL pain patients and find out what is really going on. I was only apprised of this 2016/2021 policy today, so this email is off the cuff, but very accurate. I would be more than happy to apply the duct tape, and sit down and have a weeks long discussion with any representative so you can get a deeper and more detailed idea of what we are going through.

I am seeing my 51st dr at Johns Hopkins on Tuesday next week, to see if anything new has been developed to help me. I am not hopeful.

As I said I had little time to read this 2021 revision, but on the surface, it is a disaster. You will cause much needless suffering, and will be responsible for many a suicide.

Just out of curiosity how many are on the board that you selected from pain doctors' patients. ???

As I said you are more than welcome to try the duct tape test, and remember there is a $1,000.00 dollars in it for you tax free as a gift. All you have to do is live like me.

Thank you
Jerry Gruber

301-728-6828

From: Jeannah Swick Haber
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:34:17 PM

Please stop punishing human beings in chronic pain! Please add my comments to this sorry state of affairs that has brutalized people in chronic pain and driven thousands to suicide.

Taking away an opioid that might be working doesn't take away the pain that we have that we need pain medication for to begin with.

I've lived with pain every single day since 1998 from fibromyalgia, for 12 of those years I took low dose (5mg) hydrocodone 2 x a day every day. It allowed me to hold down full time employment, get my housework done, do a little gardening and yard work, be a semi active productive individual. It was very affordable ($15 for a month's supply) and while it didn't take all my pain away, it kept it down to a 3-5 for the part of the day I needed to be most active. I did not develop a tolerance to it, I had no negative side effects and never "wanted more" (unless I over did it on the yard work or too many activities in one day then a third one would have helped yes but I didn't take any more than I was supposed to.) My family physician prescribed it. I haven't had insurance for the last 13 years, I cannot afford more expensive meds, treatments, pain management or insurance through the "affordable care act" ($400+ a month with a $6,000 deductible).

I didn't know how good I had it with a semi-normal life. I panicked and took myself off medicine that humanely relieved a fair amount of my pain when the new opioid rules went into effect in Oct. 2014. I couldn't take going to my Dr. and having her tell me she couldn't/wouldn't prescribe them any longer and had to send me to pain mgmt. I don't even know if she would have done that but I couldn't take the prospect so, stubborn woman that I am, I stopped the pain meds and stopped seeing my dr. altogether (have not been in 7 years). I found an herb (not cannabis) that helps take the edge off but doesn't help anywhere near enough, doesn't allow me to be active and I didn't think it would happen but the pain and neuro symptoms are getting worse and worse. Yes I did this to myself but it was out of fear of the humiliation I was witnessing chronic pain patients go through. A very sorry state of affairs. Something has to change, what’s happening is not sane or humane.

Thank you,

Jeannah Haber
Sarasota, FL

From: Jonathan James
To: NCIPCBSC (CDC)
Subject: Chronic pain guideline comments
Date: Saturday, July 17, 2021 12:27:48 AM

Im not going to be long winded as i just cant focus though the pain. Im literally wasting away, dying bedridden in utter agony because i can't get adequate pain control even being seen by a clinic following their rules. Im only 33 and have been suffering in increasing agony, the kind where if i didnt have a son i would have killed myself years ago, now i havent been well enough to even take him in a year.

All because a dental implant, the surgeon crushed an artery in my face and denied any fault leaving me going through a hundred doctors to find the cause. Now even with it so much damage is done my next surgery may not help the constant infection and necrotic bone formation from no blood reaching past the compression. Im so weak and over whelmed in constant agony i cant make progress finding a willing surgeon to correct it or be run from uncaring pain clinic to uncaring clinic to find someone willing to up my dose enough to function and not be destroying my body from the stress, the necrotic toxins and literal hell i live in.

Your punishing patients that cant defend themselves for the choices of addicts are why im dying and havent seen my 6 year old in a year. I hope you and the DEA are both sued into oblivion and the ones that caused this imprisoned for life. We didnt deserve this, we are fathers, mothers, soldiers, workers that suffered accidents, victims of violence or severe accidents; not addicts.. and you ruined our lives and drove many of my friends and support group members onto dangerous street drugs, to suicide, or bankrupted by the uncaring pain clinics milking us for 300$ monthly appointments and forcing us onto often $500-1500 dollar a month medications.

Youre crooked, deceitful, and if i do survive im going to join the class action suits and protests to have your institutions abolished. You directly caused my literal torture and my being abandoned by my family. Likely caused my agonizing death as well. You are no better than Nazis exterminating the Jews in my eyes.

From: Joseph Kapler
To: NCIPCBSC (CDC)
Subject: BSC, NCIPC Meeting Recommendations
Date: Wednesday, July 21, 2021 9:14:21 PM

I have noted a couple of recommendations regarding the changes to the Opioid Prescribing Guidelines.

1. The use of the term Dependency should NOT be used in conjunction with the terms of Alcohol Addiction and Abuse and Opioid Addiction and Abuse. Dependency is NOT Abuse of any sort. It is NOT Addiction of any sort. Dependency is the body's dependency on the Opioid to manage Chronic Pain in those that have required Opioids to manage their Chronic Debilitating Pain. The human body adjusts it's Tolerance of the level of Opioids used long term to manage their pain. Eventually, either the dosage needs to be increased to successfully manage pain and allow them to function in human society, or to change to a new, sometimes stronger, Opioid prescription. This is the case with many medications, not just Opioids.

   The vast majority of Chronic Pain patients who use Opioid medications to manage their Chronic Pain, due so at the direction of a Pain Management Specialist, under careful guidance. In most cases, both in Canada and in the United States, the Pain Management Specialist or Physician will enter into a Contract with the Patient, outlining how the medication is to be used, strong wording stating discontinuation of the Doctor Patient relationship if this Contract is breached. With regular visits, and periodic Drug Tests, the Pain Management Specialist ensures that there is no Abuse of the Opioids. When Abuse occurs, the patient is immediately cut off from any Opioids or other strong non-narcotic Pain meds. In most cases, the Pain Management Specialist or Physician will stop seeing the patient.

2. My second point. I have noticed time and again, that the goals of the Opioid Guidelines is to take the Chronic Pain patient OFF all Opioids. The following is from the current Recommendations to the Guide:

   > Patients on high doses (=90 mg MED/day) should be prioritized for gradual opioid tapering. The balance of benefits and harms often becomes unfavourable at doses above 90 mg MED/day. For these patients the potential harms of therapy often outweigh the benefits the patient can achieve in terms of pain and function.
   >
   > Patients should be actively engaged in a discussion about the merits of gradual dose reduction, including the potential for better pain control and quality of life. Prepare the patient for tapering by optimizing non-opioid strategies for pain management, setting realistic functional goals, optimizing psychosocial support, creating a schedule of dose reductions and follow-up visits and having a plan in

place to manage withdrawal symptoms and emerging pain. Establishing a plan with patients takes the uncertainty out of the process and helps engage them in the process (see ationalpaincentre.mcmaster.ca/guidelines for a Patient Information Sheet for Tapering).

I have suffered from ever increasing levels of Severe Chronic Pain for over 30 years. For the last 15 to 20 years I have been on various Opioid medications, most recently on Fentanyl Patch and Hydromorphone for break-through Pain. Thankfully, I have a Pain Management Specialist that is more concerned with my level of Pain and ability to function. My current MED is >90 mg MED. At my stage in life, without the Opioids at their current level, I would not be able to function at all without them.

The vast majority of US and Canadian patients with Severe Chronic Pain can not live without Pain Management. With the vast majority of Physicians and other law makers taking the Guidelines as Law, are currently tapering patients off all their Opioid Medications in fear of losing their License to Practice for Prescribing Opioids >50 mg MED. They take the Recommendation (Recommendation 9: For patients with chronic noncancer pain who are currently using 90 mg morphine equivalents of opioids per day or more) as Law and Taper their patients completely off their Opioids, leaving them unable to Function. Many of these Patients commit Suicide as they can not manage their Pain and see no Hope.

The Guide needs to take better consideration for those with Severe Chronic Pain. Those people that require much stronger dosages of Opioid Medications to manage their Pain to the point that they can function at 30% or higher. It should state clearly that the Goal of Prescribing Opioids for Severe Long-Term Chronic Pain is to manage the Pain at a minimal level of 30% or greater Pain Relief. And to titrate levels to get the best Pain Management possible with the least amount of Risk.

Isn’t a Physician supposed to Do No Harm?

Thank you for your time.

Joseph (Joe) Kapler

From: JANE KOHUTH
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:30:25 PM

I am writing to express concern about the proposed Updated Guideline for Opioid Prescribing. Unfortunately this draft does nothing to acknowledge or mitigate the documented harm that followed the implementation of the current guideline.The new guideline focuses exclusively on the risks of opioid prescribing without talking about areas of potential benefit, especially for those for whom other methods are not enough or are not options. It also fails to mention the risks of uncontrolled pain and forced tapering, which include loss of function, livelihood, and suicide. It continues to rely on arbitrary MME dose limits, which have no basis in science, and singles out particular conditions for exclusions while ignoring other equally painful conditions, such as Ehlers-Danlos Syndrome.

I live with HEDS. Tramadol makes up only a part of my multifaceted pain control strategy, but a key one. Until there is specific, effective treatment for EDS, this medication will continue to be necessary. I have been on a stable dose of medication for many years and continue to be able to take less on lower pain days. Access to medication means that I can work part time, participate in my community, and be an active parent. There are millions of people like me and our lives are no less important than those of any other demographic.

Sincerely,
Jane Kohuth
M.T.S. Harvard Divinity School

Jane Kohuth (she/her)
Find information about me and my books at www.janekohuth.com
Instagram @janekohuth

From: Joseph KRAMER
To: NCIPCBSC (CDC)
Subject: CDC guidelines
Date: Thursday, July 22, 2021 7:31:34 PM

Dear Members, As a person who was electrocuted by 440w fell from overhead crane, fractured back, severe whiplash , shock , nerves burned up in my spine ended up with Adhesive Arachnoiditis, 6 sinus surgeries with staph infection & csf leak w polyps /allergies. The other disease that runs in families I have Ulcerative Colitis and it sucks. The opiates help calm my Ulcerative colitis and when I stop taking I start bleeding from, I almost died from this because of the 2016 guidlines caused me to loose my doctor. I started to bleed and dropping weight I lost 45 lbs looked like death, my ankle swelled because my valves in vein refluxed and it still aches. I was absorbing 0 protein and the hospital close to me sent me home after putting fluid in me. They didn’t want me there because the meds I was on would go there records. The doctor told me to get some joints and chill out on some weed. I was furious. The opiates work for my pain , let me shower, grocery shop, help around the house, do the finances. I am in a dire situation , the guidelines have ruined my life, and I will probably loose my family and life if you keep destabilizing my care. The cost of care has at least doubled if you think someone like me can just go down the street and find care your wrong. Every doctor is scared to take care properly. The pill mills are gone and I beg you to include me in what ever decision you make. I am 61 and I need care and I can’t get it because of 2016 guidlines. Congress was warned what would happen, and I am not alone families all over are upset with you and there will be accountability of who hurt all these families. My doctor told me Arachnoiditis is worse than most cancers yet you forgot about me and many others, we should not have to beg. You could be next needing help so distraught wondering why my country is listening to these Ugenics ableism elite. I understand we need a change in thinking but crushing those who were receiving care is not the proper way. Yes addicts need help and locking them up is wrong but I never met one you could force into sobriety, they will search for help when they are ready. But trying to tell patients with many damaged body parts and disease that pain meds don’t work is insulting. Most hate these drugs anyway and everyone of us is different . Some have allergies to them and some need more then others ,but again trying to tell stable patients that throwing them into duress and possible death is proper you have forgotten the basic Tennant’s of health care. I ask everyone in the group how much would you accomplish if your smoking weed? Please bring back hope to patients like me. We have to get our teeth fixed, go to doctor apts and be productive members of our homes and society. Make it fair for all. If the guidlines were done right the first time with pain doctors they would have been better accepted. There are patients who need these meds the rest of their life, how would you like it if some doctors told you that it doesn’t matter if you suffer or it’s all in your head when you know it’s not. The guidlines helped cause misery and suffering don’t you think it’s time to fix that and bring respectability back to the CDC. Heaven knows how many have gotten rich off my suffering.

Sent from my iPhone

From: Jay Kuchera
To: NCIPCBSC (CDC)
Subject: Time dependent - Public comment schedule July 16th
Date: Thursday, July 15, 2021 7:22:06 PM

Gwendolyn H. Cattledge, Ph.D., M.S.E.H.,

Bonomi, Amy E., Ph.D., M.P.H.

Drs. Cattledge and Bonomi,

We are experiencing a critical collapse of opioid care in pain medicine with profound consequences for public health. I have discussed gaps in CDC policy as they relate to pain medicine with Dr. Debbie Dowell and Roger Chou over the years. The lack of policy support has become urgent.

I am registered for public comment, however I have clinic duties until 3:30 PM Eastern. Would you kindly be able to schedule me after 3:30 PM?

Whether or not I can attend tomorrow, additional dialogue would be most appreciated.

Thank you for your service,

Jay Kuchera

JAY KUCHERA, MD, FASAM
Algiatry, Addiction Medicine, Anesthesiology
Director, Specialized Opioid Support Services
Resolute Pain Solutions
Envision Physician Services
Member, University of Florida CTSI Community Advisory Board
C: 561.262.5141 | W: 772.337.7676

From: Jessica Lavoie
To: NCIPCBSC (CDC)
Subject: Opioid workgroup BSC recommendations
Date: Friday, July 16, 2021 4:59:35 PM

I would ask that intractable pain conditions such as ips, ehlers-danlos and other painful condition that, with current available treatments and science is not curable and lacks effective alternative treatments also be added alongside sickle cell, cancer and end of life for exclusion from the CDC guidelines. I see that palliative care is in there but unfortunately I'm 35 and even though I have others and a number of other intractable pain conditions I cannot currently get into palliative care. I have been on disability since 2008 and started going to a pain clinic just before I was approved for disability. I was functioning before the CDC guidelines were applied and I was abandoned by my doctor. Moving to a new state in 2017, having been tricked like many others into trying Suboxone and then later buprenorphine, after Dr abandonment, I cannot find a pain management doctor to even except me as a new patient because like so many others, as we all know they are terrified of the DEA. I also STRONGLY agree that the arbitrary MME number be completely stricken from the CDC guidelines if the guidelines aren't completely removed, which in my opinion would be best. I am 35 years old and have been in pain since 2007. I don't expect to ever be pain free but I am currently on the equivalency of 60 mme, which is four 10 mg immediate release pills a day. I cannot be intimate with my partner and often times know that just doing the dishes and feeding the dogs will mean I can't do anything else for the day if not longer. I have been told by doctors that I am doing everything right because I do so many alternative treatments yet pain medication is something that they still are not okay prescribing due to the extreme damage caused by the CDC and now DEA. I make under $10,000 a year on disability and therefore cannot afford things that partially help, like medical massage.
Thank you,
Jessica Lavoie

From: Jessica Layman
To: NCIPCBSC (CDC)
Subject: CDC opioid guidelines revision
Date: Thursday, July 22, 2021 3:15:10 PM

Hello,

I'm writing to ask for a revision or suspension of the 2016 MME prescribing guidelines.

I've been a chronic pain patient for 18 years, since I was 20, due to a genetic malformation of my vertebra. Since the CDC's MME guidelines were published, I've had my medication reduced by 50%, had to leave my full-time job, almost died from an allergy to a lesser medication (since I couldn't access what I actually need), and called over 100 doctors to find someone who will take me as a patient.

I have an entirely manageable condition; I just need access to my medication, like anyone with diabetes or high blood pressure. I have never abused or misused my pain meds, never felt "high" off anything, never failed any of my monthly drug screens, and yet I'm spending close to $10,000 a year in order to get half of the medication I need. I've also done pharmagenetic testing that demonstrates I have a gene mutation that creates a higher tolerance to opioids.

Without the MME "guidelines" I would still be working full-time. I would still have my home and I would still be living in the city I love. I would be a normal person, just like you. If any other chronic condition was discriminated against the way chronic pain has become, it would be national news every night. Can you imagine if diabetics or kids with ADHD were give a blanket dosage limit with no consideration for age, physical size or severity of their disease?

Numerous studies have determined that chronic pain has an addiction rate of 1%, or less. Prescribing has fallen dramatically, yet overdose deaths have tripled because of illicit fentynal. The CDC, and organizations like PROP and Shatterproof continue to double down and insist that pain patients are the problem, despite all evidence to the contrary. In fact, the number of medication-only overdoses is so small that the CDC doesn't even track it; data appears to show that of 48,000 OD's, less than 500 involved solely pain meds.

The CDC's MME guidelines have done an incredible amount of harm to the 50 million Americans living with chronic pain. This inhuman disregard must stop, and the 2016 MME guidelines must be retracted.

Jessica Layman

From:	Julia Litten
To:	NCIPCBSC (CDC)
Subject:	Comment on Updated Guideline
Date:	Friday, July 23, 2021 4:48:14 PM

To Whom It May Concern:

I write these comments as both a retired Physician Assistant, who graduated from George Washington University, and as a chronic pain patient of eleven years' duration. As a PA, my colleagues and myself read and highly regarded the weekly Morbidity and Mortality Reports. I had never heard of the CDC National Center for Injury Prevention and Control prior to the 2016 Guidelines.

My first comment, or premise, is that any opioid prescribing guidelines from the NCIPC, if at all, should only apply to people who have been diagnosed with Opioid Use Disorder and concurrent or new onset pain. People with chronic pain from all diseases and/or conditions, but no diagnosis of OUD, should not be included under these Guidelines, either from 2016 or the newer version. The CDC does not write prescribing guidelines for any other disease or co diction. This comes under the purview of the FDA.

The FDA recently held a workshop on the subject of Morphine Milligram Equivalents. Public comments are still open in the Federal Register. Expert testimony has revealed inconsistencies in MME ratings and in changing from one opioid to another. The MME method also does not take into account differences in metabolizing or processing various opioid medications. I myself have tested to be, a slow metabolizer, which is known to my providers. Therefore, certain opioids are more or less effective for me than others.

The writers, advisors, and committee members who contributed to the 2016 Guidelines already know how they were misapplied to create hard limits in state laws, law enforcement criteria, including the DEA, and in causing fear among doctors, so that many refused to prescribe needed pain relievers anymore. It is unknown how many providers force tapered or completely cut their patients off, forcing some to go into withdrawal.

The Guidelines have added to the stigma felt by legitimate chronic pain patients, who do not now and never had Opioid Use Disorder. We have been punished by being forced to have pain contracts, regular urine drug testing, and pill counts. For some patients, this is done on a monthly basis. We have been denigrated, accused of being addicts, and dismissed as patients.

Lastly, I am curious why the CDC feels compelled to chime in with recommendations for chronic pain patients, when a perfectly good framework was already created and approved in 2029. It is the HHS Pain Management Best Practices Final Report, which includes input from all the agencies under the HHS, including the CDC. It already speaks about individualized, patient-centered, multi-modal care for chronic pain patients. It already includes care for special patient populations by race, ethnicity, age, gender, and certain medical conditions like sickle cell disease. It also addresses the issue of stigma, which affects the ability of both chronic pain patients and, I might add, also people with addiction, from getting good medical care.

The 2016 and proposed, revised Guidelines for Opioid Prescribing will only add to the fear, shame, and stigma of being a chronic pain patient. There is nothing in the Guidelines that will prevent them from being used once again for new and continuing laws, policing, and health care provider shortages, which add to the pain and suffering of all chronic pain patients.

Respectfully,

Julia Litten, P.A.-C., Emeritus

From: Joy Maxwell
To: NCIPCBSC (CDC)
Subject: ill.”
Date: Sunday, July 18, 2021 4:13:16 PM

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ill.”
Houston DEA Special Agent in Charge Daniel Comeaux is warning Americans that a “counterfeit pill epidemic” is to blame for the increase in overdose deaths in the U.S., he said in an exclusive interview with the Daily Caller News Foundation.

The U.S. saw a record 92,183 drug overdose deaths in 2020 which was a 29.6 percent increase from the previous year, according to Centers for Disease Control and Prevention data that was released Wednesday. Overdose deaths caused by synthetic drugs increased by 54.9 percent and fentanyl is the primary driver of those overdose deaths, the DEA told the DCNF.

From: Joy Maxwell
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:30:32 PM

Thanks for taking comments in your meeting, my name was called. I don’t know why I couldn’t comment. I have very painful spinal stenosis, AA, disc at 4L/5L bulging. My back and legs are numb from the inside out with a pinched nerve . The pain is 24/7 never goes away, I have been in PM for 40 years. When I had my prescription pain medicine I was on the same medication same dose for over 22yrs. With my prescription I was able to work PT, see my grandkids and go to their activities. I volunteered at the VFW weekly did fund raising I held office for two years. I had a productive life then BAM 2016 guide lines I was forced taken off my Long term and short term prescription pain medicine, no tapered just no we can’t give out medicine. My productive life was just ripped away. I thought what did I do wrong?!? I did nothing wrong I looked up to see if anyone else had this happen to . Yes , yes yes millions over 50 Veterans and non veterans being harmed forced off our narcotic opiate opioid Pain medicine. Please reverse the guide lines today please we just want to live we yes do other treatments with our prescription. I have more to my painful journey as so many others do MY story is Millions of others yet we have never met or spoken. Opiate opioid narcotic Pain medicine lets us lead productive life’s my chemistry is mine so whatever works for me I should be able to take, whatever works for all the millions being harmed forced off should be able to take whatever works for them . Please my painful journey can be helped with my prescription pain medicine. Please don’t wait we in The pain community have lost too many due to suicides they were unable to get their prescription pain medicine the latest is the attorney Erin .

From: David Miller
To: NCIPCBSC (CDC)
Subject: CDC Guidelines Comments
Date: Monday, July 19, 2021 10:14:13 PM

I’ve been a Chronic Pain patient for 30+ years, due to multiple failed back surgeries. I was very stable with the use of 30 years of pain medications until the CDC Guidelines forced cut my daily dose by 70%(220mme cut to 90mme). This has caused nothing more than hell on earth for me and my family. I was very independent before the force tapper, now I’m unable to function without the help of family. Ive tried all the alternative therapies over the years with no success, the only thing that made me functional was the higher level of pain medication, well over 90mme. Been in pain management with the same doctor for 23 years, was told by my doctor sorry I know your higher level of pain medication helps your quality of life, but I have to cut to below 90mme or I could lose my license & face prison. Something needs to change & soon, we are losing the war on Chronic Pain due to 2016 CDC Guideline. It’s a heroin fentanyl problem not a prescription pain medication problem. Without proper pain medications, not a one size fits all, needless fellow United States citizens will suffer needlessly and many more will pay the ultimate price of death by heart attacks, stroke, suicide and overdose death by street laced drugs with illegal fentanyl, due too the one size fits all guidelines. Please consider doing away with MME for pain medication and let Doctors practice medicine, not politicians and the DEA.

Thanks,
Jim Miller
Delaware, Ohio

Sent from my iPad

From: Jim Nance
To: NCIPCBSC (CDC)
Subject: My Untreated Chronic Pain
Date: Friday, July 23, 2021 2:14:24 PM

To whom it may concern,

My name is J.M. Nance of Simpson Il.

I am a disabled 49 y.o. Social Security Recipient.

I'm not going to bore you with the sad state of affairs in the handling of chronic pain patients in the U. S. and my torture.

Instead, I will focus on some numbers.

I can walk, bend, etc. with a single 5mg. Extended Release Morphine Sulfate, every two days.

I can do nearly as well with Tramadol 5mg. But, as with many synthetic opioids, I have some severe behavioural, as well as gastrointestinal reactions that further dibilitate my ability to function and impede my daily life.

Other than Morphine, my body does not react well with synthetic opioids.

As a result, I live in severe debilitating pain that could be treated if the 2016 Opioid Guidlines were corrected and made clear to these bums, masquerading as physicians.

Were I properly treated, for the several debilitating conditions I have, the taxpayer would not be paying $2600.00 per month in insulin to keep me alive.

If I could be properly treated adequately with 15, 5mg. ER Morphine per month, I could remain moving enough, to halt altogether or drastically reduce the amount of insulin required to keep my incapacitated body reasonably healthy.

I also believe the members of the D.E.A. should be imprisoned for as long as the family members of all the suicide victims as a result of this ignorant fiasco, say so.

Sincerely,

JMN

James Milburn Nance
Jim M. Nance

From:	janeihart66@aol.com
To:	NCIPCBSC (CDC)
Subject:	Comment on Updated Guideline
Date:	Thursday, July 22, 2021 8:03:21 PM

This issue has already caused so much damage. I have inoperable degenerative disc disease, with virtually no discs left in my neck, and 3 discs gone in my lower back. The rules on opioids are already draconian. I quit cold turkey on 1/1/19. My life is now a nightmare. I have intense pain constantly, and live my life lying on ice packs, taking more OTC meds than is healthy. Sleep is hit and miss. I broke my leg in three places in 2013, and it was merely inconvenient because I couldn't walk on it. My neck exceeds that pain on a daily basis. I used to enjoy life, I actually had a life, a busy life, now I nightly hope I don't wake up in the morning. I got fed up with being treated like a felon on parole with the constant urine tests. I'm not a criminal, I'm in pain. My pain clinic was also a long drive, which caused more pain all by itself. It also stinks that you have to have the right amount in your urine at all times, forcing people to drive under the influence. Too little, and you must be selling it, too much, and you're abusing it, neither is acceptable. You also have to take it all the time, not just when you need it, which lessens the effectiveness and causes addiction. I think very few opioid deaths are from people who actually need them. They are mostly people who want a buzz and don't have them legally. People die from alcohol poisoning, but alcohol is not regulated like this. If someone told these monsters that rat poison was an awesome high, they'd happily take that too. I may sound cold, but if people take meds that weren't prescribed to them and end up dead, that's their mistake. If it had been heroin, their use of it would be frowned upon instead of punishing the people who need opioids to have any quality of life. It's not right to punish people with chronic pain because selfish people decide getting high is all important. The people who really are in extreme pain shouldn't be treated like this. No way a bunch of people crippled by pain can protest like BLM either, we're home on ice packs, helpless. Speaking of which, did George Floyd have a prescription for the meds he had taken? No! I now hate doctors, unless I can't stop the bleeding, have a broken bone, or need an antibiotic, I want nothing to do with them. I won't allow any tests for diabetes or cholesterol. I won't take meds for any of it. I hope it kills me. My opinion is that doctors should not be able to pick and choose what to treat, when the thing they refuse to treat is the only thing that can actually improve someone's life. These rules force doctors who used to care, to harden their hearts and refuse to treat chronic pain patients, so we're expected to drive all over the place to doctors that will help, as long as you sell your soul and any rights away by signing a narcotics contract. Doctors are afraid of losing their licenses. The best doctor I had got suckered by some unscrupulous patients, and he's now gone. People in pain already have rotten lives, you shouldn't strive to make matters worse, what we need is help.

Sincerely,

Janet Neihart
janeihart66@aol.com

From: Jefferson Nunn
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:15:33 PM

Hello,

I have been living with terrible pain since being exposed to toxins five years ago. Currently, there is no emphasis on pain research. Your updated 2021 guidelines is the same as the 2016 guidelines that does nothing for pain management.

We need to establish a better understanding and research into effective pain management. Rather than saying NO to everything that can even help with pain – and without any scientific basis, we need to say YES to a scientific basis of pain management.

This needs fixing NOW. When you're in pain – it's hard to do anything.

Jefferson

From: J.O. Tobin
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:36:16 PM

Dear CDC,

Your recommendations are completely one sided. Chronic pain is just as real as any other pain and opiods are highly effective in treating chronic pain. While opioid abuse is a health problem it will not. E solved by making all opiods difficult to obtain and it will cause a lot of pain among the many patients who have benefited from opiods. Ipiods are the only really effective drug for pain both acute and chronic.

Everybody knows the “War on Drugs” has been a colossal failure and that people for whom opiod abuse is a way of life they will continue to have many ways to obtain opioids outside of there Doctor’s office.

The approach you are advocating will hurt many patients whose use of opiods has allowed them to resume a functioning life with chronic pain and will not deter chronic opiod abusers for whom the black market is always open.

Restricting supply for the millions of Americans and trying to interfere with there relationship with there Dr. by advocating a one size fits all policy will cause many people a great amount of pain and all so you can see if the chronic abusers will change there behavior. Catering to the lowest common denominator is rarely a successful strategy and generally has unintended consequences.

Joseph Tobin

--
J.O.Tobin
41565518550f
4154252863c

From: Jeanne Peterson
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Thursday, July 22, 2021 8:44:36 AM

I have had 8 failed back surgery's, they are to the point now that all that's left to do is manage my pain. They cannot do that with the guidelines you keep enforcing which takes away my quality of life. I no longer can play with my grand kids, I can no longer walk more than 1/3 of a block without having to sit down in extreme pain, I feel worthless, I am only 53 years old and I feel worthless. I live in daily pain, I am able to do dishes but then have to sit, I am able to vacuum then have to sit, I am able to do activity's of daily living in short staunts but have to sit, I spend the majority of my day sitting because I'm in so much pain. I sleep only about 2 hours per night then have to go sit in a recliner. Without my pain managed I mise well be dead because I literally have no quality of life. It's MY body, why do I have a choice on abortion but not a choice as to what I put in my body? Isn't it better to have SOME quality of life than none? Not having my pain managed has caused significant weight gain due to the lack of activity. The weight gain has caused high blood pressure, isn't it better to just treat my pain than cause me a lot more health problems? Stop telling the physicians how to do their job they spent many years in school learning how to do! Stop threatening criminal charges for them doing their jobs!! The amount of scripts being written have been cut in less than half, yet the increase in over doses continues to rise, can't you see it's not from prescribed opiates?? You have taken the lives from so many without blinking an eye and continue to do so. Leave chronic pain patients alone an allow us to have some quality of life !!

Jeanne Peterson

From: Jan Poole
To: NCIPCBSC (CDC)
Subject: CDC Updated Guidelines
Date: Thursday, July 15, 2021 4:18:16 PM

To Whom It May Concern:

I am an intractable severe pain patient with Complex Regional Pain Syndrome, the highest rated pain on the McGill Pain Scale (above amputation, cancer and childbirth)! It feels like someone is pouring acid on my legs and feet, which came about due to a crush injury 22 years ago.
My pain was managed by what is now considered a high dose of Fentanyl patches (150 mcg daily) because the government pressured the drug companies to re-formulate them. They used to come in gel patches with a backup reservoir film that allowed a distribution of medicine for 2-3 days. Now they come in sticky adhesives which gum up the Fentanyl only lasting daily. But the doctors don't know this and continue to prescribe for 3 days if you're lucky enough to find a Dr who will prescribe an opioid!

I had pain control for 22 years, up until the CDC Guidelines which then made it impossible for ANY DR. to prescribe because THE GOVERNMENT BECAME INVOLVED IN THE PRACTICE OF MEDICINE! They are fearful of DEA prosecution and censure from their boards and those people including CDC politicians have NO understanding of opioids and how they work for pain!

When my Primary Dr. wasn't allowed to prescribe for me anymore by his corporation, I had to try to find another doctor. All of the pain management doctors want to do either injections at $2,000-$3,000 a pop, or devices like drug implant pumps or Spinal Cord Stimulators because that's where the money is and it allows them to avoid being surveilled by the Government!!!!
My pain Dr retired 2 days ago and the new pain Dr. WON'T PRESCRIBE OPIOIDS SO NOW I AWAIT AN AGONIZING TAPER WHICH WILL END UP KILLING ME!
Patients are committing SUICIDE daily, but no one cares.
Your Guidelines were written by PROP (Kolodny, Chou, Ballantyne) a bunch of addiction psychiatrists who want everyone off of opioids and into addiction centers where they can prescribe Suboxone! Kolodny owns a chain of 9 centers (the Phoenix House) and now makes half a million dollars being a witness for the prosecution of drug companies!

He is a liar who stated opioids are ineffective for chronic pain, basing it on a study of back pain. You don't give opioids for back pain. But you certainly give them for NERVE PAIN and opioids are the only thing that are highly effective for this and other types of pain.
Also, when you came out said 70,000 people died of overdoses in 2017, those people had combined them with alcohol and benzodiazepines! LESS THAN 1% OF PATIENTS WITH PAIN EVER BECOME ADDICTED TO OPIOIDS BECAUSE THEY DO NOT GET "HIGH"!

No one asks the patients or does their research. All of this is proveable.

UNTIL YOU RESCIND YOUR GUIDELINES NOTHING WILL CHANGE. YOU HAVE DONE IRREPARABLE DAMAGE TO PAIN PATIENTS AND THEIR ABILITY TO BE OUT OF PAIN. IT'S REALLY A HUMAN RIGHTS ABUSE!

From: Juliet Post
To: NCIPCBSC (CDC)
Subject: Chronic Pain Restrictions
Date: Sunday, July 18, 2021 12:24:50 PM

I wanted to share my story with you. I am a 43 year old otherwise heathy woman. Before I had my hysterectomy three years ago, I had run 15 half marathons, 2 full marathons, rode my bike exclusively for transportation, and was a yoga instructor for a profession. I was incredibly good shape, and took very good care of my body.

I had a period that lasted over 80 days. We couldn't stop it and so an emergency hysterectomy was performed. I initially felt wonderful. As my blood counts returned to normal I realized I had not felt good for years. I was severely anemic. All guidelines say to wait 6 weeks for intercourse. My doctor advised 8 weeks. I was nervous, and waited 11. I had an 11 week check up and my doctor chuckled at me gave me a physical exam and told me to "have fun with my husband".

My stitches (though I question if there were stitches-that's not the point) failed. I blacked out and came to in blood and pain. The pain has never gone away. I live in a state of constant pain. Medicated I'm at a 7/10. My narcotics won't be raised any higher because of the opioid restrictions. I have no chance at a normal life. I spend most of my days crying, in my chair, miserable. If I didn't have a child that would be forever hurt by my absence I would absolutely consider suicide. We have tried everything. The only thing that even sort of worked was Botox injections which insurance does not cover and I can't afford.

There is major collateral damage in your war on opiates. People in pain are getting left behind. It is cruel. It is causing harm. I'm in so much pain that I vomit and pass out. That causes harm. I'm not unique in that. I have lost 40 pounds in 8 weeks. That causes harm. Please do comprehensive research on pain. Please be aware that the pendulum has swung way too far the other way. People are dying due to untreated pain.

Juliet Post
303-917-3552

Sent from my iThing please excuse any typos or autocorrect silliness.

From: Julia Quinn
To: NCIPCBSC (CDC)
Subject: CDC comments re: opioid guideline revision
Date: Friday, July 23, 2021 5:00:45 PM

I am submitting my comment to the CDC to urge a radical overhaul to the CDC's problematic, harmful guidelines on opioid prescribing. These guidelines have wrought terrible harm to pain patients, put providers in a terrible position, put a dangerous weapon—and dangerous language—in the hands of insurers, PBMs, and others with adverse interests to patients, and has indirectly harmed people with opioid use disorder. Policy responses to the overdose crisis such as these guidelines have had two primary effects: worsening, not improving, that very overdose crisis and wreaking havoc on the ability of chronic pain patients. The CDC has meekly asked insurers, states, regulators, and providers not to misapply the guidelines. That humble effort has failed, and the CDC working group has set out in its recent report that was adopted by the BSC has raised very serious alarms that the CDC has not learned from the disastrous fallout from the guidelines. I hope that the myriad comments that the CDC receives, including mine, will convince the agency to own up to its mistakes and make affirmative efforts to rectify them.

First and foremost, the CDC should abandon this approach entire and rescind the Guidelines in their entirety. To be clear, that this the only way to begin to mitigate harm. If the CDC is unwilling to do this—and I fear that it is—despite its previous acknowledgement of the domino effect of cascading harms that stem from these Guidelines, the agency must be radical and serious revisions to the Guidelines, and it must proactively ensure that physicians, insurers, state licensing boards, the DEA, and others that have used the Guidelines as a blunt weapon against patient.

Should the CDC be unwilling to rescind the Guidelines that even the agency has acknowledged have been misapplied in various contexts, then it must—at a minimum—adopt the revisions that were put forth by "many" or "a majority of" the working group in response to each of the 12 recommendations set out in the revision, as currently constituted. Although I endorse the views of "most of" or the "majority of" the working group for all 12 recommendations, I would like to underscore the fact that the CDC must eliminate and renounce the provisions that have caused the most harm. This means:

Removing all references to MMEs and/or thresholds or dosage or duration limits. Measuring "success" by the number of MMEs—a controversial topic in and of itself—and/or by the number of pills or number of prescriptions issued is reductive and harmful. I was very disappointed to see that one of the CDC's listed guideline authors, Dr. Dowell, appeared to be either completely unfamiliar or completely unconcerned with the latest research regarding MMEs. Specifically, new research that shows that there are multiple ways to calculate "MME," one of which, this paper argues, should never be utilized:
https://journals.lww.com/clinicalpain/Fulltext/2021/08000/Inches,_Centimeters,_and_Yards__Overlooked.1.aspx.
Presumably, this utilization of MMEs is to limit overdose, despite the fact that the CDC itself, as well as other government agencies, have dismissed both the risk of overdose in pain patients taking opioids and the utility of MMEs and hard dosage caps. The study cited in the CDC's own telebriefing from 2016 however, found "opiate-related" death to occur in 59 of 32,449 (0.2%) patients taking opioids for more than three months.
http://www.cdc.gov/media/releases/2016/t0315-prescribing-opioids-guidelines.html.
The context of these deaths was unknown (e.g., whether medications were taken as prescribed or from intentional overdose) and there was no corresponding control cohort of patients in chronic pain without opioid use. The senior author noted that the "generalizability of these findings to other patients is uncertain." A prior study by the same authors put the rate of overdose death at less than 1%, even for "high dose" prescriptions. Gomes T, Mamdani MM, Dhalla IA, Paterson JM, Juurlink DN. Opioid dose and drug-related mortality in patients with nonmalignant pain. Arch Intern Med. 2011;171(7):686–691. doi:10.1001/archinternmed.2011.117; Sullivan MD. Limiting the potential harms of high-dose opioid therapy: comment on "Opioid dose and drug-related mortality in patients with nonmalignant pain". Arch Intern Med. 2011;171(7):691–693. doi:10.1001/archinternmed.2011.101. In its review of a Citizen's Petition to limit doses of chronic opioids, the FDA found that "the scientific literature does not support establishing a maximum recommended daily dose of 100 mg MED [morphine equivalent dose]." FDA CDER Response to Physicians for Responsible Opioid Prescribing Partial Petition Approval and Denial. September 10. 2013.
https://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0818-0793.

- Inclusion of language and studies illustrating benefits of opioids
- A clear, unequivocal statement at the beginning of the guidelines that these are recommendations for a

small subset of providers, they should never be considered outside of a clinical context and in fact previous application in such situations has been inappropriate and against the CDC's intended purpose in creating these guidelines (for example, by insurers and/or payors, pharmacy benefit managers, or other non-clinical contexts).

- A statement that the guidelines do not support the decisions of providers to refuse to treat or work with patients who are prescribed opioids or patients with chronic pain (whether treated with opioids or not), as well as a clear statement that no provider should utilize or rely upon the guidelines in making blanket policies—such as hard dosage or duration limits for all patients, a refusal to utilize opioids at all in the treatment of chronic pain, or other absolutes that have been justified by the Guidelines.
- An unequivocal acknowledgment that the opioid crisis it not being driven by prescription opioids—diverted or otherwise—and that supply-side reductions have significant data showing their harm both to people with opioid use disorder and people who live in pain.

Second, if the CDC is not going to remove its reference to what the working group called privileged conditions, then the CDC must add Ehlers-Danlos Syndrome as one of the named, excluded conditions to which the Guidelines should not be applied, in addition to cancer pain, sickle cell anemia, and palliative care. The Guidelines already purport to exempt acute pain—and rightfully so. Ehlers-Danlos Syndromes, especially type III (hyper mobility type) is characterized by myriad acutely painful manifestations, such as recurrent dislocations, subluxations, and muscle spasms, as well as early-onset arthritis, joint instability, and other long-term painful conditions. These are precisely the type of scenarios for which opioids are indicated. To exclude EDS from the list of supposed safe harbor conditions is not consistent with data and further stigmatizing a debilitating condition for which there is no cure, only supportive treatment. It is well-established that many individuals with EDS, particularly the hypermobility/type III variant, is responsive to long-term opioid therapy. *See, e.g.*, https://www.painphysicianjournal.com/current/pdf?article=NzA4Mg%3D%3D&journal=128; https://www.tandfonline.com/doi/abs/10.3109/09638288.2015.1092175.

Although people with sickle cell, cancer, and even those in excruciating pain while dying, such as my grandmother, have nevertheless been victimized by the CDC Guidelines, the CDC's decision to privilege certain illnesses and types of pain as worthy has downstream effects. If patients must live in a world where these Guidelines are omnipresent—and they are—then the CDC must take interim steps to minimize that ubiquity by ensuring as many patients as possible may be treated with opioids when appropriate. There is no doubt that EDS is one such condition, as explained above. This is a life-long, unbearably painful condition. If the CDC is going to stick with its current formulation of the rules, at the very least, widen the circle of named conditions.

To be clear, the modest acknowledgement of harm that three CDC Guideline authors published in a 2019 JAMA article was welcome, but it was worthless. I wish it had not been, but the data show accelerating harms between the time of the clarification in 2019 and the present—there has been virtually no evidence that this public acknowledgement of the devastation that the Guidelines have wrought had any effect. When in the wake of this clarification the then-Surgeon General Jerome Adams publicly pleaded with providers and others who have misapplied the Guidelines to "PLEASE read this article" about the "unintended impact on patients" as a result of "inflexible application of recommended dosage/duration thresholds & policies encouraging harm limits & abrupt tapering of drug dosages, causing sudden opioid discontinuation or dismissal of patients from a practice" (emphasis in original), patients and medical providers alike both mocked the notion that this clarification would do anything and told their personal stories of harm borne out of the Guidelines. Tweet from @Surgeon_General, 5/30/19 at 7:14pm. Dr. Jessica Johnson Pharm.D, wrote in response "I work as a prescriber educator and can absolutely confirm, that MDs/NPs/others feel that regardless of clarification, their license [is] at risk if continuing to prescribe opioids to pain pts. Guidelines misapplication by DEA/reg autos terribly hurting patient care." Tweet from @Jessnimm, 5/31/19 at 11:46am.

I am fortunate in my own treatment in that I currently have access to proper pain relief. Many are not so fortunate, such as my grandmother, who at 92 years old after shattering her femur and becoming bed-ridden, struggled to find a provider in Houston, Texas to consistently provide adequate pain relief in the last years of her life. Her internist eventually relented, but eveyr single month that provider referenced the guidelines as the reason she believed her license was on the line, each time she wrote a 92-year-old woman a modest (far before 90MME no matter how calculated) dose of morphine each month.

Somehow, I have found myself more fortunate than my grandmother was before she died, as I have a provider who is caring, open-minded, believes in patient-centered, individualized care, who runs a practice where we spend anywhere from 30 to 60 minutes together during each visit. I have in place a complex, multi-model treatment plan, and we utilize a wide range of treatment modalities to address my EDS. We arrived at this combination of therapies after literally years of trial-and-error, trying well over a dozen medications and other therapies before arriving at my current treatment plan. Currently, I am treated with non-narcotic medications (NSAIDs and anti-depressants), injections, physical therapy, specific exercise (walking, swimming, some types of pilates), massage, hot/cold treatments, kinesio-taping, dry needling, and, yes, opioids (both extended-release and short-acting).

I have been prescribed opioids for many years, and without issue. I suffer no side effects, and I have never inappropriately taken my medication. Opioids have indisputably increased my quality of life. Where I was once bed-ridden, unable to exercise, in pain and often unable to sleep, I now work full-time without issue and without missing days of work as I did before; I live an active life; I take care of my two dogs; I swim multiple times a week; I maintain relationships and a social life. I live a good life now. I did not before we introduced opioids. And from there, once stabilized on my medication, I was able to integrate exercise, physical therapy, and other treatments into my life. But before I could do that, I had to manage my pain.

I see my doctor regularly for follow-ups. He meticulously documents my functionality, my exercise and physical therapy regimens, and any side effects I have experienced from my medications. He is in regular contact with my other providers. I have to endure specific indignities unique to being someone on opioids. For example, I will be screened for illicit drugs and to make sure that my opioid medication is in my system. I have had to switch pharmacies several times, because of pharmacists who refuse to stock or fill my opioid prescriptions. I was once lectured by a pharmacist at CVS who, meeting me for the first time, loudly mocked my prescription history—all while a line of people waited and eagerly listened in. These are the attendant humiliations that come with being prescribed the medication that gave me my life back. I accept them and I live with them.

However, there is an undeniable culture of fear around prescribing opioids—regardless of the medical benefit they confer—is endemic, and providers are rightfully terrified of putting their licenses on the line to treat patients—patients like me. The CDC is one of the primary authors of this humiliation of patients and the threats to providers. This extremely detailed Human Rights Watch report explains further, and I ask that it be included in the record and that it is addressed in any response to comments. This report gets to the heart of this very issue and contains numerous interviews with patients, doctors, and other providers about the harm that the guidelines have brought to people who live with pain and those who treat them (or, in some cases, used to treat them, before they stopped after the guidelines and related restrictions were implemented): https://www.hrw.org/sites/default/files/report_pdf/hhr1218_web.pdf

Considering the way that the CDC guidelines have been misapplied—to use the CDC's own word—in so many contexts, continuing to utilize the MME concept, especially without clarity as to how the CDC defines such a term, is unconscionable. There is no doubt that opioid prescribing in the United States peaked a decade ago (depending on which index is used). Overdose deaths are reaching new highs. How much more data—and suffering—does the CDC need to show that its approach has not worked? Unless the CDC is solely interested in reaching an arbitrary number of opioid prescriptions each year, without concern for any of the attendant circumstances and context, continuing to utilize the guidelines and merely tinkering at the margins is indefensible.

I am not sure what more information you need to consider this approach a failure. A record number of people are dead from overdoses, and you have untold stories from patients and their providers alike begging you to acknowledge that, in your supposed effort to save people from overdose deaths, you've only caused harm to pain patients. This includes suicides of people from untreated pain. You can start with Erin Gilmer (https://www.nytimes.com/2021/07/17/health/erin-gilmer-dead.html) or speak with Dr. Stefan Kertesz at UAB, who is studying suicides in the context of prescription opioid stoppage, using case-control and psychological autopsy methods, in order to develop, test, and evaluate strategies to mitigate suicide risk in this population. There has, as far as I can tell, been no benefit to these guidelines, unless the CDC is so unsophisticated as to use raw numbers of opioid prescriptions written each year as its one and only measurement of success.

This may be the CDC's one and only measure of success, considering that the CDC previously stated that there is no evidence for use of opioids in chronic pain patients and only evidence of harm (one of the leading critiques of the CDC's approach made in the working group report), I hope that this time around the CDC has abandoned this flawed stance, considering that it previously defined chronic pain as pain lasting longer than three months but previously only included studies that lasted over one year in support of this. This is shockingly inconsistent and, at best, sloppy. At worst, it is a cynical effort to denigrate these critical medications, regardless of harm to patients. This means that the CDC excluded at least one independent systematic review that found evidence of benefit. Noble M, Treadwell JR, Tregear SJ, et al. Long-term opioid management for chronic noncancer pain. *Cochrane database Syst Rev*. 2010;(1):CD006605. doi:10.1002/14651858.CD006605.pub2. This also ignores the ethical, practical, and actual barriers (if not outright prohibitions) on producing the type of studies illustrating benefit of opioids in people with chronic pain. Finally, when coupled with the fact that the absence of evidence is not the evidence of absence, plus that in those types of cases, where “conventional” evidence is limited and suffering is high, use of individualized provider judgment and reliance upon patient reports for improvement is considered a model approach. *See, e.g.*, Reuben DB, Alvanzo AAH, Ashikaga T, et al. National Institutes of Health Pathways to Prevention Workshop: the role of opioids in the treatment of chronic pain. *Ann Intern Med*. 2015;162(4):295–300. doi:10.7326/M14–2775; Cohen MJ, Jangro WC. A Clinical Ethics Approach to Opioid Treatment of Chronic Noncancer Pain. *AMA J Ethics*. 2015;17(6):521–529. doi:10.1001/journalofethics.2015.17.6.nlit1–1506.

From: Josh Rappaport
To: NCIPCBSC (CDC)
Subject: Comment on Guideline Update
Date: Friday, July 23, 2021 1:37:44 AM

Hello,

I am a chronic pain sufferer.

I am writing to share some concerns about the CDC's Guidelines for Opioid Prescribing.

I have been impacted negatively by the 2016 Guidelines. Cutbacks in my medication have led me to be less functional than I used to be.

I work as a professional tutor. Before the 2016 Guidelines, I was able to tutor a full load of students. But after the Guidelines were implemented here in New Mexico, my medications were cut back dramatically.

Some of the cuts were ok. I found that I could function just fine at about half the dose that I used to have because my medications were tapered gradually. So that was a positive change. But my medications were cut back further than that. Cuts were made on the order of 70% reduction. When that reduction was made, I lost much of my functionality because my pain started to go out of control. And it is still out of control.

As a result, I can now tutor only half as much as I used to tutor, which significantly impacts how much I can contribute to my family's finances. As the head of household, this is very problematic, and it has led to all sorts of problems that I won't discuss here, but which I'm sure you can imagine.

I therefore urge the CDC to recognize that many many chronic pain patients like myself are hard-working family people who want nothing more than to have access to medications that will enable us to live fully productive lives. I have been on opioid medications for 17 years now with no adverse consequences or effects. I have never failed a drug test.

Please consider the impact of your
upcoming Guideline review on chronic
pain patients who need these medications
to live fully functional lives and for no
other purpose.

I would appreciate your taking my experience
and views into account.

– Josh Rappaport
Santa Fe, New Mexico

From: Joe
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:10:45 AM

You guys need to do something for all the damage you have done to CPPs with your "guidelines" for doctors to follow. As you were doing that, the DEA was intimidating doctors. So both of you gave the CPPs a 1-2 punch. Many are still suffering because of it. Many are still killing themselves because of it. You guys NEED to convince doctors they WILL NOT be punished for treating their patients with opiate pain medication at THEIR discretion NOT YOURS! Sincerely, Joseph Rietdorf CPP for 6 years and still fighting my doc every month to get a "proper" dosage of pain medication!

From: John Schoellman
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Thursday, July 22, 2021 2:07:45 AM

Hi
I suffer from DDD. I have has many surgeries the last 30 years. Rods/screws/fusions on back and neck. I've had a knee replacement and I wore off over 1/2 inch of bone in my knee. I have taken opioid pain meds and never abused them. I suffer daily in pain. I am subject to urine test, pill counts and the PDMP.

My question is why am I having to suffer in pain? I have a proven need for pain treatment but doctors are scared of treating me properly. Why?

What we have learned:
Less then 1% get addicted taking pain meds that suffer in pain.
Overdoses keep going up even though the DEA has cut Opioid Manufacturing in half.
AG Bill Barr said the government in April 2020 now realizes overdoses are coming for illegal drugs coming across the border.

It's time to allow doctors to treat patients that have a proven need for pain meds without fear of the DEA throwing them in jail for doing their jobs...

With all the safeguards in place (UA's, pill counts, PDMP) why are we still seeing over 50 million, 19 million in high impact pain still suffering?

Do the right thing and allow people that are suffering in horrific pain to be treated with opioid pain meds what ever the amount it takes until we find better technology..

i pray this doesn't happen to you are your family. Only then, you would understand what 24/7 pain really is. No one should have to suffer like I have since the 2016 CDC guidelines came out.

John S
College Station TX

From:	Joan Small
To:	NCIPCBSC (CDC)
Subject:	Comment on Updated Guideline
Date:	Thursday, July 22, 2021 7:33:50 PM

Hi, my name is Joan Small, I have been a chronic pain patient for about 25 yrs. I have had alot of issues to deal with getting diagnosed, treatment and just being treated fairly. I went without any prescription drugs for many years because I didn't want to take opioids. As I got older I couldn't go any longer without help. Since then I have been through withdrawals from a fentanyl patch 3 times, one time by my choice. I eventually got with a Dr who treated me without over medicating. In 2017 when the government made changes I again went through withdrawals not only from the pain meds but another medication for PTSD. Since then my life has been hell. No effective med for PTSD and little pain relief. I struggle everyday with pain and trying to stay active alone is a struggle. I'm ill and I just moved back to SCarolina and the morphine was cut in half again. I'm ready to find a nursing home because I'm afraid I can't take care of myself much longer. I'm 66yrs old and I'm not ready to give up. I have a life I want to live. If there is another cut in medication I know I'm done. I've spent 3months titratng down and have leveled off a couple of months now. I'm a Jesus believing women for strength and unless a miracle happens I don't know how this is going to end for me. I'm in a pain clinic with a Dr who is doing what he's allowed to do and it's not enough for me. I'm pleading for you as decision makers to consider those of us who depend on these medications. It's not our fault because others abused the system with medications. I'm responsible for the prescription I receive, no one else, if someone violates that don't take it out on me. There are good Dr's out here who want to help but their hands are tied. The Dr I had here lost so many patients he closed his office and moved away to another state. I was left high and dry again when he left and I went to stay with family in FL for a year and a half to get a pain management Dr because I couldn't get a Dr here at the time but I came back because this is home and I knew that meant a lesser dose of medication. The mental part of dealing with this is too much some times and finding mental health care in S.CAROLINA is another story let alone having a medication for the PTSD (that I don't have meds for). Please take into consideration all of the many people who depend on these medications and are responsible with their medications. I remember many years ago a hold back on these drugs and the rules where changed because someone spoke up and said these medications were made for a reason, to treat pain, so people should be allowed to have them when needed. Well in my condition I've haven't been able to have knee replacements because my pain is not in control enough for me to have it done, I've seen 3 different surgeons and they all said the same, this has been over 10yrs now, on top of the arthritis in my spine, where the pain began and now arthritis in every joint in my body with osteoporosis stage 2-3. My bones are distorting in my knees, hands, feet, shoulders and I have scoliosis in my spine now. Think about how it is for me to do everyday things like showering, dressing, cooking or taking the trash out, let alone going out to get prescriptions or groceries, I would love to do delivery if I could afford the extra delivery fees. I was able to do these things when I had good pain management, why do I need to suffer? On top of all of this the treatment I have received from pharmacies is a whole other story by itself. I have been accused of forging a prescription or illegally trying to use insurance I didn't have to just being a low form of life for getting a pain medication. Why? I don't understand why I have to go through so much to get the prescription filled because it's an opiate. This has happened to me several times and many others go through the same. In FL I really had trouble finding a pharmacy to fill the scripts. One independent pharmacy told me he couldn't fill it because he couldn't make any money on it. I went to several CVS and Walgreens and finally got it at a Publix. I've used these other pharmacies for many years and to be treated like that is demoralizing. I see why some turn to street drugs, less hassle. So please consider everything that goes into being a pain patient, you shouldn't have to be told you're dying from cancer to get a medication to help you, after all that is what they were made for, pain.

Thank you and God Bless,

Joan Small

From: J. Smith
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 3:14:49 PM

Hello everyone,
I am a chronic pain sufferer with many chronic illnesses. I have suffered from pain ever since my first car accident in 2008. Since then it's been an uphill battle.

I was first diagnosed with Fibromyalgia....In 2019, I was side impacted by a Super Duty Ford 150 truck, my door was caved in. My leg was leaning against the door & took the blunt force of that truck. In 2020, I was rear-ended while parked. I went to my appointment early, relaxing in my car, when a man rear-ended my car. His truck was full of work equipment.

I believe the color of my skin has created difficulties in the way which I am treated. I don't have make-believe injuries, I have injuries that can be corroborated by physical examinations and MRI's, etc.

I am the mother of a child with Autism & intellectual disabilities. I am a wonderful parent. I've been very involved in every aspect of my child's life. Her teachers would say they wish other parents were as involved like I am. My child was accepted into a private college & I'm the transportation. I'm dreading the long drive every day!

I was in so much pain one day, my pulse was 121. My pulse has never been that elevated & I know this because I have all my medical records. I turned my neck slightly & had the worst spasm in my life! My head wouldn't turn. I couldn't lift my arms up, neither could my doctor. My doctor gave me a few Trigger Point injections & that's not what my appointment was for!
I feel like I'm dying every second of every day! Why must I suffer? Why do some people get pain relief & I'm left to suffer? I am willing to take any test when asked! I have nothing to hide! If I seem depressed, that's because I am depressed. I cry myself to sleep at night & force myself out of bed during the day.

There are days when I can't get out of bed! I don't have health problems because I drink, smoke, or do drugs because I don't do those things. If a person abides by the rules, doesn't fill prescriptions too early & doesn't exhibit mental illness or addiction, why can't we receive real help?

I've been to physical therapy, but how am I supposed to exercise when my body doesn't allow me to do so!! I take 2 to 3 Tylenol with a Tramadol. Tramadol is as effective as baby aspirin! Years ago I declined to take medication, but I'm 51 now + two car accidents later.

I have Carpal Tunnel Syndrome, Tendonitis, Avascular Necrosis in my left wrist, Lumbar & Cervical herniated discs, Levoscoliosis, Myofascial Pain Syndrome, Degenerative Disc Disease, Spinal Stenosis, Raynauds, Small Fiber Neuropathy, SLE/Lupus with organ involvement, Sjogren's, Complex Regional Pain Syndrome, Fibromyalgia, Peripheral Neuropathy, Osteoarthritis in hands,& back, bone spurs, Dry Eye syndrome, Retinopathy, High Blood pressure due to pain, Migraines, Hypercalcemia, Low Vitamin A, Atherosclerotic Vascular Calcification, Hiatus hernia, Lumbar radiculopathy, Hyperparathyroidism, Tricompartmental osteoarthritis with patellofemoral compartment predominance,, Distal Radioulnar Joint disease of left arm, Cervical radiculopathy & no reflexes, Cervical Anterior subarachnoid space, Cervical Lordosis, Lumbar Lordosis, Chronic Pain Syndrome, ganglion cysts, lumbarization of S1, severe bilateral foraminal stenosis stenotic, cervical disc protrusion, cervical fatty degenerative endplate marrow changes, endplate spurring with bilateral uncovertebral hypertrophy. Lumbar Degenerative disease with broad-based central/right paracentral protrusion, meibomian gland disease, Blepharitis of upper, lower eyelids, Undifferentiated Connective Tissue Disease & recently diagnosed with a Movement Disorder/Cervical Dystonia.....my head literally gets stuck! The pain is unbearable! This is off the top of my head!

I pray to God every day for all the people who take medicine that doctors know doesn't work. I pray for people like me who go to Physical Therapy, but can't do anything!

Why do law-abiding citizens have to suffer, WHY?

Thanks for listening!
J. Smith

From: judy spielberg
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:19:30 PM

To whom it may concern,
Please realize that not everyone that takes opioids becomes addicted to them. I have had 6 operations that required opiates immediately after. On the last operation my Dr kept me on the medications for chronic pain. I never wanted to be on the opiates and have tried many other pain treatments. I've gone off the opiates several times without a problem. I never took more than I should and always followed the recommendations of my Dr. When I first started on the opiates I was a designer of a company I owned designing and manufacturing home lighting, accessories and furniture that I had manufactured in China and sold world wide.I traveled to China twice a year as well as to many shows to sell my products. I raised my 3 children while starting 3 different businesses. Today without any pain medication I'm no longer working and rarely leave my home. I can barely walk and have difficulty taking care of my everyday needs. Is it really fair to me to be punished for the actions of others? I may have had a physical dependency that was over in a few days but I never developed a psychological addiction where I took more medication than I should or turned to the streets to find substitutions. I'm aware of the need to protect the people that do become addicted but what about the people like me? What are my options? I've left no stone unturned in looking for answers. I just feel myself further deteriorating day by day. What answers do you have for me? If it was not for my 23 year old daughter I don't think I could continue like this. I was a vibrant busy woman with a very rewarding life. Now I just spend my days home alone in bed. There is nothing rewarding i can do in my life now. If your going to cut off the pain medications at least have some type of alternative that people like myself can turn to in place of the opiates. No one knows our cares about my story. It does not make for sensational news. Just please be aware there are many people like myself that do deserve to live a full and rewarding life and deserve a chance. Your supposed to be doing this to protect me but it's only pushed me into a life that's really not worth living. I can no longer do any of the things I once enjoyed. Is there a point where you can say I never abused my medications took them responsibly and deserve a chance to live my life fully? Is it just no for everyone regardless of their circumstances? It's difficult to accept this kind of life when I know there are medications that could help me. What answers do you have for me?

From: Shamus
To: Tom Norris
Cc: ksapp@theacpa.org; NCIPCBSC (CDC); pcowan@pacbell.net; sfarmer@theacpa.org
Subject: Re: Personal comment on Observations on Updated Guidelines for Prescribing Opioids
Date: Friday, July 23, 2021 3:56:31 PM

Thx Tom. This is so well written and exactly what i was hoping u could mediate to them for us. Thx. T

Perfection

On Fri, Jul 23, 2021 at 11:49 AM Tom Norris <tomn482171@aol.com> wrote:

> Dear CDC,
> Thank you for this opportunity to provide some of my personal experiences and thoughts about the observations on the updated guidelines for prescribing opioids. My thoughts on the observations are based on the on-line discussion of these guidelines on Friday, 16 July 2021, and the documentation provided of that discussion.
> I am aware that my comments are addressing the observations only – not the actual updated guidelines themselves.
> I have lived with chronic pain for over thirty years. The pain started because of being over-irradiated during treatment for testicular cancer. This pain now includes all my spine (from the coccyx to the nape of my neck), all my abdomen, both hips, my groin, and my left leg.
> I have tried almost every therapy and therapeutic for chronic pain management. I was prescribed Fentanyl for ten years. I did not like what Fentanyl and other opioids did to my mind and body. I took myself off all opioids and other medications and now exist on my faith, the love my wife and I have for each other, the lessons I have learned through my support groups, Virtual Reality, epidurals, and my attitude. Regrettably, my situation is the exception rather than the rule. Most people with chronic pain must have the help of medications to be able to have a life of even minimal quality.
> I speak daily with people living with chronic pain who have been cut off from their medications and those who are terrified that they will lose access to their opioids as opioids are the only medication effective in minimally controlling the pain they live with constantly. These individuals are not opioid abusers; they are people with chronic pain who are trying to have lives with dignity. This fact should be recognized and appreciated when giving guidelines for opioid utilization.
> General thoughts:
>
> 1. Patient centered healthcare/shared decision making should be used in any decision concerning therapies and medications.
> 2. We need to take action to ensure the correct interpretation is made of these and any “guidelines.” “Guidelines” have become the law of the land – not guidelines.
> 3. There appears to be a distinction drawn between cancer pain and chronic pain. I believe “pain is pain” and individuals with pain should not have their options for relief curtained by the distinction of cancer pain and chronic pain.
> 4. People with pain should be allowed access to the medication/therapy that helps them live with pain. Otherwise, we are

allowing people to continue to hurt or be in pain needlessly.
5. The benefits of opioid therapy is not discussed or considered.

My specific comments are provided on the attachment.

Again, thank you for this opportunity and thank you for including my comments in the upcoming report.

I am available for any questions

Sincerely,

Joseph T. Norris, Jr., Lieutenant Colonel, USAF (Retired)
1656 West 25th Street
Los Angeles, CA 90007
323-775-2311
tomn482171@aol.com
jtomn482171@gmail.com

Attachment: Specific Comments

Specific comments on the recommendations

1. The biggest problem I have encountered with the 2016 Guidelines is the interpretation that the guidelines are law.
    a. I have not figured out who is at fault in that outcome: DEA, federal government, state government or local governments.
    b. Who would be the one to ensure that does not happen again?
    c. If we do not address that issue, how can we prevent these guidelines from being used to scare people?
    d. What is going to be done to preclude any misinterpretation of new guidelines by national legislative bodies, state legislative bodies, and the media?
2. I believe we should continue to stress patient centered healthcare in all matters dealing with chronic pain management.
    a. This is not consistently addressed in the comments.
3. I also believe that people with pain should be able to use the therapies that work for them.
4. Education of both clinicians and people with chronic pain continues to be of upmost importance.
    a. This is not addressed in the comments.
5. I am concerned the inequities of access to chronic pain management for all people with chronic pain.
    a. Not only is there often a dearth of chronic pain management doctors in some regions (racial and economic barriers), but many people with chronic pain do also not have access to medications or treatment due to their insurance.
6. I am concerned that the use of opioids for post-operative pain is not specifically addressed.
    a. Are opioids not to be used for post-op pain?
7. I am concerned that use of opioids by dentists is not addressed.
8. There appears to be no mention of paying physicians for the time required to

perform an individualized assessment before the prescribing of any therapy.

9. Recommendation #1*: Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient. (Recommendation Category: A; Evidence Type: 3)*
    a. Person with pain is not involved in decision making process. (Patient education would be required to be included in decision making process.)
    b. Post-surgery pain doesn't seem to be considered.
    c. Recommend removal of "only."
    d. As pain and reaction to medications (including opioids) is individual to each person, how is the risk assessment to be standardized.

10. Recommendation #2*: Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate. (Recommendation Category: A, Evidence Type: 3)*
    a. Here again it appears that the person with pain is not involved in the decision-making process.
    b. Do the revised guidelines indicate how the person with pain is informed or educated to be part of the decision-making process?
    c. How are the goals for pain and function established and made part of the partnership of doctor and person with pain?
    d. If the person with pain is unable to communicate, does this mean that opioids are not considered as a possible therapy the
    e. Suggest reordering of sentence: Clinicians should consider initiating opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the person with pain.
    f. Since pain and reactions to medications are specific to each person with pain, how is the risk assessment standardized?

11. Recommendation #3*: When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. (Recommendation Category: A and Evidence Type: 3)*
    a. When are extended release/long-acting opioids considered?
    b. Is the person with pain involved in making the decision to move to extended release/long-acting opioids?

12. Recommendation #4*: When opioids are started for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to =90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day. (Recommendation Category: A and Evidence Type: 3)*
    a. As each person with pain is different and has different interpretation of pain and different tolerances, doesn't the inclusion of specific, seemingly arbitrary limits, preclude helping

individuals live with pain?

13. Recommendation #5**:** *For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation Category: A and Evidence Type: 4).*
    a. This in an important area for patient involvement in the decision process.
    b. Are the benefit and risks assessments arbitrary or standardized?
14. Recommendation #6: When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed. (Recommendation Category: A and Evidence Type: 4.
    a. It appears that the person with pain is not involved in this process. Patent centered healthcare would require this involvement.
    b. I believe the last sentence of this observation is too defined and limiting and should be removed.
15. Recommendation #7: *Clinicians should continue opioid therapy for subacute or chronic pain only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. (Recommendation Category: A, Evidence Type: 4)*
    a. How is "clinically meaningful improvement in pain and function measured and standardized?
    b. How is "risk to patient safety" measured and standardized?
    c. Where is the person with pain involved in this decision-making process?
    d. How are "benefits and harms "measured and standardized?
16. Recommendation #8: *Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan strategies to mitigate risk~~, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (=50 MME/day), or concurrent benzodiazepine use, are present~~. (Recommendation Category: A, Evidence Type: 4)*
    a. Recommend excision of "including offering naloxone . . .are present" as too specific.
17. Recommendation #9: *Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages ~~or dangerous~~ combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for acute or chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. (Recommendation Category: A, Evidence Type: 4)*
    a. Recommend removal of "or dangerous" as judgmental, not specific.

    b. The person with pain needs to be involved with this decision.
    c. Is this recommendation for both chronic pain and acute pain?

18. <u>Recommendation #10:</u> *When prescribing opioids for chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. (Recommendation Category: B, Evidence Type: 4).*
    a. The definition of illicit drugs is not standardized.
    b. Who would bear the cost for repeat verification tests for possible erroneous testing?
    c. When is this discussed with the person with chronic pain?

19. <u>Recommendation #11</u>: *Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids ~~and other central nervous system depressants~~. (Recommendation Category: A, Evidence Type: 3).*
    a. Delete "other central nervous system depressants" as too general.
    b. How are the benefits and risks validated on a person-to-person basis?
    c. When is the person with pain brought into the discussion?

20. <u>Recommendation #12:</u> *Clinicians should offer or arrange treatment with medication for patients with opioid use disorder. (Recommendation Category: A, Evidence Type: 2).*
    a. Who defines opioid use disorder?
    b. When is the person with pain involved in the decision-making process?

From: Joe Tellez
To: NCIPCBSC (CDC)
Subject: CDC Guidelines
Date: Thursday, July 22, 2021 11:48:21 PM

As A Legacy patient of 24 years, my concerns regarding the 2016 and 2021 CDC update revolve around the concern that long term patients are not properly represented .
We as a whole have been limited in ability to receive proper care and are seen as a burden to the nation's quest to lower opioid statistics with regards towards proper dosing, forced tapering and overall refusal by doctors that chose to use the 2016 guidelines as hard level statutes to deny care through MME constraints .
I urge the FDA and CDC to realize that punishing long term pain sufferers to limited care and forced tapering is a HARM. It is not conducive to restrict law abiding patients the medicines needed for basic life activity.
I have personally experienced the negative effects of hastily and politically driven discriminations against people just trying to have some level of normalcy after being stricken by accident or disease. It Is an atrocity to condemn long term patients to suffer while refusing us the appropriate accommodation to medical relief. The guideline glosses over the adversity and life long suffering that chronic pain sufferers live with every day. The doctors who know how poorly this guideline protects the interests of long term pain patients are cancelled and rebuked for their need to provide realistic and meaningful options including opioid therapy.
For the people in all forms of institution and medicine, just beware, disease and accident may not have touched you in your life, but if and when it does you will know the extent of harm and suffering that is needlessly realized by patients who have been forced to endure through the confounded notions that the current guideline and its modified perspectives are taking into account the growing numbers of sick and injured who have lost quality of life and function . to explain and defend these guidelines as a solution and provision of effective care for thousands of lives is a short sighted and self satisfying illusion.
Incorporate unambiguous language to fully describe the totality of the plight of the chronic pain sufferer devoid of realistic remedy or continue to denigrate countless lives who have no alternative but to realize the inequity of unjust medicine.

With Sincerity,

Joe Tellez Legacy Patient

970 310 9104
po 1431 LaPorte co 80535

From: Julie Verke
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 9:56:55 PM

My name is Juliana verke, i have 6 major medical issues. I have been forced to take very small amounts of oxycodone. My whole life has been destroyed!!! I lost my company and now am disabled because the amount the CDC (you) are forcing me to take is not enough for MY BODY.
I can't believe that thousands of us have lost everything and you want to continue with this TOTURE.
WE NEED CHANGE!!!!! Please get out of our lives and let us live. If you continue we will end up dead!!
Juliana Verke

From: Joyce Volant
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:59:19 PM

As a chronic pain patient who has NEVER misused or abused medication, I demand that you make actual CHANGES to these guidelines that have horribly affected patients in the past few years!

The only thing you seem to be concerned with is "keeping people from becoming addicts."

WE ARE NOT ALL ADDICTS, and opioids work GREAT for those of us who do not abuse them!! This is about QUALITY OF LIFE. If I am in constant, excruciating pain, I HAVE NO LIFE and would likely become a SUICIDE statistic. Having access to medication means that I can FUNCTION in my household and my society! YOU ARE CAUSING MASSIVE DEATH AND SUICIDES WITH YOUR RIDICULOUS GUIDELINES! If you REALLY want to do some good, SHUT THE DAMN SOUTHERN BORDER WHERE TONS OF FENTANYL & HEROIN ARE ENTERING OUR COUNTRY! WHY the hell would you punish citizens who are in pain while allowing all these ILLEGAL drugs to flow across the damn border?? IT'S INSANE! Go after THEM and LEAVE US ALONE!!

Joyce Volant

From: Jeanette
To: NCIPCBSC (CDC)
Subject: Updated Draft Opioid Prescribing Guideline
Date: Thursday, July 22, 2021 8:13:31 PM

(The U.S. Pain Foundation is gravely concerned that the Updated Draft Guideline presented and discussed at the meeting is virtually identical to the original 2016 Guideline)

Hi,
America continues to treat patients in pain like drug addicts, makes it very, very difficult to obtain the pain treatment needed to have any quality of life, be functional and not feel like we are being very discriminated against. Doctors treat us like we are as low as dirt on their shoes, making it very difficult for true patients of pain to get the relief needed to survive. Nothing has changed in any way towards allowing patients in pain to be treated humanely and with compassion. At lest it has gotten worse now for pain patients.
Even for patients that adhere to all the hoops that have to be jumped through and have shown an excellent adherence to protocol , their lived have been made extremely difficult to get the pain meds needed to be functional. Many people have lost jobs, homes, spouses, taken their lives and given up on life due to these in-humane measures. Pain is used a a mean of torture and the reason it is used is because anything alive with do anything to get away from bad pain, even a lowly earth worm will squirm when cut, or hurt, and it isn't because they are happy. Treatment of pain in this country is ay an all time low, and it needs to change, people should not have to suffer worse then we let a dog suffer. This is in no uncertain terms —INHUMANE.
And no one should be made to feel less then a human just because their body is hurting.

Any one of you can wake up tomorrow and be in incapacitating pain, how do you want to be treated, like something less then human, you would expect to be treated with respect and dignity, but guess what, you would not be, no matter whom you are, or who you were, you would be treated worse then human, like you are scum , less then human, and not worth saving.
Patients in pain do urine testing, and a number of other things for their treatment, doctors treat them like scum, even the staff treat them like scum and the pharmacists also dent them their meds if they can do it, they will telling them they are out of tick, it will be weeks before it is in stock and so on. Anything to punish them for no reason other then they have a health issue through no fault of their own.Tell me, how is this right, for the richest nation in the world to treat patients ;like scum, just because they are in pain. Making them lose hope, and also their jobs, lives, and life in some cases. This needs to change and since Nixon and his buddies brought the drugs in to pay for the contra war, and figured they could control it,the blame rests on the government, sadly. Would it have ever gotten this bad here, maybe in time by itself, who knows, but this was a major mistake and now you b;lame the people for the government mistake. You are doing so little to change all this, and it is so very wrong, this needs to do an about face from the original guide lines, it is horrendous the way pain patients are treated in this country. I honestly do not know how you all sleep at night knowing how you are treating your fellow people who by no fault of their own have been attacked by horrible pain from all kinds off disease's and health issues, including chronic pain as well.. I am asking you to make this all change so that patients are better understood, treated like humans with dignity and not shame, not like scum , like the patients that they are, like any other patient who has any other illness. I am begging you to do this, and though I am begging you to do this, those in power do not care about pain patients so I doubt it will change, but maybe someone there will listen to us...Please.

I have told you all that warm water pools help us alot and have yet to see any of those pop up anywhere that we can all afford to go to, 90 degree water, so why did you even ask us what would help, if you were not going to listen, being able to get anything else that helps has not been addressed at all, all those answers were a waste of out time, insurance doesn't cover it, and none of the pools with the temperature exist, except for kids. No one is listening to us as usual, unless there was a monetary reason for you to listen, you wont, sadly we are usually low income etc. due to losing everything , houses, jobs, assets etc. If we could offer you millions of dollars then and only then would you listen to us. So then the torture continues, and that is exactly what is is, our country is not supposed to agree with torturing its people, but it is doing just that each and every day and night.

To win the war on drugs we need to treat drug addicts like they do in Portugal and not like we do now, we need treatment centers that are affordable, and offer medications and not suffering for withdrawal symptoms, thinking that making it awful will make them not go back to the drugs. IN order to get someone off drugs they have to have a reason to live a batter life, we need to make their lives worth living. Only the rich get treatment worthy of a human being now.
thanks for your time, though I know this is a waste of time, only by offering you money would you make any difference. Sad, but true,
bye

From: Jo
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:30:27 PM

To the CDC
I have suffered with CRPS for 7 years and am on Permanent Disability. I am concerned about your guidelines because people like myself who have Chronic pain are tired of being treated like addicts because we need pain meds to take at least the edge off the pain. Doctors hands are tied and we as the patients are tired of feeling like criminals just because we want a little relief from our pain.
Please think of those who need pain meds for at least a minimal quality of life.
Thank You

Sent from the all new AOL app for iOS

From: Jodi L
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:37:25 PM

Quit blaming people in pain who use opioids for these overdoses of drugs bought on the street laced with fentanyl and heroin. The doctors have drastically reduced their prescriptions to people who deserve to not be in pain. So much so that people are ending their own lives because their pain is that bad. It's 100% obvious, at this point. The numbers of overdoses have increased drastically, but the prescriptions have decreased. It isn't fair to people in pain. My disease is uncurable. I didn't ask for my body to get RSD/CRPS. Although my small amount of opioid takes about half of my pain away. It feels like someone is frying bacon inside the affected parts of my body. I didn't ask for this. I have begged my doctor to amputate my leg to take this pain away, because that's where it hurts the worst. People have their own stories that should be considered. I have also tried medical Marijuana one time, and I couldn't stand the way it made me feel and it wouldn't go away. It did nothing for my nerve pain.

Thank you for listening to my concerns,
Jodi Merkel

From: Joy & Blessings
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:44:33 PM

I am a chronic pain patient whom suffers with CRPS and LUPUS and I must say that the opioid draft and the world wide crisis has to be addressed so many of us are going without or medications or being treated less than human just because we suffer with pain .I understand some people may abuse medicines but millions of us aren't abusing anything instead we are suffering because facilities treat us like it's a crime to treat us something like a muscle relaxer has become a huge problem doctors fear perspiring us meds insurance companies have all these insane rules and long waits for medications then they treat us like we are criminals when we get our meds filled questioning us not allowing us to drop off a script before the date it can be filled it's been torture I do think something has to be done to better help those of us who need pain meds because yes some people go through withdrawals due to missing meds some are suicidal but imagine if you felt the worse pain you've ever had constantly 24/7 .

Joycelynn P

From:	Judi L
To:	NCIPCBSC (CDC)
Subject:	Opiate guidelines
Date:	Thursday, July 22, 2021 3:21:00 PM

I am so thankful I found out about this situation in time to make a comment. A couple of times in the past I have written to you and the state anonymously because I don't usually delve into anything political.

First a little history:

Years ago it seemed I could hardly stay out of hospital for 6 -12 months before another round of trouble with my lungs, asthma, etc. I also had side issues of IBS, unexplained abnormal liver functions that led to a biopsy and a total of 3 surgeries to remove unexplained scar tissue from my bile duct since it kept being restricted and causing severe pain. Finally my internist realized that whenever I was taking Advil for flares of arthritis and pain issues, my lung issues were exacerbated and I would end up on antibiotics, extra use of inhalers, Prednisone, etc. I had known that I was allergic to aspirin but hadn't made the connection.

My body likes to make extra bone spurs and I have had both shoulders repaired for torn ligaments at which time the surgeon also removed extra bone. I have arthritis in the spine as well as having ruptured a disc and also there are extra bone spurs pushing on the nerves. I have so far had one modified lumbar laminectomy to remove some bone and every couple of years have radio frequency lesioning done to help ease pain. I have also had a fall that knocked me out and caused a lot of damage to my left hand resulting in 3 surgeries including a CMC joint repair. The same fall also caused damage to the cervical spine and the neurosurgeon said the only way to fix that would be to fuse two levels. I did not do this because of worry about mobility when driving. Later I fell and had a much simpler fracture of my right wrist, with later surgery to help with complication of that. Besides all that I have other pain my doctor feels is caused by fibromyalgia. I have had a full workup with a rheumatologist but she said she can't help me because of being allergic to salicylates.

Yes, I do know some call this an intolerance instead of an allergy but whatever the term, the result is the same. Lungs clog with fluid, breathing is affected, IBS, etc.

So, let's talk opiates:

I have been safely taking Fentanyl and oxycodone for over 20 years. During that time I have not once been hospitalized for a breathing issue, other that the sudden ER visit for anaphylactic shock that happened during allergy testing.

I did have one period (about 2 years) of escalated trouble after my husband watched a video about juicing fruits and vegetables to help with inflammation and pain. We did the juicing and I kept getting sicker and sicker. Twice I had CT scans because my lungs were bleeding. Then my husband was out of town for a week and I didn't do the juicing but I did start feeling better. I turned to the internet to try and find out why and discovered many of our fruits and vegetables, especially those that are "supposed" to be healthier for you are high in salicylates. I gave up eating "healthy" and over a few months started feeling so much better.

In terms of my lungs and other health I was doing great. Then suddenly my access to Fentanyl and oxycodone were put at huge risk. Last year my husband who does all the lifting in our house including grocery shopping and laundry had a motorcycle accident fracturing a leg in 5 places. He was also diagnosed with lymphoma. It was a rather stressful and painful time for me because besides still working at 69 I also had to take over with meal prep, shopping, laundry, etc. since we two live alone. From time to time I had help from friends but in rural NH distance is an issue. 3 months in a row I picked up my Fentanyl 2 days early as with the heat and extra duties I was having a hard time keeping them on. At the time I went to pick up the 3rd time, the pharmacy I had switched to because of being able to get my preferred brand was running late and because of Covid I waited in my car. I told the clerk but apparently, he was too afraid of the pharmacist to tell him and locally we hear lots of people have issues there. Anyway after 2 hours I got annoyed with the pharmacist and take full responsibility for being angry when I should have been patient. The result was this pharmacist threatened my doctor with reporting him because of the dose I was on. I was asked to find somewhere else to get my medications. To sum it up I am now on way too low a dose to really help me so am also turning back to taking Advil to help me. With the extra pain I have higher blood pressure and I haven't figured yet a way to stay relaxed to keep the BP down when pain keeps me from being able to concentrate on my work. With the Advil comes the evils of heartburn, IBS, constant clearing of goop from my lungs. Even driving is more dangerous when in too much pain. I am now 69 years old and still, after over 30 years, working as a bookkeeper for a contractor. I do every aspect of work in this office other than final year end taxes. If my taking opiates was interfering with my work, my boss would know in an instant. Instead of which, at fiscal year end last summer he gave me a $20,000.00 bonus.

Now let's talk about your prescribing regulations:

It is because of all the hype surrounding opiates, addicts, etc. over the years as well as your misplaced "guidelines" that the lives of people in pain are made a misery, even when they can get the medication.

PLEASE stop making the lives of those who are in pain so miserable. Our misery is not helping anyone who to takes extra drugs to alter their mental state. Plus, it is because you make it so miserable to get help that people turn to the black market or street or whatever you call it. STOP blaming the opiates for what people choose to do with them. Did that work with alcohol during the Prohibition? We don't blame the alcohol for someone driving drunk. We blame the person for their own actions. Personal responsibility has taken a hike in this country with everyone looking for someone or something else to blame. If doctors were not so afraid to help someone wean off this drug when they no longer need it there wouldn't be such an issue.

For anyone legitimately taking these meds this is the life you condemn them to:
<u>This has been my life for 20 years</u>.
<u>Every Single Month Year In, Year Out:</u>

Annually, sign a contract stating that the meds are for myself, even though they have my full medical history. Of course this is already the law for all prescription medications and I don't see everyone having to sign a contract for every prescription they receive.

Randomly, pee in a cup

Week 1, use the meds as prescribed

Week 2, use the meds as prescribed

Week 3, call physician's office and advise that I will need my prescription the following week. Or, as it is with the new office, make a sit-down appointment.

Week 3, call the pharmacy and advise that I will be bringing in my prescriptions the following week. Or, with the new office, they wire in the prescription but then there is a day's wait for the medication to be ordered.

Week 4, leave work early (losing pay and disrupting work flow of my job) so that I can drive to the physician's office, before they close, hope they actually did get the prescriptions ready, (which they mostly did), sign for the prescriptions, randomly pee in a cup to prove that I am innocent and do actually use these meds for myself.

There is **NO** presumption of innocence until proven guilty, that would be too much to ask. And, yes, I am truly thankful that I live in a country where I can obtain help. It's just that the process is demeaning.

Week 4, deliver the prescriptions to the pharmacy, and either sit and wait an hour or return the next day to pick up.

Costs: Usually 1.5 to 3 hours lost or interrupted work that has to be made up later
Gas and mileage, wear and tear on the vehicle.
In NH with fairly long distances, these costs add up.
Insurance copay, after deductible, and not including any medi-gaps, approximately $70/mo. or $840 a year.

Do you find it a wonder that some people try to avoid the "system"?

Now, let's talk risks:
Yes, if abused, there are risks and every person using this should be advised to have a lock box to put their medications in if there are others, especially children or teens in the house.

Beyond the risk of overdose, with having been on it for so long, I find the risks of long-term Tylenol use or Advil use to be higher, not to mention all the different medications on the market for arthritis.

Ask yourselves – have your efforts so far been at all helpful? How about letting the patient's doctor actually function as their doctor?

Thank you for allowing me to vent. Whatever conclusions you come to, I will have to live with.

From: Kelly Anetsberger
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:31:03 PM

I have been on opioid pain medication since 20001. I have EDS which is a connective tissue disease which caused spondylosis. I have a decompression and fusion surgery in 2003. I also had around 30 epidural spinal injections to try to minimize my chronic pain. I also have 3 herniated discs in my neck. At this time I lived in IL. I was on 175 mcg of fentanyl and 60 mg of oxycodone. I moved to WI after discussing my history with a Doctor here who told me he would continue my medication as prescribed by my current Doctor. A couple years later in 2016/2017 this Doctor quickly removed me from all my fentanyl in 25 mcg incriminates as well as most of my oxycodone and told me I need to go to a pain clinic in the area because he would no longer prescribe me my opioid medication because he had to protect his own ass. This caused extreme pain and months of withdrawal symptoms. I went as told and they informed me that they would be weaning me off all my pain medication. I was able to find a EDS specialist an hour and a half away that continued my reduced dose of oxycodone. This has greatly affected my life. I have been on permanent disability but was able to do some personal care while on full dose of fentanyl and oxycodone, but now my life is laying in bed or on the couch suffering in constant pain. I am only 53 years old and have no life. I can no longer take care of myself and rely on my family to take care of me. This whole thing has been so humiliating being made to feel like a drug addict. My body is dependent on pain medication but I am not an addict! You may say that Doctors have the ability to describe pain medication that see a need for it but I have yet to find one. Please reconsider the guidelines for opioid pain medication.

Thank you,
Kelly Pennington

From: krista brack
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:50:02 PM

My name is Krista, I live with multiple medical conditions that have no cure and barely any treatment. I was born with multiple rare medical conditions that are poorly understood and any treatments available are experimental and expensive. I have spent all of my life in pain. I have spent the last 20 years in daily non stop, no breaks; **pain**. From September 2019 to July 2020 alone I underwent 4 brain operations and 3 abdominal surgeries, all but 1 was done as an emergency. I had to endure these operations with inadequate pain control because of the CDC guidelines. These guidelines do not take people like myself into consideration. I do everything possible to have a positive outcome, I attend physical therapy regularly going three times a week and I have a set of approved exercises I do at home in order to keep my body in as good shape as possible, I eat well and cook most of my own food from scratch when I am not in too much pain to do so, I see a therapist to talk out my frustrations of living a life of pain and I attend support group meetings. I engage in art and other hobbies as a distraction from pain, I meditate, I see over 20 different medical specialists and I follow their advice, and even doing all of that I am still in moderate to severe pain every single day. Up until 2017 my pain was well managed with opiates, however early in 2017 I was informed that my medication would start to be reduced from that point forward, not because of a change in my health but because of the CDC guidelines, I have been suffering ever since and now I often wonder how much more I can take, is this life really worth living?

I am a positive person with a great family and lots of support however this past year for the first time in my 43 years of living with pain I started to wonder if it was worth it. Living in constant never ending pain with no hope of relief in sight because people who are not my doctors and who do not have any idea of my medical history are making rules regarding what medication and how much I am allowed to have. This has had a direct negative impact on my life and in turn my family's life. Living with less pain control has caused me to put off and refuse surgical interventions due to a complete LACK of pain control in the hospital setting. I require much more hands on care and my husband has had to help me bathe and dress, I can no longer help with housework at all, I have been unable to engage in the volunteer work I had been doing for years. All of this is as a direct result of having less pain control. I am in much more stress and have a constant low level of anxiety about my pain and how I am going to control it, this is NOT how my life was prior to 2017. What is happening now is my life revolving around pain, everything is weighted out and measured in pain and how many pain pills I have left, can I shower today or will it cause too much pain? Can I make dinner today or will it be a smoothy again because I am in too much pain, am I able to engage with my family or am I in bed crying because I am in too much pain? I am living a quarter of the life I once had and that is directly due to my pain no longer being controlled.

I am begging anyone who reads this to please stop putting up barriers to pain patients accessing necessary medical treatment like pain medication. I deserve a life, my family deserves to HAVE ME HERE and even if you do not think a life in pain and medical crisis is worth living, I disagree, this is the only life I have to live. Please **please** stop making it more difficult and nothing more than a miserable existence locked in my bed. Don't wait until the next epidemic is suicide, **please help me while I am still here to be helped**. This is my call for help, please help us. I am disabled, cognitively impaired and I struggled for hours to compose this email, I apologize if I got the words wrong and pray you can feel my need and sincerity. I need your help to access pain control, I urge you to consider protecting me and people like me who rely on opiates.

KRISTA BRACK
KRISTA@RIEDS.ORG
WARWICK, RI 02886

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC's endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

We hope that in drafting the final Guideline, the CDC takes these views into consideration.

From: Kate Casler
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:24:11 PM

Good morning,

I'm writing to discuss the Updated Draft Opioid Prescribing Guidelines, as it is quite a dangerous thing to pass. Ever since the CDC created the new guidelines I've watched populations suffer, including my own. Whether it's the chronic pain community dying because no one will treat them or even believe them anymore. Even if they do find a doctor that will believe them, they won't prescribe anything because it's too much paperwork and hassle. So the people truly in pain are suffering. To top it all off my doctors have shared that the laws in place do nothing to actually protect people with addiction issues. So they do nothing but cause harm. If my medication is taken away I will go back the the violently ill person I was when I couldn't stand to live. Being put on my current medication was not a light decision. We would have done anything else if possible. I've even tried to go off it once but was created with something worse than withdrawals. Something that now nearly a year later I'm only just starting to recover from. You have absolutely no idea what harm these guidelines will cause and lives that will be lost. Please think of ALL the populations it affects and reconsider your decision. What you're doing is the wrong way to fight your fight. People will die due to this decision being made.

Sincerely,

Kate Casler

From: Doug, Karen Hughes
To: NCIPCBSC (CDC)
Subject: Comment on the CDC Opioid Prescribing Guideline
Date: Friday, July 23, 2021 9:26:58 AM

Email to ncipcbsc@cdc.gov

Dear CDC & FDA,
Concerning the Opioid Prescribing Guideline and its rewrite:
* my apologies for not being professional in this statement, but I am hanging on to life by a thread at your own hand as are 19-million other Intractable Pain Sufferers you took Patient Centered Care from carte blank!

The Guideline is a causal nexus appearing intentional the longer it exists! Like contemporary western wildfires, not caused by lightning igniting them, but rendered incendiary from decades of Global Warming, history will not glean CDC's innocence because it published a recommendation which was promoted with the PPR Firm.

The little old lady no longer capable of baking Apple Pies for her family because she lost arthritis treatment for her hand, or the mechanic unable to earn a living for the same reason, the CDC caused a disgruntled society and disabled more than you lost.

Morbidity skyrocketed in countless ways from the zeitgeist you created, a decade's drug control expense of $250-billion Federal and the same by States, and yet reprisal exists in this rewrite being allowed you.

Data incompetence since 2005-7 for IDC-10 codes, OTC, polysubstance, alcohol, methadone, counterfeits, 8% autopsies, and IMF these 16-years, the 4th Estate parroted 10-million times. Are retractions realistic?

Your "appeal to possibility": left this excoriated machination, and further track into this maelstrom, futile. Right the ship!

You know damn well Dentist's first exposures of adolescents and theft in the supply chain & Hospitals caused this, and not overdose of legacy Chronic Pain Sufferers!

Where doctors like John Freedman on April 10, 2021, corrupted your already corrupt data by stating;

"According to the Centers for Disease Control and Prevention, since 1999, nearly 850,000 people in the United States have died from overdoses related to prescription drugs involving opioids."

"In 2020, in the middle of lockdowns and quarantines in states nationwide, the CDC reported 81,000 opioid overdose deaths in the 12 months ending May – the highest ever recorded in a 12-month period."

When a friend called to the attention of Dr. Freedman, that next day, the Charleston Gazette-Mail's changed their "archived record version", removing the word prescription from the first paragraph, and changing the date of publication to April 9, 2021 instead of its actual publication on 4/10/21 !

I am sending you a hard copy of this letter, and this Newspaper and another column, as only my copy is proof these lies are promoting the "All Payers Claims Databases" soon to be Total Personal Surveillance, the death of democracy, and CDC's lasting legacy!

I followed the big three Opioid Distributor's Trial in Charleston, WV from May to July, 2021 and among the scores of half-truths, CDC misquotes, and outright lies, one truth was missed, which portrays your zeitgeist's lasting axiom.

The testimony of Kevin Murphy, a health economist for the Distributors made a statement during questioning by Cabell Attorney Paul Ferrell, Jr., which others made the similar unremarkable statement in the 3-month trial, but it was never examined, because it was what they had all believed in years of your PR efforts to cover your collective asses.

Though this reporting by Courtney Hessler was about Mr. Murphy's testimony, she always editorialized more than quoting the statements of the Distributor's witnesses.

"Murphy said the people who are getting the pills are not the ones dying from them later. Ferrell (Plaintiff's attorney) said, it could also be true that the people receiving the pills were diverting the pills to others, who later move to the illicit drug market."

"It tells you there is other stuff going on, he (Murphy) said.'

"The other stuff was the suffocation of pill supply, Ferrell countered. As demand, in this case for opioids goes up, so does the supply, he (Ferrell) said."

"He (Ferrell) then asked where in Murphy's evaluations he accounted for government restrictions, which around 2011 dramatically cut the number of opioid pills allowed to be shipped each year. Without the supply to fill demand, he (Ferrell) said, people with opioid use disorder were forced to find an outlet."

Aside from the obvious reporting of the Plaintiff's views instead of the witness statements themselves, Ferrell gives us what all of society have been brainwashed to believe: that **everyone taking prescription opioids have Opioid Use Disorder!** They never elaborated to say legacy pain patients also were forced to replace legitimate Opioid Therapy with often lethal street drugs.

A similar statement was made three other times, confirming they all believe everyone taking prescription opioids have Opioid Use Disorder!

The DEA have consultants on both Plaintiff and Defendants legal teams in the Drug Trials, ensuring DEA impacts closing Pain Clinics and Pain Specialists intimidations to lower prescribing since 2003, that I can prove, never sees the light of day.

The sheer extent of DEA and State Medical Board's Pain Clinic closures over the last two decades, each with a thousand patient abandonment forced to replace legitimate treatment, has been tracked by multiple offices of the CDC. You have the proof of what has happened in your data and this "Guideline Rewrite" is your opportunity not only to rescue the former stellar reputation of the CDC, but also to save the United States from the complete societal collapse we see before us!

In many areas Officials, News Media, and Police Departments are covering up the existence of counterfeit pills laced with Fentanyl. You risk yet another generation of our youth who will see these counterfeit pills as a safe buy on the streets, merely because of ignorance to their existence! This is all in the States, CDC and DEA. Let the FDA have this problem, by using your data the right way and ending this!

A recent July 11, 2021 article in the Washington Post, "violent Crime is up, There's no one cause" (It's to pat to blame any one cause for the recent surge in violent Crime), by Aaron Chalfin & Mac Donald, examined the 25% increase in homicides in 2020, without a conclusion other than it must be caused by a systemic change.

The 54% decline in such murders from 1991 until 2014, was noted. The long decline waned from 2010-12 when Opioid Prescribing began massively reduced across all societies, lastly homicides crossing the threshold to increased homicides in 2014 as a result. From 2014 to 2019, homicides increased 13%, and was not deemed a factor in analysis of 2020, yet it is easily explained by taking pain treatment, a first ever in a society. It is easily proven intentional at this point!

Taking pain control from all of U.S. society, has caused an overdose epidemic from former legacy patients naïveté in replacing legitimate pain treatment, a Suicide Epidemic disgruntled from suffering untreated pain conditions from simple to complex pain syndromes since 1.39 million Veterans lost long-term treatment in 2013, a Fentanyl (IMF) overdose Epidemic, a Homicide Epidemic, as well as elderly were being tortured to death in Hospitals with nondisclosure policies in order to curtail death malingering. Either fix it, or take credit. The CDC will be blamed because there is more proof this is intentional than any other justifiable explanation.

Dentists had by far the most “First Exposures” of adolescents of any medical discipline, without follow-up to insure drug abuse was not caused. Pain treatment by Dentists was one of few that CDC, DEA and Medical Boards did not investigate because you needed this treatment. As well, Health Insurances, the big winner in this fiasco, had no liability in dental work, and thus they were never part of this Faustian nightmare.

I'm nola persona, and I doubt you read thus far. Rest assured with the growing descent against the CDC Guideline as a concatenation, this Rewrite is your last chance to correct this conflagration you had no business controlling in the first place. CSA excrement desecrated medical disciplines and only the CDC in confession can lay bare its turpitude. I know you have even tracked it, you track everything!

Whatever possessed this permuted canard is being exposed as I speak. You knew this intrigue would never hold up!

Do you truly believe the disabled tortured to death instead of taxing the wealthy and establishing personal surveillance, the death of democracy, makes your efforts worthwhile?

The overdoses, suicides, torture, and even gun murders in this disgruntled society your zeitgeist made, will condemn the CDC, it's staff and democracy itself, forever!

No PRR effort can emboss this duplicitous collusion to forestall history condemning your dereliction of morality!

Clean your own house if you must, but end this serrate now, by blaming State's for the data & the lack of autopsies (only 8% nationally), misapplication, and DEA for its enforcement, while you are being called on for this last do-over as a democracy !

Now with the $26-Billion Opioid Supply Chain Settlement, you have someone to pay for your mistakes, or about 5% of it, it's time to save democracy, do the right thing and end this!

You already have the Guideline amendment finalized, show it now and get blamed for this GREATEST EVER CRIME AGAINST HUMANITY later, or stop this bonfire of servility by blaming the responsible States and Agencies you protect.

All working at the CDC with knowledge of this travesty and murder of innocents are condemned for all eternity and should consider becoming carillonneur's, to serenade eternally with Hell's Bells!

~~~~ END ~~~~

Karen D. Hughes
Logan, WV

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From: Kimberly Ann
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 8:43:10 AM

I have been a chronic pain patient for over 20 year's. The decrease in opioids has effected me and my quality of life.
I have been on extended release oxycontin 80 mg and immediate release in the past they changed me to 20 mg extended release this dosing doesn't last the 12 hours for me it helps for about 6 hours.
They never tapered me just took it away and the pain put me in a wheelchair.I went through terrible withdrawal and extreme anxiety and depression and the worst pain cycle that I've been in for about 5 year's.
It has a negative impact on my every day life. The pain clinic will not give back the 3 rd dose.
Living in chronic pain is no fun and not being able to get enough relief to even take care of myself is a real problem especially knowing that a medication at a little higher dose would help me.
It seems like the dosing is one size fits all. Everybody is different.

From: Kelly Goodson
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 9:44:26 PM

Dear CDC

I was told in 2014 that I have a rear disorder called RSDS/CRPS. I had no clue what it was. I was also told I have fibro. So my pcp had no idea what crps rsds was .

With all the pain I was in and no doctor knowing what to do what was this nerve disorder was. My pcp doctor and I went to work.

I learned and are going through it the pain level plus, the flares, sharp dole, and pain that never let me sleep.

Besides the pain it was mentally hard and I lost who I was, friends, family, and felt like a burden to my husband. I found out the nick name to CRPS is the SUICIDE DISEASE. Yep their are 4 stages not many make it past the 3rd.

I was in pain my body was not mine again. The medication I get today is the same as day one. Narco 10mg x4 a day, gabapen 600mg x 4 a day, more mental pills also. Xanx ect...

I found out to your new guidelines I could not get the medication I needed, but got what I call 2nd hand junk that now effects my kidney and liver.

I'm not a druggie I pee in a cup every month and live in a state that pot is legal but medication for pain and mental health well sucks.

I've lost 100s of friend I kept track on a poster. I gave up in 2018. I lost 2 very dear warriors like my self to suicide. I've asked my mental health doctor to up my xnax back to a 1 or 2 MG x3 a day . She say "no I can't do that, the cdc won't let me" omg can Noone hear me.

I'm only saying this because I will fight for my rights, and stand up for all in pain. Stop scaring doctors mental and pain management. Do no harm is all doctor moto. But for you cdc as doctors do harm. By not giving the medication needed with out a doctor worried about losing there dreams to do no harm are scared.

I see so may doctors for every body part I have because of you the cdc. I won ssdi this year and only paid for 2020 to March 2021 fair .... no but something 900.00 a month covers 17,000.00 in medical bills.

Same 2nd hand medication for me since 2014. I hope to say I'm still alive to see patients put 1st and stop comparing us to druggie. But I might not be we will never know.

If you won't do this for me do it for the one after me. When you go home tonight think of you having to learn about rsds crps from goggle and the civil war doctor who found it. I'm never going to walk or do what I once did ,again.

I sound like I'm all over the place just like my health. I'm going to stop writing my mental health and my pain are going to a dark place my eyes watering and to be honest you people don't care.

Kelly Goodson
Pain warrior 2014
Mental 1988

Remember wear orange Nov 3rd for crps awareness.

From: Kathy Hartzler
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:25:05 PM

Hello. I’ve had upper back and right arm pain for over two decades. Ive had 3 cervical surgeries and all other procedures prior to surgery. Nothing has helped. They cannot find the source.
I am in pain mgmt. I take 10mg opioids 3x daily and muscle relaxers. It has helped me immensely I would not be able to leave my home without it. I would not be able to concentrate, read a book or recipe or have a Hobby. I would sit in a chair or lie in bed 24/7. Sometimes The pain is so intense that I feel like I’m losing my mind. I am very careful not to make certain movement that irritate it so I can get through the day. I turn into someone I don’t recognize if I have trouble controlling it.
I never take more than what is prescribed the thought never enters my mind. I try other efforts to help it calm down. I would say my level of pain daily is 5-6 intensity sometimes higher.
My doctor tests monthly which I don’t like but I do it. This pain has changed my life and taken so many things from me. These opioids have given me back a bit of what I lost.

Sent from my iPhone
Kathy Hartzler
214.536.0632

From: Kenneth Hyatt
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 6:17:44 PM

It's an absolute shame the 2016 guidelines were implemented with no regard for people who count on opioids and benzoides like me to live a better life so if the new guidelines are more of the same shame on you .It used to be me and my doc who managed my health needs now we have a new partner the government who has no idea what I need . Thx Kenneth Hyatt

From: Kaler john
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:08:06 PM

I suffer pain every day because of the severe restrictions in your guidelines. You are also causing more deaths from overdose and suicide that you prevent.

From: Koa"nani Kai
To: NCIPCBSC (CDC)
Subject: Public Comment July 16, 2021 BSC Guideline meeting
Date: Friday, July 23, 2021 12:47:58 AM

My name is Koa Kai, a patient, advocate, and Ambassador with the Chronic Disease Coalition, which represents over 10,000 patients with chronic illnesses and disabilities, many with severe, high impact pain, such as CRPS, pancreatitis, and trigeminal neuralgia. I appreciate the opportunity to comment on the revision of the Guidelines.

The 2016 Guidelines have caused a devastating amount of patient harm. The broad implementation of the Guidelines by federal legislation, state legislation, medical boards, and prescription data monitoring databases, payers, Medicare and Medicaid, pharmacies, pharmacy benefit managers, and law enforcement has caused incalculable harm to patients. The 2019 clarification issued has been ineffective in decreasing the amount of patient harm caused by the Guidelines.

We continue to hear daily from patients who are abandoned by providers, abruptly tapered or discontinued from opioid therapy that benefits them, and cannot access any pain management or often basic healthcare. Many providers have stopped prescribing opiates altogether for any reason and the number of pain specialists has declined due to fear of prescribing liability.

We have serious concerns that the **AHRQ evidence used for the 2016 Guidelines and the revision focuses on mild to moderate pain from uncomplicated, common conditions, while the Guidelines disproportionately affect patients with complicated and rare conditions with moderate to severe high impact pain.** Additionally, we believe it is inappropriate for a federal public health agency to issue recommendations at the highest rating while all but one recommendation use poor to very poor quality evidence.

We are highly concerned the Guidelines continue usage of the MME metric. As recently as last month the FDA held a two day conference to gather gaps in knowledge for the MME metric, and the consensus was the MME metric is not scientifically valid and does not account for wide variation in patient genetics and pharmacokinetics. The metric also has wide variation in calculation among clinicians. It is also disturbing that the broad misapplication of the Guidelines centers around the arbitrary numerical threshold of 50-90 MME. The scientifically unsupported MME threshold has effectively become the standard of care and a legal limit used by the DOJ/DEA to the detriment of patients and providers. It is disturbing Dr. Debbie Dowell, a co-author of the Guidelines, referred to this metric as a “rough guide” in the July 16, 2021, NCIPC BSC meeting, and appeared to have little understanding of its profound impact on policy misapplication, erection of barriers to access pain management care and medications, and law enforcement.

A similarly deeply concerning issue is the wildly inappropriate conflicts of interest with Dr. Roger Chou. Dr. Chou developed the evidence through AHRQ, authored the 2016 Guidelines, co-authored the CDC's 2019 clarification, developed evidence through AHRQ reviews, is the lead author on many of the references used in the revised Guidelines, co-authored the revised Guidelines, and sits on the Board of Scientific Counselors with the ability to manage others' conflicts of interests and approve his own work. The substantial influence of a single physician on federal Guidelines is categorically inappropriate and against CDC policy and federal law under the Federal Advisory Committee Act.

The devastation of the results of the Guidelines caused to patients has not declined. It can only be described as reckless to implement federal Guidelines based upon poor to very poor evidence when implemented with the full magnitude of a federal agency to expectedly become the standard of care and policy/law. While we believe adopting the recommendations of the Opioid Workgroup in full will decrease the amount of harm to patients, we hope to see a pause in release of the revised Guideline and retraction of the current Guideline until a reevaluation of the process can be conducted and higher quality evidence becomes available.

Thank you for your time.

Kind Regards,
Koa Kai

Koa Kai | **Ambassador** | **Chronic Disease Coalition**
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Koa Kai
about.me/kchronically

From: Kim Keen
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:19:19 PM

I am emailing you about the updated version of the guidelines for pain management. As this directly effects my life and well being greatly.

I suffer from a progressive terminal illness called Pulmonary Atrial Hypertension. The side effects of this medication I have to take gives me extreme pain in my legs. I also have fractured my tail bone in a horse riding accident and now have a new injury in my neck from a car accident. My lower back injury pain had been controlled with opiates and physical therapy including deep message in the past. My neck injury leaves my arm in severe pain and it's my right arm and hand effected . (In which I write etc)

Now that the drs have taken me off the dosage which gave me pain relief and much better quality of life, it has effected my whole body. I have gained weight which has effected my breathing. And most importantly my quality of life. I am in severe pain constantly. It even wakes me up in the night.

My progressive lung disease gives me a life expectancy of 10 years if I am on proper medication to help my blood vessels relax to allow blood to flow. At this point I am only able to tolerate one of the three dosages a day or I am in so much pain I am no longer able to tolerate it along with my other pain. This in return has made me fight depression and make me question daily how I can live like this.

I am not an addict. I have never in all my years on opiates called in for an early refill. And so much more as you can clearly see this information in my chart.

Please take people like me under consideration when you are updating these guidelines. I don't no how many times I have been told by drs that pain won't kill you. But I disagree. The pain I have makes me feel helpless and have me asking myself what is the use of fighting . I have so much life I want to live while I'm alive. I am newly married and want to make life time memories with my husband. It makes me very sad and angry that at this point pain is whats keeping me down WAY more than my lung/heart disease. That should be something I hope you think about while doing these guidelines.

Thank you for your time and if you have any questions or if I can do more please don't hesitate to email me.

Sincerely,
Kim Keen Gunaratne

From: Keith Kiser
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:59:17 AM

It’s about time you get out of the practice of medicine you have no business in the practice of medicine you do not know what you’re doing you are destroying millions of lives with your barbaric brain dead policies your crimes against humanity should be punished

From: Kirsten Klang
To: NCIPCBSC (CDC)
Subject: Comment regarding CDC Prescription Opioid Review Group
Date: Thursday, July 22, 2021 11:57:02 PM

To whom it may concern:

The world of medicine is designed by healers, by people who love and revere the role of medicine in American society. Medicine was designed to adhere to science, to be ruled by the virtues of integrity as supported by the promises of those individuals who solemnly pledge to "Do No Harm."

The CDC was supposed to be an a reflection of American medicine, an altruistic tool of the medical community, to stand as the guiding beacon of health for our respected American healers in times of disease and hardship. The CDC was designed to help physicians provide better care for the American public by providing a central source for scientific medical information from the healthcare field.

The CDC was never designed to insert itself between the doctor-patient relationship to destroy lives. It was never designed to help empower a militarized DEA and DOJ to terrify doctors not to treat pain conditions. It was never designed to manipulate public policy to make huge profits for rehab investors, huge companies like Reckitt-Benckiser, Indivior and corrupt corporations like Physicians Reciprocal Insurers (of New York. Yet, sadly, that's exactly what happened...all of it.

Prescription opioids never had anything to do with the fentalog crisis. All of our suffering was for nothing. And now you know the story. And we hope you will stand up in our defense

We the pain patients of America and our doctors are here today after years of being ignored by the federal government. There are 50 to 100 million of us and we are not doing well at all. Some of us have lost our jobs and we are bedridden. Some of us are pulling into a job, and coming outside at lunch to cry quietly in our cars. Others are just out of hip surgery and lying there alone in a hospital bed, screaming. This is not just just abuse, this is torture of human beings. This is a return to the Dark ages into a time when Civil War soldiers would bite on leather straps and lead slugs as body parts were removed without pain relief. The CDC is directly the cause of this nightmare.
Let's suffice to say that it has gone far beyond incompetency by the people who wrote this initial guideline. This policy is firmly anchored in corruption. And are complaints go beyond the fact that we are not being treated appropriately for our pain conditions, it also includes the fact that we think that the CDC has been dragging its feet on rewriting the 2016 Opioid Prescribing Guidelines to do as much damage as possible to the opioid manufacturers. We just happened to get in the way. So that is why we are here now and we implore you to please, finally hear our voices, and consider the weight of what has happened to us and why. We our mothers, fathers, children, grandparents, caregivers, employees...and we have been denied reasonable pain care at almost every turn. We have been forced to take medications that make us sick

and don't touch the pain. We have been forced to take epidural shots in our spines that are not FDA approved and can cause catastrophic damage over time. We are tearing our stomachs up with NSAIDS. Right now I know a person who is taking 60 tablets a day. 60. He can't eat without vomiting anymore and I don't even want to know what's happened to his kidneys or liver. But this is what they have done to us. Most of us have stories of being accused, being embarrassed, being treated like second class citizens because our bodies are broken. These things just break our spirit, and destroy our dignity. If we dare to complain, we are fired from our doctor's office and given a lecture about how opioids are a problem for people in America. We don't know these addicted folks, and we wonder why you are endlessly lecturing us about them, because we have done nothing wrong and their issues do not apply to us. We just feel abused and tortured by the CDC and the people who took control of it when America wasn't looking.

I know it's hard to wrap your head around why pain patients were targeted by the CDC. It used to be hard for us to understand, too. But once we looked into how the CDC declared a mislabeled opioid (street drug toxicity) issue to declare an epidemic, thereby pushing the FDA out of the way, and targeting the prescription opioid pain medications, it became clear what was going on. Many of you now also understand this too, and that's why we have hope now when we ask you now to look at this situation with true fairness. We believe that you truly understand the reason we ask you to now respect us as human beings with treatable conditions, and not to misdiagnose us as people with addiction or drug abuse issues. That's not who we are. In fact, we are mostly pretty good people who are just physically dinged up a bit, bit are being refused effective pain treatment for no just reason. We are being maligned for something none of us have control over -- the real source of the opioid epidemic -- huge quantities of incredibly dangerous counterfeit methyl fentanyl (fentalogues) that are currently streaming in over the southern border.

Everything went downhill for chronic pain patients when the CDC's considerable power was abused by people appointed to the 2016 CDC Core Expert Group. The members of this group were fraught with embarrassingly blatant conflicts of interests. When caught with these conflicts, the CDC just allowed them to apologize and make an excuse. This was allowed several times for one individual who should have never been a part of the process, Dr Andrew Kolodny. Basically, several of the CDC's Core Expert Group in 2016 consisted of members of Dr. Kolodny's activist group, Physicians for Responsible Opioid Prescribing (PROP). Kolodny did play a part in writing the CDC guidelines, and he also responded to an allegation of CDC indiscretions which originated from Washington Legal Foundation. Kolodny was/is a paid member of the board for Physicians Reciprocal Insurers (a large provider of malpractice insurance that was started by his father, was in financial trouble around the time CDC Director Tom Frieden took the reins at the CDC). Kolodny also had direct marketed Suboxone on the streets of New York between 2002 and 2005 and worked directly for Tom Frieden at the City of New York Health Department. (Keep in mind that in 2009, Reckitt Benckiser, the manufacturer of Suboxone at the time, was looking at trouble because they were losing their patent for Suboxone and wanted a way to skirt the system and hang on to the patent...they didn't succeed though). Kolodny also worked for the City of New York, reportedly between 2015 and 2017, providing physicians with direct buprenorphine prescribing training. Oh, and Kolodny, a psychiatrist, also ran a study for Maimonides Medical system in an attempt to show that Suboxone was a safe and effective alternative to opioid pain medications...but he never completed the study. It enlisted four subjects in it and apparently it ended before Kolodny got a result. (But Kolodny regularly used the study in his testimony at Oklahoma versus Johnson & Johnson to say that he had treated chronic pain). The above were a short list of Kolodny's highly compromising schemes in a long string of highly compromising jobs.

None of this was ever listed in Kolodny's conflicts with the CDC. But I expect him to submit a correction very soon, as he always does, and it's totally likely that the CDC will do absolutely nothing about the disgusting fact that Kolodny was clearly hiding this information from the agency in order to manipulate CDC policy. He should have never worked for any Federal agency regarding opioids.

Kolodny also had his employees at PROP on the 2016 core expert group, gunning for the manipulation of prescribed opioids as his next cash cow...even with his level of corruption and conflict of interest, he planned to become a star witness in a number of lawsuits against opioid manufacturers for a rate of $750 an hour. He did exactly that. And who knows how many lawsuits were thrown by this very dishonest man.

Kolodny and his group led the bulk of the attacks against American pain patients for greed and power. Kolodny went on numerous media outlets claiming that Suboxone was, "pretty much the cure for addiction" and downplaying Suboxones very significant side effects. The CDC played right along with Kolodny's game, corruptly usurping the legitimate power over prescription drugs from the FDA, after Kolodny. failed to get the FDA to accept his ridiculously random MME limits. Once Frieden was at the CDC, Kolodny was in control and he placed the horrifying mme limits in the 2016 Opioid Prescribing Guidelines. His goal was to push more pain patients and doctors, out of fear and desperation, to Suboxone. His quest for profit cost countless innocent lives as a result. Over the years since 2012, the CDC, along with contributing agencies and political figures, deftly covered up much of the crooked background of the Frieden/Kolodny years. But they were not able to continue to hide the fact that the opioid epidemic of opioid related deaths was actually a result of contaminated street drugs that had been around since 2004-2005. It protected the drug cartel quite cleanly for a good many years as well.

In a perfect world, people might understand that it is not proper to make one person suffer the consequences of another person's actions or bad choices. But that is what the CDC has been doing. We might also have the logic to realize that physicians should be treating the person in front of them, not just some abstract concept based on a fashionable media trend. But that is not what the CDC has been promoting at all. They barely made any kind of announcement regarding counterfeit fentanyl. They actually only distributed that information to a group of first responders just in case the first responders touched something with fentanyl on it and were rendered unconscious by skin contact alone.

The CDC played a long-running game with their pals at the DEA and DOJ... Even though the DEA and doj both knew that counterfeit fentanyl was the real killer. The DEA used the CDC as a proponent of unconstitutional attacks compromising doctor-patient relationships and jailing innocent doctors for simple mistakes in bookkeeping.

Everything the CDC has touched in the last few years has gone to hell in a corrupt handbasket. We must begin to heal the wounds caused by former CDC director Tom Frieden and the insiders from his own circle (mostly based on his role in the New York Department of Health). We think that Frieden may have guilty feelings and maybe try to say that he was somehow "a lost voice in the wilderness" now that he is out of the CDC office, but he had no trouble leading the CDC in this terrible insult against chronic pain patients for a number of long years. He is well known for undermining ethical boundaries (as is written in the book "Saving Gotham") Frieden quickly eroded the CDC's cautiously balanced relationship between the government, doctors and patient to allow his handlers (Bloomberg) cater to group of pro-rehab and pro-suboxone activists to push for extreme limits on prescribed opioid pain medications. Yet, after freedom was prosecuted for sexual assault, in a moment of guilty conscience he did an interview for the Washington Post in 2017 where he proclaimed that he knew that counterfeit fentanyl in poisoned illicit street drugs was the real cause of the opioid crisis. He knew. But he didn't care until the damage was already done. Or maybe he wanted probable deniability. It's hard to say.

At any rate, we hope that the CDC has finally come to know the destructive effects of their 2016 Opioid Prescribing Guidelines. We hope that they understand that they never should have inserted themselves in between physicians and their patients and that so many innocent lives have been lost as a result of Tom Frieden/Andrew Kolodny's team's actions. Some pain advocates attempted to keep a running tally of all the suicides that have occurred since 2016, but people are quiet about it and it's really just hard to keep up...within a period of about 4 months, we had informally tallied up about 46 suicide cases...just from a doctor's reporting them and online, social announcements. One can only imagine how many suicides there were total that we didn't know about. The CDC has made no effort whatsoever to tally the number of chronic pain patients who have died by suicide. You see, if the CDC doesn't like the data, the CDC just chooses not to know about it. They brush it under the rug. That's not science.

I read through some of your group's recent review on the 2016 OPG. I'm encouraged that you noticed that chronic pain patients are being put behind persons with addictive disorders. Bottomline, we're at being asked to sacrifice our lives on the off chance that we might be able to keep someone with addiction alive...and that probably wouldn't work anyway. What a strange choice we are being asked to make? Many of us wonder who this "ghost" patient is in the office with when we visit our physicians, and why that patient is liked so much better than we are. (We are in pain, but we are actually a likeable group). We just want the world to know that we don't believe that it is appropriate in any form to keep treatment away from a patient who needs it...especially for the lame reason that because another person might get their hands on it. And nobody wants addicted people to die, but clearly from the OD death numbers that have skyrocketed in the past year while prescribing plummeted, prescribing has very little to do with the problem.

When are we going to start thinking differently about making the world a better place and really helping people with drug addiction who are struggling with internal pain?
And that's the point isn't it? Their pain is no more catastrophic then mine? So theirs gets

treated, mine doesn't? Clearly the CDC appointed itself judge and jury and has sometimes alsi decided that there is no such thing as physical pain. It's all in our heads. We should be able to psych ourselves out of our pain. Well, if the power of the mind is that good, why aren't we psyching people with addiction out of their habits? Why do they receive Suboxone on a silver platter, as much as they want, for as long as they want (we don't want it, no thanks... vomiting isn't much fun when you're in chronic pain believe me). Doesn't anyone care that Suboxone/Butans is now the fastest growing black market drug today and it's being attributed with severe side effects, including severe withdrawal issues? Why is this being ignored...especially as doctors try to push Suboxone onto more and more chronic pain patients?

Every person with pain is an individual and every person deserves to be treated in a way that is respectful to their own choices and feelings. Being told my pain is in my head doesn't wash with me at all because for me, my pain issues really happen at night and wake me out of a dead sleep. There is no way for me to psych myself out of my physical pain while I'm sleeping. I am asleep. Speaking of sleep, it's important for health right? obviously. So one would think that an extended release opioid drug would be helpful for people like me, only for at night, of course. But STOP!! Remember, in the CDC's funroom of distorted policies, lots of traps that you can fall into. That's why when you're a chronic pain patient you learn very quickly never to rock the boat. Never ask about extended release opioids... Never ask about certain types of opioids and really do your best to never ever ask for an increase even if you're dying of pain. Because if you do, you are taking a risk that even after 10 years of responsible and conscientious opioid therapy, that you might suddenly be given side eyes by your physician and can guarantee a 6-month run of urinalysis calls that would all come up clean. And why? Because it's wrong. And cruel. And dumb. People in severe night time pain deserve and want a solution. But even after years and years of being a conscientious and trustworthy person, it's still seen as suspicious to ask for certain things. Asking for anything that's extended release or inquiring about other types of pain treatment or wanting to try something new shouldn't be considered suspicious. Why can't someone who has a trusted history have some kind of pass that allows them to speak freely to my position in pain and not be treated like an addict? Why don't I get credit for being conscientious all these years and doing what I'm told and trying my best to manage my pain in other ways as I am able? I am most certainly not a problem drug user. At all!

But yes, there are problem users, and they usually end up getting weeded out over time. Let's imagine that a person who abuses drugs did get their hands on a prescription opioid. At least they would still be safer than they would on meth or methyl fentanyl-laced heroin. But that was never the CDC's agenda anyway. No lives were saved by limiting chronic pain patients...none. And in fact more lives were lost because of suicides due to the CDC's actions in the end.. Although clearly the CDC made more problems than they fixed, because its preferable to anyone to have a drug that is FDA approved and prescribed, problem drug abusers are now pushed to deadly contaminated street heroin.

Additionally, it's cruel that the CDC has now given people with anxiety and chronic pain an impossible choice...for these sad folks, they must either choose to take opioids or antianxiety drugs. Why couldn't a person will sign a waiver that releases a doctor from liability for this issue? Is it really necessary to treat people in this fashion?

We want you to know that if you choose to help us that we do not take your actions lightly. We fully realize that this could make waves for you. After being maligned for

years now, and wrongfully being called "addicts" and "junkies," (sometimes whispered by nurses who have grown cold and apathetic over years of overwork.)
We understand that the media has followed the false narrative about prescription opioids and they'll probably take it out on you. We are sorry, but it's true. But we also realize that someday what the CDC has done to chronic and acute pain patients in America may be considered one of the greatest medical injustices of our nation's history. We hope that you choose to take a part in fixing this great wrong...because people with legitimate, diagnosed pain conditions have been suffering needlessly through no fault of their own for too long.

We humbly ask for your compassion and your help. Please restore the gift of modern pain care to the sick, the wounded and the dying. We ask that you grit your teeth and remember the humanity and compassion that some of you have delivered to your own patients in the past. Remember the opioid pain treatments that helped get your patients back up and working, back to caring for their children and back again to living real, independent lives. Remember these patients who walked into your offices and cried for help...we once had dignity like you do. And please remember that in the blink of an eye, any of you could be any of us. Imagine being left to suffer and die slowly in agonizing pain because someone else, someone you don't know, and never even met, had an addiction. You all probably never abused a drug in your lives and never would...and neither would we. But whenever you discuss you're uncontrolled pain with your doctor he tells you about someone else's problem. It feels extremely patronizing. To add insult to injury, several studies have shown that very few chronic pain patients who are treated long-term with opioids ever become problematic users of prescription opioid medications. The number is less than 5%. That is barely a blip. Yet, here we are.

We, the pain patients of America and our doctors, pray that this time that the CDC does not harm us further and that their overall cure for this 2016 disaster is not worse than the problem it seeks to treat.

Thank you very much for your efforts.

Respectfully,

Kirsten K.

From: Karen Koski
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:49:28 PM

I’ve been on opioids for almost 6 years since I had hernia surgery with mesh. I’ve had horrible burning pain and it has definitely changed my whole life.
I had surgery for a left inguinal hernia in June of 2015. I had bad pain that continued to get worse.
I’m October 2015 I had an exploratory surgery to search why I was in so much pain. They removed the mesh but replaced it with more mesh
I have horrible burning pain in my groin area. My dr gave me many different kinds of meds but nothing helped.
He finally gave me opioids and I get some relief from my pain but it doesn’t take all the pain away
It has made a dramatic change in my life.
I’m 79 years old but I was always a very active lady. This pain has changed my life dramatically.
I have never abused the use of my pain medications and don’t think it is fair to take them away from me or anyone else that doesn’t abuse them
I can’t imagine my life without some relief for my horrible pain.
So please think about all others like me that have never ever abused their pain medications.

Sent from my iPhone

From: Karen Langlois-Stewart
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:03:05 PM

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

I hope that in drafting the final Guideline, the CDC takes these views into consideration.

I am a chronic pain patient and, unless something changes drastically, I am liable to remain to remain chronic pain patient for the rest of my life. Please don't make it harder for me to obtain relief.

Thank you,

Karen L. Stewart

Sent from Yahoo Mail on Android

From: Kelly M
To: NCIPCBSC (CDC)
Subject: Pain medication
Date: Friday, July 23, 2021 12:40:41 AM

I am writing due to the fact that I have complex regional pain syndrome, Ehlers-Danlos syndrome, degenerative disc disease, severe arthritis, migraines, Diverticulitis among other things.

I was on 5 MG of oxycodone 3 times a day and now I am being told I don't need any pain medication.

My previous provider was fired for prescribing pain medication at a pain clinic! Isn't that what they're supposed to do?

I always go to my appointments, always pass my drug tests and I never am off when they count my pills which is at every appointment.

I take my medication the way it is prescribed even if my pain is through the roof and I need some relief. I suffer because I follow my doctors orders but yet I am being punished for being in chronic pain!

I had 5 ankle surgeries in 3 years with the last one being an ankle replacement which caused the complex regional pain syndrome and I wouldn't wish this on anyone!

My life has changed drastically. I went from being a very active, on the go person to someone who suffers daily and I can never make plans because I never know from one day to the next what my pain is going to be like.

People that are following the rules with pain medications and people that actually need these medications are suffering all over and it isn't right.

I have all of the tests and documentation needed to prove my diagnoses so why is it that I am being questioned?

Something needs to change!

Prescribing pain medications has gone down but overdoses have gone up. What does that tell you right there? This is NOT from legally obtained prescriptions and is from illegal drugs so pain patients need to stop being punished for this!

PLEASE help us!!! All we want is to try and live a somewhat normal life the best we can and we are tired of being ridiculed and treated like drug seekers or addicts!

Walk a day in our shoes and I bet things would change.

We didn't ask to be in pain and to suffer every day.

You wouldn't punish a person that drinks alcohol because of another person that was drinking and driving would you?

Thank you

From: Kathy McCabe
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:52:08 PM
Importance: High

I have been adversely affected by the previous guidelines and with the new ones being so similar – I'm assured to not receive the pain care I deserve. Since the 'guidelines' were released, I have lived in pain – it has affected every aspect of my life.

I really resent you being able to determine how I am treated. The vast majority of chronic pain patients are not addicts and to have you suggest it is insane and insulting.

Because of your guidelines, I have been forced to endure YEARS of vicious chronic pain. We have no problem medicating our pets, but as soon as a human patient is labeled with chronic pain, they are forgotten, thrown away, and marginalized because of your interference.

I would like to see the pain community be treated once again with dignity and compassion, as it was before you got involved.

Please remember we are people too.

Kathy McCabe
thebestva@msn.com

From: kellynaill@
To: NCIPCBSC (CDC)
Subject: how the CDC guidelines has ruined my life as a pain patient
Date: Friday, July 23, 2021 2:17:37 PM

Hopefully this will reach you before the deadline. I am speaking on behalf of 3 pain patients that lives have been devastated by the CDC guidelines, the DEA's rampant control of the way doctors prescribe, and government interference in medical practice where it does not belong.

I speak for my family.

First I became disabled over the course of ten years. I am a blue collar worker that has lifted half my body weight for years as part of my job. I worked long hours and long work weeks. The pain I have comes from multiple areas. I have back issues, neck issues, torn ligaments, pinched nerves, thoracic outlet. You deal 24/7 with pain from multiple areas and it becomes exhausting. I tried everything. I had multiple injections that only ate my tissue away, I tried medical cannabis, I had surgery (surgery does not always result in permanet repair), I had physical therapy, I tried multiple types of drugs, but what worked was a low level of oxyc odone. Low level meaning well below the 90 mme.

Guess what??? I can't get a doctor to prescribe it because they are AFRAID OF THE DEA!!!!! Doctors don't want to prescribe any narcotic now even if you have a valid medical history, have never abused your medication, they don't care. They are only concerned about keeping their medical license and avoiding any interaction with the DEA. I moved and doctors are screening patients before accepting to make sure they are not on any opioids because they don't want the issues that the patient brings to them about pain!!!

We live in pain 24/7 and are treated like three world country dogs!!

My spouse worked 38 years in the medical profession as a MRI tech. Johns Hopkins broke her down physically by working with skeleton staff leaving her to lift intubated medically induced coma patients with two people. A 5ft 2 inch 115 pound woman having to lift repeatedly all day long. She actually tore he r elbow tendon to the point that it took two surgeries to fix!!! She has metal in her neck, herniated discs in her back, torn areas in the shoulders, and than shattered her ankle.

> Which brings me to the kind of treatment she received from an orthopedic surgeon. He did not give her enough pain medication after surgery and she suffered!!! She had to use a walker and kept complaining her arm hurt her. He sneered and told her to go to pain management. Her PRIMARY CARE doctor did an xray and she had a break in her forearm.. This is the kind of treatment people are getting across our nation. Horrid medical care if you even want to call it that. She had to go onto disability. Then what they did was slowly taper her down after the CDC guidelines to the point of nothing because her doctor wanted her on Suboxone. Something that we can't even afford!!!! Well we got a loan so she could get in a program for it . It worked for about a year than like any other opioid type of medication the effects where worthless and she was already at the highest dose. So there was nothing left because doctors are refusing to give patients anything to help for pain. We could afford pain medication. Now she DRINKS ALCOHOL TO DULL THE

PAIN!!!!!! How healthy is that???

Once again another person that spent thousands of dollars on other types of treatment only to wind up having to drink alcohol for pain relief.

Lastly but not least I saved my sister. My sister was always going and doing stuff. Living life, working hard, and enjoying life. Then she started with throat issues that required a simple bronchoscopy. Her husband was in the military so they used a naval hospital. The doctor made an error that resulted in her being air lifted to another hospital because they were not equipped to treat emergencies there. She spent almost three weeks in there but not after going through emergency surgery due to her lung collapsing, a trach, and thoracotomy. That changed her life. She had permanent pain from nerve damage in her side from surgery. She used morphine for years and continued to work. The the CDC guidelines hit and her doctors started cutting her back. This went on for three years. During this time many doctors were getting out of the pain management practice because of the DEA and government oversight. They knew they would be targets to loose everything they had worked for. That left us pain patients getting new doctors every year. My sister was going through this across the country. She was exhausted with the process. The insurance companies, the doctors, the government,etc.. She was in pain and no one cared. So she was set up to transfer from morphine to suboxone. She had been through all types of testing including a pyschological test. All was g ood. She kept complaining about how sick she felt and no one was listening. These doctors left her on her own after years of using opioids.

It was a Sunday early am the day before her doctor appointment. She went to her bedroom got a gun out of their safe then walked into her bathroom and used a 9 millimeter to take the pain away. It was not an opioid overdose. It was a person pleading for pain relief. A government that failed her. Doctors that failed her.

We are three ordinary people. We did not grow up as drug addicts, We were contributing to society and living life. Things happen in life that cause people to have pain. They should not have to suffer like dogs because our government has intervened to keep us from being comfortable. Government should not be harassing doctors that prescribe opioids.

What the CDC has done has caused people to commit suicide. Caused people to suffer with relentless pain 24/7, caused doctors not to be able to do what they are trained for when it comes to prescribing medications and has just upset the balance of hundreds of thousands of people that have the need for opioid pain medicine.

I am sure my sister would have written to you but she is no longer here thanks to the CDC!!!!!!!

Sincerely,

Kelly Naill

NPAC
NATIONAL PAIN ADVOCACY CENTER

Kate Nicholson
President and Founder
kate@nationalpain.org
nationalpain.org

July 23, 2021

Dear Dr. Bonomi and Members of the NCIPC Board of Scientific Counselors:

Thank you for the opportunity to provide input regarding the revision of the CDC Guideline for Prescribing Opioids for Chronic Pain. The National Pain Advocacy Center is a new nonprofit that takes no industry funding and advocates for the health and human rights of people living with pain.

Collectively, we are a group of scientists and clinicians with expertise in pain and addiction, civil rights and health policy experts, and people with lived experience. Our membership includes people with a range of conditions causing serious pain, such as cancer, multiple sclerosis, sickle cell disease, spina bifida and many other high-impact conditions – as well as those in recovery from an opioid use disorder.

We submit this statement based on information in the public record.

The misapplication of the CDC's 2016 Guideline by insurance companies, legislatures, Medicare and Medicaid, state agencies, pharmacy benefit managers, and law enforcement has resulted in immeasurable suffering and harm to our community.

Our members, and those we hear from on a near-daily basis, have been tapered off medications they required to function, often in abrupt or involuntary ways. Others confront mounting barriers in filling prescriptions on which they have relied, either long-term or on a periodic basis, for years. Too many have been abandoned in care and are currently unable to find a provider who is willing to treat them at all.

Unfortunately, tapering, abandonment, and heightened barriers to care have continued despite the CDC's 2019 clarification[1] of its 2016 Guideline.

Among those to suffer disproportionate harm are our members who are people of color. We appreciated the comments during the July 16 meeting suggesting that the CDC will prioritize health equity, and note that doing so is especially important in the area of pain care and opioids. Studies show that the effects of systemic racism, for example, profoundly shape the access to and quality of pain care people receive. Many have demonstrated that providers rate the pain of Black or Latinx patients as being less severe than that of their White patients

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[1] Letter from CDC Director Robert Redfield, April 10, 2019 https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/5caf661d7f312b0001bac1b8/1554998814907/Alford+Final+.pdf; Dowell, D., Haegerich, T., Chou, R., *No Shortcuts to Safer Opioid Prescribing*, 380 New Eng. Jol of Med., 2285-2287 (2019) noting the danger to patient safety in misapplying the guideline, especially given the low evidentiary basis for the dosage and supply provisions.

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due to false ideas about racial differences.[2] Black or Latinx people are also less likely to be prescribed pain medication.[3] We urge the CDC to consider that not everyone is equally affected by barriers to care or by the misapplication of its policies. Many groups, such as women, people who are transgender, and people with disabilities, among others, may face heightened barriers to pain care.

Several organizations, government commissions, and emerging studies corroborated the harms we report. Human Rights Watch[4] labeled the consequences to patients of misapplication of the 2016 Guideline a humanitarian crisis. The HHS Pain Management Interagency Task Force Report similarly highlighted harms.[5] In addition, several observational studies on dangers associated with tapering[6] have emerged over the past few years, as have studies showing that providers are increasingly unwilling to treat people who use prescribed opioids.[7]

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[2] Hoffman KM, Trawalter S, Axt JR, Oliver MN. Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. Proc Natl Acad Sci U S A. 2016 Apr 19;113(16):4296-301. doi: 10.1073/pnas.1516047113. Epub 2016 Apr 4. PMID: 27044069; PMCID: PMC4843483.

[3] See, e.g., Lee P, Le Saux M, Siegel R, Goyal M, Chen C, Ma Y, Meltzer AC. Racial and ethnic disparities in the management of acute pain in US emergency departments: Meta-analysis and systematic review. Am J Emerg Med. 2019 Sep;37(9):1770-1777. doi: 10.1016/j.ajem.2019.06.014. Epub 2019 Jun 5. PMID: 31186154; Sabin JA, Greenwald AG. The influence of implicit bias on treatment recommendations for 4 common pediatric conditions: pain, urinary tract infection, attention deficit hyperactivity disorder, and asthma. Am J Public Health. 2012 May;102(5):988-95. doi: 10.2105/AJPH.2011.300621. Epub 2012 Mar 15. PMID: 22420817; PMCID: PMC3483921.

[4] Human Rights Watch, Not Allowed to be Compassionate: Chronic Pain, the Overdose Crisis, and Unintended Harms in the US, December 2018, https://www.hrw.org/sites/default/files/report_pdf/hhr1218_web.pdf.

[5] Final Report, Pain Management Best Practices Inter-Agency Task Force: Updates, Gaps, Inconsistencies, and Recommendations, May 23, 2019, https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

[6] See, e.g., Mark, T.L., Parish, W., Opioid Medication Discontinuation and Risk of Adverse Opioid-Related Health Care Events, 103 J. Subst. Abuse Treat. 58-63 (2019). https://doi.org/10.1016/j.jsat.2019.05.001; Oliva Elizabeth M, Bowe Thomas, Manhapra Ajay, Kertesz Stefan, Hah Jennifer M, Henderson Patricia et al. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation BMJ 2020; 368 :m283 doi: https://doi.org/10.1136/bmj.m283; James, J.R., Scott, J.M., Klein, J.W. et al. Mortality after discontinuation of primary care-based chronic opioid therapy for pain: a retrospective cohort study. J GEN INTERN MED (2019) 34: 2749. https://doi.org/10.1007/s11606-019-05301-2; Glanz JM, Binswanger IA, Shetterly SM, Narwaney KJ, Xu S. Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy. *JAMA Netw Open.* 2019;2(4):e192613. doi:10.1001/jamanetworkopen.2019.2613; Perez, H., M. Buonora, C., Cunningham, M. et al., *Opioid Taper Is Associated with Subsequent Termination of Care: A Retrospective Cohort Study*, J Gen Intern Med (Aug 19 2019). https://doi.org/10.1007/s11606-019-05227-9; Fenton, J., Agnoli, A., Xing, G., et al., Trends and Rapidity of Dose Tapering among Patients Prescribed Long-Term Opioid Therapy, 2008-2017. *JAMA Netw Open.* 2019;2(11):e1916271. https://doi.org/10.1001/jamanetworkopen.2019.16271; Neprash, H.T., Gaye, M. & Barnett, M.L. Abrupt Discontinuation of Long-term Opioid Therapy Among Medicare Beneficiaries, 2012–2017. *J GEN INTERN MED* (2021). https://doi.org/10.1007/s11606-020-06402-z

[7] See Lagisetty PA, Healy N, Garpestad C, Jannausch M, Tipirneni R, Bohnert ASB. Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open.* 2019;2(7):e196928. doi:https://doi.org/10.1001/jamanetworkopen.2019.6928; Quest Diagnostics and Center for Addiction, HealthTrends, *Drug*

The CDC's 2016 Guideline provides a role for prescribing opioids in pain not managed by other means. We appreciate that the intent of that Guideline and its update is, as stated during the public meeting, to ensure access to high quality pain care. Yet, the common misapplication of the 2016 Guideline—and, especially, of its day and dosage thresholds—has resulted, however, in the denial of care to a subset of patients.

Specifically, we highlight the following concerns:

- **We were alarmed by revelations in the BSC/NCIPC Opioid Workgroup Report suggesting that the CDC may come out with the same day and dosage recommendations that were widely misapplied.** Doing so will predictably both undermine any good done by the agency's 2019 clarification and, more disturbingly, signal its approval of future misapplications that result in harm.

- **Of particular concern are morphine milligram equivalent (MME) thresholds, which fail to account for variability in genetic, metabolic and disease processes and methods of MME calculation.** Recent evidence presented at the Food and Drug Administration[8] examining underlying CDC data found wide variation in MME calculations, such that the same medication given at the same interval could be translated as having an MME either above or below the 50-90 MME threshold. Rather than emphasize dosage thresholds, or characterize certain doses as "high risk," the CDC's recommendation should reflect current evidence that risks increase with dose.

  Wherever ranges are discussed, whether for supply or dosage, it should be made clear that they are simply benchmarks for guidance that cannot possibly anticipate or represent the range of patients and circumstances providers may encounter. We also concur with the BSC/NCIPC Opioid Workgroup Report that they should not be included in the language of recommendations.

- **The CDC should be especially cautious given limitations in the evidence.** The evidence reviews underlying the CDC's update

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Misuse in America: Physician Perspectives and Diagnostic Insights on the Evolving Drug Crisis (2019) [https://questdiagnostics.com/home/physicians/health-trends/trends/pdm-health-trends.html], accessed 11/20/19.

[8] https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and

prepared by the Agency for Health Research Quality (AHRQ) generally address people with moderate level pain from common conditions and not people with severe pain. The 2020 review, "Opioid Treatment for Chronic Pain," acknowledges as much, citing "limited applicability to patients with severe pain" and "significant gaps in the evidence base."[9] But recommendations based on this body of generally low and poor quality evidence apply with equal consequence to those with severe pain.

Finally, we were concerned with language highlighted in the BSC/NCIPC Opioid Workgroup Report that suggests that the CDC is embracing unidirectional tapering. Among our advisors are experts in tapering who were especially alarmed by the suggestion that providers should "never go back up" in dosage during a taper. Especially given evidence that simply destabilizing dosage can put someone at a 3-fold greater likelihood of an overdose death,[10] doing so seems both incompatible with CDC goals to reduce overdose harms and inconsistent with HHS Guidance on Tapering.[11] The CDC should ensure that any new opioid guideline is fully harmonized with this existing guidance from HHS, so that confusion is not generated by the introduction of language that conflicts with this guidance and current evidence (whether that appear in the recommendations, the supporting language, or introduction of the document). Opioid tapering should be individualized and patient-centered.[12] As with opioid initiation, the relevant calculus in opioid reduction or cessation should be ongoing risk/benefit assessment.

In light of these concerns, we urge the CDC to correct its course in order to protect the full range of patients likely to be affected by the update to its Guideline.

Finally, we conclude with concerns about the process for updating the Guideline.

Specifically, the public has been invited to comment on draft opioid recommendations but has not been given access to any of the introductory messaging, framing, selected evidence, or supporting language for each

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[9] Chou, Roger, et al. AHRQ Comparative Effectiveness Review "Opioids for Chronic Pain," https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/opioids-chronic-pain.pdf

[10] Glanz JM, Binswanger IA, Shetterly SM, Narwaney KJ, Xu S. Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy. ***JAMA Netw Open.*** 2019;2(4):e192613. doi:10.1001/jamanetworkopen.2019.2613

[11] HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics (October 2019) https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf

[12] See Darnall BD, et al. Patient-Centered Prescription Opioid Tapering in Community Outpatients With Chronic Pain. *JAMA Intern Med.* 2018;178(5):707–708. doi:10.1001/jamainternmed.2017.8709

proposed recommendation. In addition, a very short period (one week) was allowed for response. Neither is inclined to maximize the quality of public input.

Second, the OWG had substantial suggestions for revision, but now that the group has been sunset, it will presumably have no ongoing monitoring role during the revision process. Thus, we are curious about the CDC's plan for meaningful and diverse expert engagement going forward. We urge the CDC to take additional steps that ensure transparency in the revision process and provide for ongoing critiques from a variety of expert perspectives, including pain clinicians and pain scientists.

Finally, we hope that once a draft revision is published, the public will be given sufficient time to review the entire document, including all scientific references, and that the process will specifically provide opportunities to correct omissions of evidence and other identified issues.

Thank you for your consideration.

Sincerely,

Kate M. Nicholson

Kate M. Nicholson

From: Kate Burton
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:37:09 PM

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:
- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Thank you,
Katherine Pronovost
Lynden, WA 98264

From: Kathryn Radloff-Francis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:29:11 PM

The CDC guidelines need to come with a black box warning unless drastic changes are made. They exasperate stigma which interferes legitimate pain patient from not only getting medication, but most pain treatments or surgeries. The MME has confused doctors and the guidelines have become a destructive law in Oregon and many other states. I unknowingly moved to Oregon, but it has been hell. Only because I live with pain that once was adequately treated. I am still seeing my out of state doctor, but he is nervous about treating me. For the first time ever I am being treated legistlatively first and pain is addressed second as best possible. I understand all medicine needs regulations, but only in pain care is a dose limit defined by politicians and not doctors. The members of PROP are politicians first and foremost and many not even medical doctors. I am suspected to be a high metabolizer of medications, but to truly test this it would be expensive. However, all these factors are taken into consideration when meds are prescribed and it should be no different when it comes to pain medication. Also, I had a sleep study to make sure diazepam was safe to take with my pain meds. The sleep study doctor swears from studies she reviews daily that regular muscle relaxers are more dangerous than diazepam. There is a real misunderstanding that diazepam and other benzos should never be taken with pain meds. It all depends on the person, dose, and it's junk science to block a class of possible useful meds. Again, this is something that is only done to pain patients. It really needs to be stressed that these are guidelines and they should be very general like all other guidelines are with CDC. It is never good when the government starts writing a how to manual on medicine and that's what the guidelines have become. In fact it should state these should not become law as the best treatment is individually focused and doesn't apply one size fits all approach as that is lazy and dangerous. Too many things are missed by practicing medicine this way and too many patients are harmed.

They say if you don't focus on your pain, you have less pain. It's hard not to focus on your pain when you need to worry about someone prescribing adequate meds due to arbitrary guidelines.

Respectfully
Kathryn Radloff-Francis

Sent from my Verizon, Samsung Galaxy smartphone

From: Kellie Robinson
To: NCIPCBSC (CDC)
Subject: Opiate Prescribing Guidelines Comments
Date: Sunday, July 18, 2021 9:55:30 AM
Importance: High

Good Morning,

I wanted to take this opportunity to express the hardships that I have experienced to attain FDA approved opiate medications, since the 2016 opiate prescribing guidelines were published by the CDC.

My name is Kellie Robinson, and I am hundred percent disabled according to Social Security standards. I am a 61 year old, law abiding citizen who worked for 40 years with Advanced Rheumatoid Arthetis with connective tissue disorders. In 2010, I was in a catastrophic motor vehicle accident. I was diagnosed with a spinal cord injury that redendered me immobile and bound to a wheelchair for 3.5 years. I was told by two neurosurgeons that I would never walk again. From 2013-2020, I went to over fifty specialist, desperately seeking pain relief and treatments that didn't require opiate therapy. I did everything that was suggested to me, that culminated in my numerous medical conditions getting progressively worse. After twenty four surgeries, I am able to walk, as long as, I can stand; 50ft. Due to the trauma to my spinal cord and lumbar and cervical spines, my feet are completely numb. To be able to stand and walk, it takes every once of strength that I possess, to push through excruciating nerve pain while walking upright. With each step that I take, it feels like me feet are in a vice grips that keep tightening. The pressure is so intense that it feels like my feet bones are breaking. At this point, I have to stop and sit. The nerve pain ascends up my calf muscles rendering them weak and useless. By 2013, I was told by three different specialist that there wasn't anything else that I could do to mitigate the nerve pain that I had been witnessing for the past ten years; it was permanent. Some things that are broken can't be fixed.

At this point, I was sitting on the side of my bed, peeing in a cup because the pain was to severe for me to walk 10 feet to use the toliet. I was dependent on people to feed me, help with dressing myself, showering, and to be able to get to medical appointments. To make a simple breakfast of fruit and cereal, I would have to crawl on the kitchen counter; the same for lunch and dinner. After months of doing this, my under arms and elbows were black and blue from trying to propel myself upright while walking and standing .

I couldn't imagine having to live the rest of my life in such debilitating pain. I couldn't focus, long enough to write a complete sentence. How was I going to take care for myself living in an environment that was not conducive to being handicapped?

How was I going to live in pain that never waned in it's severity. I was against pain patients becoming dependent on opiates. I heard horror stories about addiction and withdraws. Like ever other misguided person, I believed the propaganda that opiate pain medication was Heroin in prescription pill, and that pain management physicians were drug dealers with a DEA license. Our media outlets have been bombarded with anti-opiate commercials. If opiate pain medication are taken as directed, it is a safe and effective way to treat severe chronic intractable pain . On opiate pain medications my pain level is a 6-7. Without pain medication it is a 13-14. Opiate therapy should never be applied to a patient that hasn't tried other

treatment options first.
In 2013, I finally decided that I would go to pain management-I knew, I was in a trick box; damn if I didn't and damned if I did. Living with severe pain not only took its toll on me, it took it's toll on the people closest to me.
I deplored the humiliations that you have to experience to get pain medications. Since the 2016 CDC guidelines were published, I have been treated like a criminal. I am never asked my pain level anymore. I am scared to ask for an increase in my dosage after almost eight years. I don't want to be perceived as a drug seeker. I am disrespected and made to urinate in front of another person! I am subject to pill counts, and in 2021 a pharmacist make it so difficult for me to pick up my monthly prescriptions, that I had to file a complaint, and find a new pharmacy. My new pharmacy is 50 minutes. Then there are the prescription carrier that are bound by federal laws. Every year, for the past seven years, it has become increasingly more difficult to get pre-authorizations for the same medications and dosage that I have been receiving for the past SEVEN years. First you have to get the medications approved, then you have to get mg (mme; bs science} approved, then you have to get the quantity of pills approved, finally, after receiving the same medications and dosage for seven years, I have to get a first time seven-day fill, over-rode. This year alone, it took me three months of extreme stress and anxieties to get my opiate prescriptions approved by Express Scripts.
I live with a chronic illness, and stress exasperates my pain generators. This year, I broke out in blisters and a rash from the stress. **In the state where I reside, I am eligible for mail delivery through Express Scripts and tele-visits, yet my pain management physician's are so fearful of the medical board and DEA that ever decision that they make is in their best interest, not mine or any other patient's best interest! I cant drive and need help with my motorized wheelchair to access medical appointments and prescription pick-ups. Sometimes, I can't find someone to do either. I should not have to go to a monthly appointment to pick up the same prescriptions every month! Before the pandemic it was a reasonable ADA accommodations to do tele-office visits for pain medication refills. I would go into the office every 4th month to provide then with a urine samples.**

The CDC is well aware of the long-term harm that they have caused the millions of law abiding chronic intractable pain patients by not walking their 2016 opiate prescribing guideline back, yet here we are in pain and suffering needlessly. WHY?

I am going to close by saying that NOBODY thinks opiates are a good idea-UNTIL you need one, and then they are the ONLY viable course of treatment for a quality of life. A drug crazed addict wouldn't go through the humiliations, demoraztion, constant stress, and rules that chronic intractable pain witness on a daily basis; if they are still privy to receiving opiate pain medications. Why are the chronic pain patients still being punished for the choices that the addict has made?

I lead my life with a purpose and usefulness that made me proud of my accomplishments.
All of us, are a phone call or an accident away from loosing everything that they worked and planned for. My husband and I worked and planned for our retirement years. We sacrificed and financially saved so we could enjoy the fruits of our labor. Instead, I spend hours almost everyday navigating the healthcare systems, writing and talking to senators aides about the

cruel and unusual punishments the intractable pain patient must endures to attain vital opiate pain medications; that has been either been taken away or lowered to a dosage that their pain is under treated. I have advocated for a eighty-year old terminal cancer patient who was in so much pain she begged me to help her take her life. I held a friend head as she went through violent opiate withdraws because her physician abandoned all his patients without notice- Nobody cared and nobody did anything to help her. This could be me or one day. Could be you or a loved one. The CDC guidelines MUST be retracted immediately. Disabled Veterans and millions of disabled patients, terminal cancer patients, surgical patients, patients with chronic incurable rare disease and illnesses, patients with Sickle Cell, and patients who have been diagnosed with Chronic Regional Pain syndrome are committing suicides' because of the direct results of the 2016 opiate prescribing guidelines.

Please HELP: nobody else needs to die!

Kellie Robinson

Sent from Mail for Window

From: Kat Scher
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 2:02:51 PM

Good evening,

As a 41 year old woman who had the audacity to be born with the "ultra-rare" degenerative metabolic bone disease named X-Linked Hypophosphatemia, I tried everything before turning to opioid pain medication:

Guided meditation with crystals placed on my body while smoke was blown across my body supposedly spiriting my pain away, bee venom therapy, NSAID pain relievers to the tune of renal damage, Vioxx & Celebrex before they were ripped off of the market for doing exactly what they did to me - irreversible liver damage, yoga, veganism, cryogenic sessions, physical therapy ad nauseum, etc. I broke my hip in 2013 when I stepped off a small curb to get the mail on a random Tuesday.

The bottom line is that I did not choose this disease; I did not choose to have a disease so painful that I made plans to kill myself by the age of 30. I worked so hard in college, in graduate school, in my chosen career just to end up desperately in pain, crying in yet another hot Epsom salt bath, and unable to function.

To continue to punish me, and those like me, for being born with horrifically painful diseases requiring opioid pain medication, which I have *NEVER* misused or increased my dosage in more than 8 years, is cruel, unnecessary, and short-sighted.

Every single month when I must drive 150 miles round-trip to pee in a cup in front of a *male* security guard and be treated like a criminal at one of the 3 legitimate pain clinics in my state simply for needing pain medication because I'd like to maybe be able to go to the grocery store and fold laundry in the same day, I cry because I am so grateful that I will be okay for another 30 days. I want to be a tax-payer. I want to adopt a child (my disease has also robbed me of the opportunity of having a healthy biological child). I want to be a member of society. Please allow me to take 3-4 pills per day to have a meaningful life.

It sure must be nice to have been born healthy, Congressmen, Senators. I wouldn't understand. My disease has robbed me of so very much but, unfortunately, my brain is fully intact so I am completely aware of the arbitrary cruelty that the CDC guidelines have inflicted on my legitimate pain community.

Karen Scher

From: Karen Shields
To: NCIPCBSC (CDC)
Subject: Comment re: CDC GUIDELINE UPDATE
Date: Friday, July 16, 2021 11:36:58 PM

Not once, in all i just read through, did I see ANYTHING mentioned about Pain MNGMNT Doctors (aka Physiatrists) ...only PCPs...with regards to prescribing opoids for their patients with chronic pain. I am fairly certain, at the CDC, you ARE aware that:

As medical doctors, physiatrists must graduate from medical school before continuing in their specialized training. This process involves:

- Four years of medical or osteopathic medical school
- An additional four years of postdoctoral training in a physical rehabilitation residency
- Gaining board certification with the American Board of Physical Medicine and Rehabilitation or the American Osteopathic Board of Physical Medicine and Rehabilitation
- So, my question to the CDC is, "Why has the CDC presumed to think they know better than the Physiatrist how to treat their chronic pain patients?
- Maybe, the CDC should send a notification to all the accredited pain management doctors advising them that they are NOW ABLE to treat their chronic pain patients appropriately. That may help to undo SOME of the HARM YOU have caused the CPPS, as well as the doctors that had been treating them.
- ONE last thing: the CDC should apologize to the families of the many CPPS that committed suicide because of their being force tapered and/or abruptly had their stabilizing medications stopped altogether due to the PROP written and misapplied "guidelines"!!!

From: Karan Smith
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:55:49 AM

Please revisit these guidelines. So many of our chronic pain patients were injured with the 2016 “recommendations.” I am one of those... a 68-year-old with severe degenerative disc disease, scoliosis, 4-vertebrae-fusion in my neck, unsuccessful back surgery, and deteriorating spine. I am one that needs multi-modal care including opioid relief... I have tried too many things to list, but know my quality of life would be horrendous without the RX help included. Please remember we chronic pain patients are individuals and sweeping recommendations like those of 2016 caused immeasurable harm and death to those most undeserving, those with intractable pain and those trying to help them. The harm from those needs to be undone, not reinforced with these “new” guidelines. I had to leave a profession I loved due to my unrelenting pain. Please don’t hurt any of us deserving help further. Dr. Red Lawhern has done rigorous research trying to help us... please listen to his words. He has done this work because he knows the damage/deaths caused by ignoring our pleas. I have specialists who will document that I am not one who has any “addiction” issues, just one dealt a difficult hand.
Sincerely, Dr. Karan Smith, MBA, MS, PhD

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Karan B. Smith, Ph. D.

From: Kathy Spain
To: NCIPCBSC (CDC)
Subject: CDC Opioid Prescribing revision
Date: Thursday, July 22, 2021 6:01:01 PM

To Whom it concerns,
The complete destruction of pain management has nearly taken my life.
I am struggling in this moment with extreme pain. I cannot write much as I am exhausted from lack of sleep & pain.
The CDC guidelines have been weaponized to created cash flow for those who have conflicts of interest. They have infiltrated all pain care. There is nowhere to go to get medical treatment of pain that is balanced, fair or safe.
I am only allowed a child's dose of pain medication despite having 4 different very painful medical conditions.
Please do the right thing & recind the 2016 Guidlines lives depend on it. I deserve to be treated humanely. I deserve a life & should not have to plead with government agencies for pain medicine for the serious medical diseases I have.
Sincerely KSPA

From: Tullia, Kirsten
To: NCIPCBSC (CDC)
Subject: AdvaMed Comments on BSC, NCIPC Meeting and Draft Recommendations
Date: Friday, July 23, 2021 2:00:44 PM
Attachments: image001.png
image002.png
image003.png
image004.png
2021-07-20 BSC-NCIPC Letter FINAL.pdf
Enclosure AdvaMed CDC pain mgmt final comments 6-16-2020.pdf

Good afternoon,

Please find attached AdvaMed's comments on the BSC, NCIPC Opioid Workgroup meeting and draft report with recommendations for updates to the CDC's 2016 Guideline. AdvaMed appreciates the opportunity to provide these comments and, along with our members, looks forward to continuing to work with the CDC and BSC, NCIPC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nation-wide opioid crisis. Please feel free to contact me should you have any questions.

Yours,
Kirsten Tullia

Kirsten Tullia
Vice President, Payment and Healthcare Delivery Policy
Advanced Medical Technology Association | **AdvaMed**
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AdvaMed
Advanced Medical Technology Association

June 16, 2020

Via Electronic Mail Only
Robert R. Redfield, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Mailstop S106-9
Atlanta, GA 30329

Re: Management of Acute and Chronic Pain: Request for Comment (Docket No. CDC-2020-0029)

Dear Dr. Redfield:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments for consideration by the Centers for Disease Control and Prevention (CDC). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat, manage, and monitor pain.

AdvaMed thanks the CDC for soliciting comments concerning perspectives on pain experiences and pain management for patients with acute and chronic pain. Though the comment solicitation sought feedback from patients, their families/caregivers, and health care providers, AdvaMed thought it was imperative for the medical device industry to also weigh in on this important issue. Medical devices are often overlooked in policy discussions regarding alternatives to opioids. For instance, the CDC Guideline for Prescribing Opioids for Chronic Pain (March 2016) refers to, and encourages use of alternatives to opioids, but provides limited direction on appropriate options for patients or providers. When referencing non-pharmacological treatments, the examples given are exercise therapy and cognitive behavioral therapy. Medical devices can and must be part of the non-opioid alternative conversation.

The opioid epidemic continues to take a tremendous toll on our country and its citizens. Given the link between opioid abuse and chronic and acute pain, significant consideration should be given to advancing care pathways that identify, address, and alleviate these types of pain, including procedures that may reduce the level of pain experienced by patients (i.e., minimally invasive procedures) and other evidence-based device interventions that can directly target and minimize acute and chronic pain, including invasive and non-invasive modalities such as spinal cord stimulators and other types of neuromodulation systems, barrier films, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, cryoneurolysis, vertebral augmentation, electromagnetic energy, digital therapeutics, ultrasound guided regional anesthesia, and portable continuous pain relief systems.

The FDA has approved/cleared more than 200 medical device alternatives to opioids that help treat various types of pain. Despite this, the CDC’s 2016 Guidance and the April 17th Request for Comment, fail to acknowledge the role of medical devices, which are used for both acute and chronic pain management and, in some instances, are proven to reduce opioid dependence. Many of these medical devices are also considered to be reasonable and necessary and are covered by Medicare and other insurance plans.

AdvaMed is hopeful the CDC will begin to change this dynamic, and that it will do so in such a way that other federal agencies and departments take notice to align their guidelines and public communication efforts. AdvaMed encourages the CDC to be explicit in referencing the use of medical devices in future guidelines—including examples of the device types that can be used. This level of information will alert providers and patients to the presence of these medical device alternatives which may be considered as first-line alternatives to opioid use. We believe the CDC's 2016 Guideline should also be updated to instruct physicians to advise patients of the medical device alternatives to opioids available to manage pain to better enable patients and physicians to make collaborative, fully informed decisions. We also encourage the agency to provide similar guidance for managing patients with acute pain.

AdvaMed and its members are dedicated to doing our part to assist in alleviating the opioid epidemic. We encourage the CDC to partner and engage with other agencies such as the NIH, Veterans Administration, and Department of Defense to create a more comprehensive approach to addressing this crisis. We further encourage the CDC to continue to solicit input from interested stakeholders— including medical device manufacturers. Members of the medical device industry have devoted countless resources and research into the development of devices which address the needs of patients with acute and chronic pain while reducing and possibly alleviating the need for opioids. The policies underlying the consideration and use of these technologies should be evaluated in a way which makes their use a viable option for patients who are managing pain. We would like to address the following issues in our comments:

- Policies that may disincentivize use of therapies that manage chronic and acute pain and that minimize opioid abuse and misuse
- Other Options

<u>Policies that may disincentivize use of therapies that manage chronic and acute pain and that minimize opioid abuse and misuse</u>

AdvaMed members manufacture a variety of device-based treatments that can be used in lieu of opioids. These devices effectively manage both chronic and acute pain and may also be used to address the management of opioid addiction. The manufacturers of many of these products have developed evidence which shows a correlation between use of the devices and a reduction in the need to use and/or prescribe opioids. Despite this, many of these devices face deployment, reimbursement, and insurance coverage challenges.

Clinicians utilize a variety of devices during surgical procedures, post-surgically, and in post-acute care settings to alleviate or reduce pain symptoms. These devices which include drug-delivery devices that administer a non-systemic non-opioid analgesic directly to the site of a surgical incision, block nerve pain at the incision site, or allow minimally invasive and/or percutaneous treatment, effectively address acute and chronic pain and minimize post-procedure pain are frequently not a viable option for providers due to lack of awareness and limited coverage. We ask the CDC to implement guidelines which promote and support the use of medical devices and the ancillary procedures that facilitate their use, where such technologies have evidence of opioid reduction and/or pain alleviation.

Barriers which impede the ability of physicians and patients to gain access to the acute and chronic pain treatments that best suit their needs must be alleviated. Existing payment policies disincentivize provider use of potentially highly effective device-based pain management alternatives as a part of acute and chronic pain management strategies— making it far easier to write a prescription for potentially addictive opioids that will be separately paid. AdvaMed recommends that the CDC partner with other agencies to resolve these payment disparities and to better allow providers who choose to deploy opioid alternative technologies in the treatment of their acute and/or chronic pain patients, especially those at risk for developing opioid use disorder (OUD), to do so without being penalized. We also support the continued tracking and production of evidence-based information by manufacturers of devices which may reduce the prescription and use of potentially addictive opioids.

Problems related to the deployment of opioid alternative devices and the inability of patients to access these innovations at the appropriate time persist. These access concerns are the result of various payment and insurance coverage issues, including delays (such as prior authorization or "step-therapy") which may require patients to undergo and/or fail drug therapy for chronic pain relief (posing possible addiction risk) prior to being able to utilize a non-opioid device-based intervention. In some instances, patients are required to undergo additional medical evaluation prior to receiving device-based non-opioid interventions for chronic pain. These additional requirements pose barriers to access and treatment delays for beneficiaries, especially those in areas with limited or no qualified providers to conduct the evaluation, prolonging their exposure to opioids and increasing their risk of addiction. The CDC should advocate for the elimination of policies that interfere with access and should promote the use of policies, such as telehealth evaluations, to minimize patient risks associated with opioid use.

The pain management issues that are the root cause of many opioid dependency issues are prevalent across patient populations—including geriatric populations. It is imperative that the CDC be proactive in working with other organizations and the stakeholder community to develop recommendations to address pain concerns across patient populations.

Other Recommendations

Materials distributed to patients should include all the available options for pain management treatment—including device based and non-systemic opioid device delivery treatments as well as recommendations regarding the referral of patients to interventional pain specialists.

Provider education and sensitivity to the risk of opioid dependence is also critical. Health care providers must be better informed of the treatment impacts that can be gained by using non-opioid devices. This will require more education regarding the range of devices and the appropriate time for their incorporation into patient treatment plans. It will also require provider education regarding the range of available device-based treatments. This education should extend to the full range of providers who are treating patients with acute and chronic pain, especially those at risk for developing an opioid dependency, including: primary care physicians other physicians, nurses, and specialists who may be involved in making recommendations to patients regarding alternative means for treating their pain. This list of providers could include neurologists, orthopods, physical medicine, emergency medicine, anesthesiologists, physical therapists, wound nurses, and others.

A variety of health care providers encounter and make care decisions for patients who could potentially benefit from an opioid alternative device. Therefore, it is critical that education regarding the epidemic, appropriate screening, and treatment options (device, drug, combinations, and restorative therapy alternatives) be made known to all care providers. Additionally, it is important for care providers to have information regarding integrating these devices into the treatment process. AdvaMed agrees with findings that were included in the 2019 Pain Management Best Practices Inter-Agency Taskforce Report (https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf) that this could be addressed through the integration of additional information into the medical school curriculum, including pain training in CME courses, and the dissemination and adoption of protocols, clinical practice guidelines, and information across sites of care. We also believe that CDC could engage with public health entities and agencies, HHS, and physician and nursing specialty societies to collaboratively develop strategies for addressing training and education shortfalls and could incorporate this information into its guidelines.

While AdvaMed supports the use of pain specialists to assist patients in managing pain and in minimizing and avoiding opioid use, we strongly encourage the CDC to promote patient access to care by other highly trained specialists who can effectively prescribe and manage pain symptoms. We also support CDC devoting research and resources to work in the interventional pain space to allow patients with a history of chronic pain, lasting 6 months or more, to effectively access non-opioid therapies.

Patients who experience chronic pain may not seek out the care of pain physicians but instead may seek care from their primary care physician or from a physician specializing in treating the area of the body in which they are experiencing the chronic pain (e.g., a neurologist). Therefore, it is important that the full spectrum of health care providers be updated regarding the latest technologies to use in treating chronic pain. Additionally, in the context of acute pain, it is equally as important to consider the risks and outcome impacts associated with the type of surgical technique that is utilized in treating a patient's medical condition. For instance, patients may experience less post-surgical pain if treated with minimally invasive procedures when appropriate. The lower pain outcomes resulting from use of these less invasive procedures could alleviate the need to prescribe opioids post-surgery.

Conclusion

AdvaMed appreciates the opportunity to provide these comments and urges the CDC to strongly consider them as the agency formulates additional policy and guidance in this area. We, along with our members, look forward to continuing to work with the CDC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nation-wide opioid crisis. Please feel free to contact me should you have any questions at 202-434-7218 or ddorsey@advamed.org.

Sincerely,

DeChane Dorsey, Esq.
Vice President
Payment and Healthcare Delivery Policy

AdvaMed
Advanced Medical Technology Association

July 23, 2021

Via Electronic Mail
Dr. Amy Bonomi and Dr. Chinazo Cunningham
NCIPC
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Atlanta, GA 30341

Re: Comments on the July 16, 2021 Meeting of the Board of Scientific Counselors NCIPC Opioid Workgroup

Dear Drs. Bonomi and Cunningham,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments for consideration by the Centers for Disease Control and Prevention (CDC) Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat, manage, and monitor pain.

AdvaMed thanks the BSC, NCIPC for hosting its recent meeting and updating stakeholders on the efforts and recommendations of the Opioid Workgroup. We also appreciate the BSC, NCIPC for soliciting post-meeting comments regarding the information communicated during the July 16th meeting.

As discussed during the BSC, NCIPC meeting, the opioid epidemic continues to take a tremendous toll on our country and its citizens. Given the link between opioid abuse and chronic and acute pain, significant consideration should be given to advancing the full range of care pathways that identify, address, and alleviate these types of pain, including procedures that may reduce the level of pain experienced by patients and therefore post-surgical opioid prescription required (i.e., minimally invasive procedures) and other evidence-based device interventions that can directly target and minimize acute and chronic pain. These include invasive and non-invasive modalities such as spinal cord stimulators and other types of neuromodulation systems, barrier films, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, cryoneurolysis, vertebral augmentation, electromagnetic energy, digital therapeutics, ultrasound guided regional anesthesia, and portable continuous pain relief systems.

Medical devices can and must be part of the non-opioid alternative conversation. The Food and Drug Administration (FDA) has approved/cleared more than 200 medical device alternatives to opioids that help treat or manage various types of pain. Despite this, the CDC's current guidelines fail to acknowledge the role of medical devices, which are used for both acute and chronic pain management and, in some instances, are proven to reduce opioid dependence. Many of these medical devices are also considered to be reasonable and necessary and are covered by Medicare and other insurance plans.

As the BSC, NCIPC moves forward with its Opioid Workgroup efforts and providing final recommendations to the CDC for revisions of the 2016 guidance and policy recommendations for the treatment of chronic and acute pain, we are hopeful that the benefits and role of medical devices as a treatment alternative to opioids are thoroughly considered and incorporated into new guidelines and policies on pain management.

Please find attached to these comments a letter sent to former CDC Director Redfield in June of 2020 outlining AdvaMed's recommendations for updates to the 2016 guidance and other policies that may disincentivize the use of therapies that manage chronic and acute pain and minimize opioid use and abuse.

AdvaMed appreciates the opportunity to provide these comments and urges the BSC, NCIPC to strongly consider them as the group finalizes its recommendations for additional policy and guidance in this area. We, along with our members, look forward to continuing to work with the CDC and the BSC, NCIPC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nation-wide opioid crisis. Please feel free to contact Kirsten Tullia should you have any questions at (202)257-5659 or ktullia@advamed.org.

Sincerely,

Andrew C. Fish
Executive Director, AdvaMed Center for Digital Health
Head, Sector Initiatives
Acting Head, Payment and Health Care Delivery Policy Department

Enclosure – AdvaMed CDC pain mgmt final comments 6-16-2020.pdf

From: Kimberly Weber, ACPA Rocky River Chapter Facilitator
To: NCIPCBSC (CDC)
Subject: July 16, 2021 online guideline discussion
Date: Friday, July 23, 2021 5:15:58 PM

Dear CDC,

Thank you for the

opportunity to have my story and

my point of view heard. I found

the July 16, 2021, on-line discussio

n

interesti

ng. I

understa

nd that
my
words
are not

going to

change

the

updated

guidelines.

I have lived with chronic pain for most of my life. I have had lower lumbar pain most of my forty-two years. Only to be diagnosed in my early thirties with Spina Bifida Occulta. I was four when I started treatment for Chronic Migraines, that persists to this day. I was twenty-three when it suspected I may have Fibromyalgia and confirmed at thirty-eight. I was diagnosed at thirty-eight with Sero-negative Rheumatoid Arthritis.

I have experienced a plethora of treatments. From epidurals, NSAIDs, opioids, steroids, surgeries, acupuncture, and physical therapy. I became disabled when these options either failed, allergies to medications, or the insurance would not cover the treatments that did somewhat help. I get Botox injections for migraines quarterly, a biologic drug weekly, and ten other scripts daily. I have made the decision to go more natural because the medications have side effects that you have to take more medication for and so on and so forth. I feel that the system is letting me down. Over the last forty years, I have had doctors ignore my symptoms because of my age, laugh at me, insult me by calling me fat, and even state “we should take you out back and shot you like a lame horse”.

I have found some amazing doctors, few and far between, that if their hands weren’t ties by insurance companies, I may have more goods days than bad. My family, friends, and support groups have kept me going on even through the darkest days of grief of the me that was.

I am not only a patient but in my former life I was a certified trained Pharmacy Technician. I have watched people go through a wide assortment of Chronic pain, cancers, mental illness, and addictions. There are differences in what those groups look like

1. Patients need to be listened to.
2. If these are “guidelines” why does it seem like they are treated like law by most doctors?

3. Why don’t we consider other countries examples?
4. We are allowing people to suffer needlessly because of the addiction of others
5. Doctors should look at the whole person including physical, emotional, lifestyle
6. Health care and disability cost would not be such an absorbent amount if we had health care teams versus scattered systems.
7. The benefit of medication varies per person and needs to be looked at that way. Humans are not one size fits all

I personally am turning to a more natural lifestyle because my body rejects medications and the chemicals we ingest in our food. This makes me question the interaction between chemicals in our food and chemicals in our medications.

Sincerely,
Kimberly Weber
17975 Boone Road
Columbia Station, OH 44028
440-668-5420
chronicpainaware@gmail.com
minedsk78@yahoo.com

From: karaokec
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:14:25 PM

My name is Robert Troutman and because of this opid war my pain mgmt Drs have been forced to cut my meds ,I'm 62 years old.work full time. Until I retire and I was taking a 7.5 mcg patch of Fentanyl and it's been cut. I was useing a 200 mcg sucker made of Fentanyl when I would toss and turn at night and wake up I would use the sucker that would last a week to take pain away on my L4 L5 rage cage failed surgery and be able to go back to sleep..now that's taken away , taken a sleeping pill is not an option ,I don't sleep well at all . Now I'm cut to a 5.0 mcg patch and I have a feeling they want to cut that as well.,my surgery was in 1995 or so and I've been using this medicine for over 20 years and feel you need to help. More pain people between the CDC ,the FDA and the DEA. Pain mgmt patients have been hurt .. we feel pain... Sure I get it there we're some bad Dr.s and drug reps... My drs should.not be afraid to treat my pain and I feel it daily that pain and weather adds to it .
It's cruel
Robert Troutman
3269 Twinleaf st
Commerce Township Mi. 48382
248-459-3412

Sent from my Verizon, Samsung Galaxy smartphone

From: Karen C.
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:55:17 PM

Dear CDC,

There were some typo and grammatical errors in my previous email. Please disregard it for the following:

I am writing regarding the 2021 Updated Draft CDC Guideline for Prescribing Opioids. In considering these changes, it seems that only the risks and not the benefits of prescribing opioid pain medication have been used. Not only will these changes place millions of lives at risk for those suffering severe pain, it threatens the medical practice of millions of physicians seeking to provide pain relief to their patients. These changes appear short sighted and do not take into consideration the patient, the physician, and the skyrocketing cost of health care due to mismanagement.

The panacea regarding opioid pain medication endangers the health, wellbeing, and lives of millions of Americans suffering with chronic severe pain. The suicide rate of persons suffering with severe chronic pain is one of the highest suicide rates in the United States. While I agree with some of the tenants of the proposed changes because they reflect ethical medical care, some of the proposals originate from individuals who have never experienced severe chronic pain and/or result from focusing only on individuals that abuse opioids for reasons other than relief from severe pain. I will comment on some of the proposals, below:

Recommendation #3) Millions of Americans that are permanently disabled suffer severe debilitating pain, whether from acute injury or chronic injury. Those American citizens that have lost the ability to function normally due to chronic disease processes, automobile accidents, and military service may commit suicide or seek illegal street drugs and/or abuse alcohol for pain relief without the benefit of prescribed opioid pain medication. Requiring immediate relief instead of extended release opioids is illogical for many patients. People will need to be prescribed higher quantities of opioids, thereby limiting the availability of medication. In addition, disabled individuals will need to take medication more frequently, requiring more health care provider assistance and subsequently increasing health care costs. Also, people are at increased risk for overdose due to the increased frequency of taking opioid medication.

Recommendation #5) 50 milligrams (mg) equivalent morphine each day is not sufficient to control severe pain. Consider the man who is a burn victim, injured in a car accident, or recovering from surgery. 50 mg/day of morphine is not a clinically effective dose of pain medication. This low dose of pain medication for acute or chronic pain frequently escalates comorbidities, including dangerous risks to cardiac and respiratory disease.

Recommendation #6) This premise of this statement is wrong. Long term opioid use does not often begin with acute pain. Many people on long term opioid medication require it due to progressive disease processes. As the large "baby boomer" population suffers age related disease, the cause of pain is chronic, not acute. Also, prescribing opioids for one to three days is not medically efficacious to control pain for acute pain in post-operative patients or other acute injuries, let alone less than that amount of time. Prescribing pain medication for one to three days will likely result in further injury to the patient, since pain is the body's signal that something is wrong. If we don't feel pain when we put our hands on a hot burner on a stove, what would be the result? The normal time frame for pain medication prescription for post knee replacement, heart surgery, and cancer patients requires weeks or months of pain management, including the remainder of the suffering patient's life.

Recommendation 7) Re-evaluating pain within one to four weeks of originating pain treatment is inappropriate for patients with severe chronic pain. By its very nature, chronic pain does not go away. It is permanent and usually disabling. Requiring re-evaluation of pain treatment within as little as one week or four weeks is not realistic for patients suffering with severe chronic pain, as well as for the physician. In addition, the costs for office visits, transportation, and time missed from work by family members and caregivers will escalate with such a limitation.

Recommendation 8) Opioid prescribing physicians do not usually permit concurrent use of benzodiazepines and opioids. In any event, this decision should be left up to the physician, not the government. The prescribing physician normally takes into consideration the patient's medical history and prescribed medications. Requiring naloxone places surgeons, pain management physicians, and other physicians in the role of psychiatrist. This is outside the scope of practice for non-psychiatric physicians.

Recommendation 9) Requiring physicians to check the PDMP for every prescription is beyond a reasonable time frame for most practicing physicians. It is reasonable to require this at the onset of prescribing opioids and perhaps periodically thereafter, depending on the length and nature of treatment.

Thank you for taking the time to thoughtfully read my comments. Many of the recommendations are already in practice, such as ongoing drug monitoring, patient medical and prescribing histories and concurrent medication prescribing. However, many of these recommendations will cause catastrophic results to patients with severe acute and chronic pain. Patients with incurable pain, ranging from military veterans to those with chronic illness and/or permanent injuries will either turn to illegal street drugs or commit suicide. Physicians already have their hands tied by excessively restrictive regulations and many have already left pain treatment medical practice for other medical practices and other professions. The monetary cost of such recommendations will be disastrous as well. Our healthcare system is already at a critical breaking point due to poor management. As a healthcare provider, I urge you to revise these recommendations with consideration to the outcomes of such recommendations.

Thank you,
Karen C.

From: KB Smiles
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:49:09 PM

This will continue to harm so many. I had surgery last year where Beth Israel in Massachusetts limited opiates during surgery. It was so bad I woke up during the surgery. People with pain aren't the enemy. Please hear us. People are dying and suffering. The epidemic isn't about pain patience and it never was because the prescribing rates have gone down (to the point of torture) but the ODs have still continued to soar. Please you don't want to find out when it's too late that your doctor won't treat your pain post op or after a severe injury. Elicit homemade drugs that are made here or smuggled in is the problem.

From: Laura Bistak
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:08:27 PM

As someone who lives in pain 24/7/365 and has for the last 35 almost 36 years it is disheartening to know that not much will change. I have a list of illnesses a mile long with most of them causing pain. Due to the "opioid crisis" I have been unable to get relief for most of my pain. I have become housebound except for doctor appointments merely because doctors are scared. This means those living with chronic pain suffer. All we are offered is psychological counseling and physical therapy. To someone who cannot even get out of bed without extreme pain, it is impossible. I have been continually offered a program that would require me to be out of bed, sitting up for hours a day for a month then a week of intense PT. No deviations. Does this really sound reasonable for someone who cannot even sit?

The point is, that I as many others would rather be reliant on pain meds, just as people are on psych, diabetes, blood pressure meds, then suffer as much as we are now. We know that the pain we feel cannot be understood unless it is experienced for themselves. All those in chronic pain want is a chance to relieve some of that pain and to have a decent way of life like everyone else.

By not allowing pain meds to those suffering from chronic pain, the government is relegating us to our homes and nursing homes, unable to care for ourselves, to be productive members of society and a drain on our loved ones if they even stick around. Government has made us second class citizens and has created a culture where we are not believed by loved ones, doctors, hospitals, everyone. We are looked down upon and eventually ignored. We are not our pain, we have much to contribute to the world, except we are not allowed relief from the thing standing in our way. Addicts will get drugs any way they can, those that really need them cannot get them due to fear and misunderstanding.

This has got to stop before too many in my situation just give up on living. That would truly be a shame, a shame on the government for shutting its eyes to the people that need them. Make the right choice for once and stop closing your eyes to the needs of the country, not your bank account.

From: Lana Bounds
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:07:39 PM

Please reconsider your guidelines regarding the prescribing opioids for pain management .... I was on various pain meds for a genetic nerve condition....I was able to live a productive life until my meds have been denied due to the guidelines... please give us back our meds that gave us hope ... an a life that we can tolerate... thank you for your time... Lana Bounds

From: Lori Bratton
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:57:37 PM

I am writing to let you know that there NEEDS to be improvement in the guidelines.
I know from experience that even though they are considered "guidelines" the physicians take them as laws.

If I have been on a higher =90 MME dose and it works and makes me a productive member of society then why should my medication be lowered to an "acceptable" level determined by someone who is not my physician?

Since to 2016 guidelines my life has changed dramatically, and not for the best. I currently can not work, I am NOT a productive member of society. I can barely get out of bed on most days. My condition will not get any better and will only deterioate to where I will suffer more pain. I am not able to taper off my medication like suggested.

I am in fear of not getting my medication at every pain clinic appointment even though I follow all of the rules of my pain contact. I never test positive for any drug that is not prescribed to me. I never let another doctor prescribe pain medication nor do I ever take more then prescribed. So why do I have to live in fear and high anxiety at every pain clinic appointment?

If that's not enough then I have to worry if the pharmacy will fill my medication. I have had nothing but problems getting my medication filled at one of the "big chain" pharmacies. If my doctor prescribes me medication, then why should a pharmacist who has no clue about me, decide not to fill my prescription for my own good?

This is just a small fraction of what pain patients have to go through since the 2016 guidelines came out.

I am asking you, no I am begging you to consider making changes in this draft that would improve my pain care.

Please recognize current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

Please consider taking these views into consideration.

Thank you for taking the time to read this. The whole pain community is waiting to see what actions will come from these new guidelines. I pray that it helps to make a difference in our lives for the better.

Sincerely,
Lori Bratton
dragonflz4wv@gmail.com
307.622.8454

From: Linda Brozik
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:55:52 PM

Hi, I’m a chronic pain patient. For 25years I’v had to deal with debilitating chronic pain. For the most part my health care providers have helped me so I can have some sort of quality of life by using a combination of opioid medication and other therapies. But as of 2016 my life took a turn for the worse. My Dr. decided to take away the pain medication I was on. She got me down to your guidelines of MME of 90mlg. And agreed to that. But it has cut my quality of life in half. I realize you want safety first, but what’s safe about crushing pain that’s 24/7. It causes shaking, rapid heartbeat, depression, stomach problems from not eating right. It’s hard to eat right when pain is gripping at you to the point you are throwing up. Isolation has become the norm because I can’t walk as well anymore. And friends have abandoned me because of my condition and pain. All this is very scary and it’s an awful way to live. YOUR NEW GUIDELINES are not any different than the 2016 GUIDELINES!!! Not that I can see!!! I thought you would perhaps put something in there about circumstances that each patient has. And that at times it requires the Dr. to go above the MME OF 50mg. Or even 90mg. This is cruel and inhumane treatment of people with chronic debilitating pain. There has to be exceptions!! I thought Drs. took an oath to be an advocate of their patients. To protect and care for us. Anyway, it seems we’re being treated like criminals and tossed aside . PLEASE try to do something to protect our lives, so we can live the best life we can. Thanks, LINDA Brozik

Sent from my iPad

From: lgbryant@glasgow-ky.com
To: NCIPCBSC (CDC)
Subject: CDC Opioid Prescribing Guidelines Revision
Date: Thursday, July 22, 2021 6:21:48 AM

Dear CDC,

I am writing because I have been hurt/affected by the 90 MME opioid limits! I was taking 60 MME of opioids day. Then in 2017 I had a life changing event overnight that left me paralyzed on the entire left side of my body! I eventually gained back most of my motor skills after long and intensive therapy. While I was in a physical rehabilitation center my daily opioid intake was increased to 90 MME. Yet and still this did not provide significant pain relief to allow me a decent quality of life. When I returned to my pain management clinic They chose to reject the changes in my opioid medication citing the CDC Opioid Prescribing Guidelines and my age as reasons. They returned me to the same ineffective dose that I was on prior to my life changing event. Since then I have been to three different pain management clinics that because of the guidelines want to start me back on the lowest dose despite knowing that a higher dose is not effective. Then I must gradually get my dose increased over a year's Tim's trying to not be pushy because of fear of being seen as a drug seeker. I was discharged from one clinic because my UDS showed positive for substances I did not take. Well, I actually wasn't discharged, I was switched to their Suboxone program which nearly ruined my life. The prescribing physician even admitted that their moving me was a hasty move as I had never presented a problem. He admitted that I would need lifelong treatment with opioids. With the Suboxone on my record it took a lot of hard, work, time, suffering, and rejection to get back into pain management! I have yet again been started at a low dose and after a year next month am finally back to the ineffective dose I was on before my event! I had a severe case of Rhabdomyolysis which caused severe nerve damage to my entire left side of my body! My case was so severe that it caused a heart attack, me to go into V-Tach, my kidneys to shut down placing me on dialysis for a short while, the loss of my ability to stand, walk, use my left arm, use either hand, or even turn over in bed. It triggered two rare autoimmune diseases one that affects my nerves and one that effects my muscles I have 6 autoimmune diseases now, most of which cause pain and some that are progressive that will lead me to eventually be in a wheelchair. Most importantly I have been left in severe pain! The pain to my left leg and foot feels as if I were walking on lava rocks and hit a soft spot causing my leg to sink down into molten lava with the addition of random rubber band thumps in rapid succession. It has been nearly 4 years of hell being forced to suffer in pain on a sub therapeutic regimen because of opioid prescribing guidelines that have been put into place and the war on opioids! All I'm asking for is to have the right to have at least a decent quality of life with the help of an effective dose of opioids without essentially being told I must instead suffer because of the guidelines. Is having a decent quality of life like the regular able body individuals asking too much? Is it asking too much to be able to participate in activities and do things a normal 40 year old is able to do?

Sincerely,

Larissa Bryant

From: Leslie Bythewood
To: NCIPCBSC (CDC)
Subject: FDA should be writing the opioid guidelines, not the CDC
Date: Friday, July 16, 2021 10:02:13 AM

Not only are the CDC 2016 opioid guidelines a myopic and false abomination, but they have caused much suffering and countless suicides in the United States all because doctors have chosen to misinterpret the guidelines as gospel, resulting in forced tapering, undertreatment of patients, or patient abandonment. It's no secret opioids are extremely effective at controlling severe pain without causing any adverse side effects. We must stop conflating compliant chronic pain patients, who take their medication exactly as prescribed, with street drug abusers, who take illicit drugs and end up overdosing and dying. We do NOT have an opioid crisis in this country; we have a street drug overdose crisis in this country, and we must stop confusing the two. In the meantime, many intractable pain patients all across the nation are being denied their pain medications needed to control their severe pain, rendering the patients unable to carry out their daily functions and crippling them. Studies have shown, over and over again, that uncontrolled pain leads to irreversible dementia, high blood pressure, insomnia and heart problems. Chronic pain patients deserve to be cared for by their doctors, and that means their severe pain must be acknowledged and recognized and then treated with pain medications. There is no one size fits all, because every patient metabolizes pain medications differently, and because weight plays a role, as do many other factors. We must stop coming up with arbitrary, nonsensical MME limits, because again, there's no one size fits all. Every patient is different, and the doctor should know that, once the pain is brought under control by the specific dose prescribed, that's the right dose for that patient, not for other patients. We must also stop fooling ourselves into thinking only cancer patients, palliative care patients, end-of-life patients or patients undergoing surgery are the only candidates for pain medication; they are not. There are many intractable pain patients who don't have cancer but who suffer from debilitating incurable diseases that require round-the-clock pain medication in order to stop their suffering and live decent lives. Intractable pain patients typically require both an immediate release AND a long-acting pain medication in order to control their severe pain. The immediate release pain medication stops the severe pain quickly, while the long-acting pain medication provides continuous pain control throughout the day and night, as required. I've been on IR and ER pain medications safely since 2007, and yet I have no history of drug abuse, drug overdose or drug addiction. Moreover, I have experienced zero adverse side effects from my pain medications. What those medications do is stop the pain quickly and effectively without causing any mental confusion, euphoria, intoxication, or constipation. By contrast, there are so many other classes of medications that claim to control the pain, but they don't (e.g., Gabapentin, Sertraline, Klonidine), and then, on top of the painful condition the patient started out with, those medications all too often cause additional serious health problems, including heart problems, intracranial pressure, headaches, swelling of the extremities, sleepiness, dizziness and lethargy, to the point where the patient can't even get behind the wheel of a car safely, let alone work out or carry out their daily activities. We must stop hoodwinking the public into believing opioids are bad. They are not bad. They are a godsend, they are lifesavers, and the vast majority of patients who take them never become addicted or overdose, provided they take their medication as prescribed by the doctor. That's the clear message we need to be sending to patients and to the general public. We also need to send the message that less than one percent of the population carries the addiction gene. Opioids are perfectly safe and effective at controlling severe pain, because that's what they're designed to do. Last but hardly least, the CDC should not be writing any opioid guidelines; that's the job of the FDA.

From: Leslie Bythewood
To: NCIPCBSC (CDC)
Subject: RE: FDA should be writing the opioid guidelines, not the CDC
Date: Friday, July 16, 2021 1:39:12 PM

I've been listening to the comments coming out of today's meeting, and I'm just astounded at how little confidence some of the CDC members seem to have in clinicians' knowledge and decision making and in how responsible chronic pain patients are. Several members commented, rather disparagingly, about the need for abuse-deterrent formulations, when, in reality, no one ever asked whether those formulations are necessary and harmful. Abuse-deterrent formulations contain a lot of excipients that can be extremely harmful to patients, but it also implies patients are children who are going to abuse their medications, when, in reality, the vast majority of patients do not abuse their medications and take them as prescribed to control their pain. We must not lose sight of the big picture. All chronic pain patients want is safe and effective relief from debilitating, incapacitating and excruciating pain so they can carry out their daily activities and get on with their lives. And chronic pain patients who take high doses of pain medication tend to be extremely opioid tolerant, so Narcan really should be provided as an option to patients, not as a requirement, since those patients tend not to overdose at all. Again, it's all about trusting patients and not treating them as people with aberrant behaviors or as addicts. Chronic pain patients who've been on opioids long term tend not to be at risk at all. And I can't tell you how insulting and ridiculous it is for anyone to think nonopioid therapies are going to control a chronic pain patient's pain. Doctors know that; they're not stupid! Chronic pain patients have serious pain that deserves long-term opioid treatment. Period! No discussion! No amount of tai chi, or massage therapy or chiropratic or acupuncture or biofeedback therapy is ever going to replace the effectiveness of opioids when it comes to adequately controlling severe pain. Whom are you kidding? Most chronic pain patients require a COMBINATION of IR and ER opioids to control their pain. That's the way the body controls the pain. If you take one or the other opioid away, it's not going to treat the pain as effectively as it would if both are on board. Let's get serious, folks, and let's stop trying to pull the wool over educated patients' and doctors' eyes. Whether or not to prescribe opioids should be left up to the doctor and the patient. The CDC and the DOJ and DEA have no business interfering in the sacred relationship between the doctor and the patient. Again, we do NOT HAVE A PRESCRIPTION OPIOID CRISIS. WE HAVE A STREET DRUG ABUSE CRISIS!!!

From: "Leslie Bythewood"
To: "ncipcbsc@cdc.gov"
Cc:

Sent: Friday July 16 2021 10:01:09AM
Subject: FDA should be writing the opioid guidelines, not the CDC

Not only are the CDC 2016 opioid guidelines a myopic and false abomination, but they have caused much suffering and countless suicides in the United States all because doctors have chosen to misinterpret the guidelines as gospel, resulting in forced tapering, undertreatment of patients, or patient abandonment. It's no secret opioids are extremely effective at controlling severe pain without causing any adverse side effects. We must stop conflating compliant chronic pain patients, who take their medication exactly as prescribed, with street drug abusers, who take illicit drugs and end up overdosing and dying. We do NOT have an opioid crisis in this country; we have a street drug overdose crisis in this country, and we must stop confusing the two. In the meantime, many intractable pain patients all across the nation are being denied their pain medications needed to control their severe pain, rendering the patients unable to carry out their daily functions and crippling them. Studies have shown, over and over again, that uncontrolled pain leads to irreversible dementia, high blood pressure, insomnia and heart problems. Chronic pain patients deserve to be cared for by their doctors, and that means their severe pain must be acknowledged and recognized and then treated with pain medications. There is no one size fits all, because every patient metabolizes pain medications differently, and because weight plays a role, as do many other factors. We must stop coming up with arbitrary, nonsensical MME limits, because again, there's no one size fits all. Every patient is different, and the doctor should know that, once the pain is brought under control by the specific dose prescribed, that's the right dose for that patient, not for other patients. We must also stop fooling ourselves into thinking only cancer patients, palliative care patients, end-of-life patients or patients undergoing surgery are the only candidates for pain medication; they are not. There are many intractable pain patients who don't have cancer but who suffer from debilitating incurable diseases that require round-the-clock pain medication in order to stop their suffering and live decent lives. Intractable pain patients typically require both an immediate release AND a long-acting pain medication in order to control their severe pain. The immediate release pain medication stops the severe pain quickly, while the long-acting pain medication provides continuous pain control throughout the day and night, as required. I've been on IR and ER pain medications safely since 2007, and yet I have no history of drug abuse, drug overdose or drug addiction. Moreover, I have experienced zero adverse side effects from my pain medications. What those medications do is stop the pain quickly and effectively without causing any mental confusion, euphoria, intoxication, or constipation. By contrast, there are so many other classes of medications that claim to control the pain, but they don't (e.g., Gabapentin, Sertraline, Klonidine), and then, on top of the painful condition the patient started out with, those medications all too often cause additional serious health problems, including heart problems, intracranial pressure, headaches, swelling of the extremities, sleepiness, dizziness and lethargy, to the point where the patient can't even get behind the wheel of a car safely, let alone work out or carry out their daily activities. We must stop hoodwinking the public into believing opioids are bad. They are not bad. They are a godsend, they are lifesavers, and the vast majority of patients who take them never become addicted or overdose, provided they take their medication as prescribed by the doctor. That's the clear message we need to be sending to patients and to the general public. We also need to send the message that less than one percent of the population carries the addiction gene. Opioids are perfectly safe and effective at controlling severe pain, because that's what they're designed to do. Last but hardly least, the CDC should not be writing any opioid guidelines; that's the job of the FDA.

From: Leslie Bythewood
To: NCIPCBSC (CDC)
Subject: RE: FDA should be writing the opioid guidelines, not the CDC
Date: Friday, July 16, 2021 2:05:28 PM

What are CDC members and BSC members afraid of? The goal has never changed: it should be about controlling the chronic pain patient's pain. That should be the overarching goal of any clinician/provider/primary care physician/pain management specialist. It is the clinician's responsibility, duty, obligation, after all, to control the chronic pain patient's pain safely and effectively, and that can be done with opioids, provided the doctor screens the patient beforehand to make sure they have no history of drug abuse, overdose or addiction. It's that simple.

The CDC needs to throw out the CDC 2016 guidelines and leave it up to the FDA. But quite frankly, doctors were doing just fine until the CDC published those guidelines. And now, chronic pain patients are suffering because of the guidelines. I honestly don't think you're being honest with yourselves as far as what you are trying to accomplish with your guidelines. Please let the FDA handle it. The CDC is not qualified.

From: "Leslie Bythewood"
To: "ncipcbsc@cdc.gov"
Cc:
Sent: Friday July 16 2021 1:39:01PM
Subject: RE: FDA should be writing the opioid guidelines, not the CDC

I've been listening to the comments coming out of today's meeting, and I'm just astounded at how little confidence some of the CDC members seem to have in clinicians' knowledge and decision making and in how responsible chronic pain patients are. Several members commented, rather disparagingly, about the need for abuse-deterrent formulations, when, in reality, no one ever asked whether those formulations are necessary and harmful. Abuse-deterrent formulations contain a lot of excipients that can be extremely harmful to patients, but it also implies patients are children who are going to abuse their medications, when, in reality, the vast majority of patients do not abuse their medications and take them as prescribed to control their pain. We must not lose sight of the big picture. All chronic pain patients want is safe and effective relief from debilitating, incapacitating and excruciating pain so they can carry out their daily activities and get on with their lives. And chronic pain patients who take high doses of pain medication tend to be extremely opioid tolerant, so Narcan really should be provided as an option to patients, not as a requirement, since those patients tend not to overdose at all. Again, it's all about trusting patients and not treating them as people with aberrant behaviors or as addicts. Chronic pain patients who've been on opioids long term tend not to be at risk at all. And I can't tell you how insulting and ridiculous it is for anyone to think nonopioid therapies are going to control a chronic pain patient's pain. Doctors know that; they're not stupid! Chronic pain patients have serious pain that deserves long-term opioid treatment. Period! No discussion! No amount of tai chi, or massage therapy or chiropratic or acupuncture or biofeedback therapy is ever going to replace the effectiveness of opioids when it comes to adequately controlling severe pain. Whom are you kidding? Most chronic pain patients require a COMBINATION of IR and ER opioids to control their pain. That's the way the body controls the pain. If you take one or the other opioid away, it's not going to treat the pain as effectively as it would if both are on board. Let's get serious, folks, and let's stop trying to pull the wool over educated patients' and doctors' eyes. Whether or not to prescribe opioids should be left up to the doctor and the patient.

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From: Laura Camp
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:13:52 PM

My name is Laura Camp . I'm a very chronic pain sufferer. I'm in pain 24/7 . I have been forced to suffer in silence since 2016, when my dr.passed away. He was the only one that didn't treat me like a criminal searching for pills. I was not . Nor was I ever a pill JUNKIE, an addict. July 16, 2004 I had a freaking accident and a fireplace mantel fell on my neck backof my neck across my shoulders. I thought I was ok but it took 9 months I felt like someone was ripping my arms off, actually I had forgot the accident. I went 3 times to ER. For them to finally give me an xray, the dr. Was amazed I was able to walk , had to get MRI and showed that It was shattered bone fragments started to sever my nerves, the nerve damage was done . I feel like bugs are crawling on my skin some times ,its painful. I had to get emergency surgery front bone fusion with hardware....2005 ....with in 6 months it all came back and its been that way since...in 2009 broke again another bone fusion from back, I was down for over a year....the pain still the same .dr.had me on 26 pills a day, 5 or 6 different kinds, neurontin, elavil, zanaflex, naproxen, vicoibupren and countless others....years of therapy, alot of shots on my neck....the antidepressants was awful I wanted to die....so I weaned myself of to just 4 pain meds a day, muscle relaxants, and gave me xanax to sleep, I researched smoking some marijuana to help with the depression I felt I was hurting so bad all the ,it helped me be happy again, I wasn't laying in bed feeling so sorry for my self, I had no friends to come over, I was always hurting so much they stopped coming by. Years of this. I went to this doctor from 2005 to 2012 Not one time did they checked my blood for anything DID THEY ASK FOR URINE TO CHECK MY LIVER FOR ALL THE MEDS HE HSD ME ON.....THEN ONE DAY I HAVE TO PEE AND ITS THE LAW IF THEY FIND DRUGS I COULD NOT GET MEDS ANYMORE ..OF COURSE I HAD SMOKE SOME MARIJUANA LIKE A WEEK BEFORE THAT. I WAS TOLD I HAD TO ATTEND DRUG CLASSES TO GET THEM BACK. I SMOKE MARIJUANA IT HELPED ME MORE THAN THE ANTIDEPRESSANTS I WAS FREAKING HAPPY AND NOT SUICIDAL...NO SIDE EFFECTS I WAS HUNGRY....I NEVER WENT THROUGH WITHDRAWAL BECAUSE O NEVER ABUSED THEM OR TRIED FREAKING HEROIN OR WHATEVER, I HAD TO SMOKE MARIJUANA TO HELP ME KEEP SANE...AND REALIZE I WAS NOT GOING TO BE TREATED LIKE A JUNKIE AND BE IN DRUG CLASSES WITH THEM..ITS NOT THE SAME, ITS NOT A DISEASE, ITS A CHOICE....I CHOICE I DIDN'T DO. BUT IM TREATED AS A DRUG ADDICT ON HEROIN LOOKING FOR PILLS. I WAS FORCED TO DEAL WITH MY AWFUL PAIN WITH NOTHING. THEN I FOUND AN DR. THAT WAS SO AWESOME AND WAS ALMOST 80 HE KNEW I WAS IN HORRIBLE PAIN, I TOLD HIM I WAS SMOKING MARIJUANA TO TAKE THE EDGE OFF..HE SAID THEY GAVE YOU NO OTHER WAY. HE SAID I DON'T CARE ABOUT THAT JUST AS YOU HAVE WHAT I PRESCRIBE IS IN YOUR SYSTEM EVERY MONTH. HE DIDN'T TREAT ME LIKE A CRIMINAL JUNKIE, FOR ALMOST 2 YEARS HE GAVE ME FIRST WAS 4 A DAY, THEN LAW CHANGED AGAIN TO ONLY 2 A DAY PAIN MEDS. THEN PASSED AWAY FROM CANCER IN 2016 . I WENT TO WHERE THEY SENT US AFTER HE DIED. I WAS TREATED LIKE A PILL JUNKIE AND NEVER LOOKED AT ME, LOOKED AT ALL MY MRI'S INSTEAD PAIN MANAGEMENT AND SHOTS THERAPY. I WAS BEYOND THAT. THERE WAS NO HELP WITH ALL THAT DAMAGE DONE AND JUST NEEDED 2 PAIN MEDS A DAY AGAIN...I WAS NOT GOING TO GET BETTER...I said all that and I was told to leave and never to return, I was sent REGISTERED letter and regular mail...ARE YOU KIDDING

ME....I WAS AGAIN TREATED LIKE A CRIMINAL JUNKIE...SO HERE I AM AGAIN I NEED ANOTHER BONE FUSION, I AM MORE PAIN WITH NO PAIN HELP THEY GAVE ME NOTHING, THE MUSCLES SPASMS HAVE ME IN BED FOR DAYS, THEY GAVE ME NOTHING...HAD AN XRAY YEP SURGERY AGAIN...I JUST FOUND OUT JULY 7TH.   I CAN'T GO THROUGH THIS AGAIN AND CAN'T HAVE HELP WITH PAIN...IT JUST KILLING ME ...

From: Louise Chen
To: NCIPCBSC (CDC)
Subject: Pain meds for Pain Patients
Date: Friday, July 23, 2021 3:18:50 PM

Dear Sir,

Over four years ago my husband and I bought a rehab house and although I have several painful diseases including psoriatic arthritis, osteoarthritis, fibromyalgia and classic migraines was able to assist in painting along with other tasks. Back in 2016 I was on pain control that covered my pain and allowed me to function.

Last year my doctor was targeted by the government people and he stopped all prescribed opioids. He has me on alternatives, but they do not cover my pain sufficiently so my activity level is greatly reduced. I struggle to just manage a few house hold chores on a daily basis and even taking a shower is major undertaking.

The 2016 CDC guidelines did not take into account of how not treating or the under treatment of pain adversely affected pain patients.

Now this non-opioid movement has crept into the post-surgery arena where patients are allowed to suffer even after such painful procedures such as knee replacements with little or no effective pain control.

Too many dangerous and ineffective non-opiod medications are being used “Off Label” as alternative pain medications so that surgeons and hospitals can avoid government surveillance. This is an unforeseen consequence that is deceptive and harmful to both acute and chronic pain patients.

People are dying because of under-treatment of pain. Someone from my husband’s last job complained to a co-worker that he couldn’t stand the pain anymore and 15 minutes he killed himself.

This is happening all across the country, but being swept under the carpet as an Inconvenient Truth.

Despite the USA’s Government war on pain patients and the deceased amount of pain meds, the death rates for illegal drugs is rapidly increasing.

Please save lives and let Pain Patients be treated with effective opioid pain medications that will not destroy their livers or kidneys. Please stop the USA from becoming a Nation of Agony

Thank you for your consideration of this matter!

Louise Chen
8010 Treasure Island Road, Leesburg, FL

Sent from my iPhone

From: Linda Cohron
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:05:16 PM

To Whom It May Concern,

RE: Health issues - Osteoarthritis, Degenerative Disc Disease, Spinal Stenosis, Self Fused discs in neck & Severe Anemia.

FACT: 94% of people who have stenosis of the spine experience standing discomfort.

As you age would you like to be faced with the possibility of eventually being wheelchair bound if there were a pain medication that could prevent if not delay this happening? Or see your parents facing this possibility if there is an alternative?

At the age of 75, I am facing this possibility. I fight hard thru exercise, healthy eating, and working with my care team to delay this happening as long as we are able. However, a very important tool has been taken away from them.

I am speaking of Tramadol. For several years prior to the current opioid epidemic I was taking Tramadol as prescribed and was able to manage my pain and my daily activities. Now, I am no longer allowed to take this medicine because of the possibility of abuse. I was told that all I needed was a healthy diet to lose weight, Physical Therapy exercise and counseling to help with the pain I experienced. I am here to tell you that 2 years later I have lost 25 pounds, have been in Physical Therapy all this time and do my exercises faithfully - i am still in terrible pain. I was referred to pain management and have had 2 denervations and repeated trigger point injections all which have helped but not relieved the pain. I am seeing a counselor. I have had to wait weeks and months because of scheduling issues with providers for these procedures all while in life altering pain. Our healthcare system is so overwhelmed they cannot cope with the patients needing care.

I am a good cook and enjoy cooking for my family, gardening, walking/hiking, enjoying a museum, a walk on the beach, a craft show, shopping - even for groceries, sewing and quilting, and cleaning my home. I am unable to enjoy these activities & many others because of pain. Physical Therapy has told me they can do no more to relieve the pain even tho they are quite please with my honest efforts. Yes, I do take Tylenol and Cymbalta during the day as well as Gabapenton at night to sleep but I am still in pain during the day as well a during the night. I have included Yoga and meditation in my daily life and made a effort to maintain a positive attitude. I am still in pain! Would you like to see a loved one unable to enjoy life and be in continuous pain when there is help out there?

Understanding that the creators of the laws put in place to curb opioid addiction did their level best to help this country and protect her citizens, i would ask you to please review and give our doctors some freedom to help those of us in such life altering pain.

In addition, we are restricting medications to honest, law abiding citizens of this country who are in need of some pain relief while we are allowing a free flow of illegal drugs into this country across our southern border!! How in the world does this make any sense?

I believe these current opioid restrictions are too strict and too encompassing and would ask that you release some of the medications to be prescribed under physician guided care. As someone who has been seriously affected by a law that is unfair I ask that you take a hard look at the ramifications of what is happening. I have faithfully followed the new protocol for pain management and it has not worked. I am in pain!!

Please help! I am in pain!!

Linda Cohron

From: lynn ebmeyer
To: NCIPCBSC (CDC)
Subject: Don"t forget the "Little People"
Date: Thursday, July 15, 2021 5:24:29 PM

I remember my convicted felon of a neighbor poppping Roxy's like candy, cocaine, spice, alchohol and any other flavor of the month.

They created a culture of opioid abuse. The whole time, I am slowly getting worse with diagnosed CRPS.

Flash forward five years, when I make the decision to choose education and family, over sunshine and no state taxes. We moved from Florida to New York state.

I picked a URMC Doctor, accepting new patients, and close by. During my first appointment, I explain my battle with CRPS, (aka: the suicide disease). She threatens me if I'll be lucky to get any prescriptions from her. In the meantime I test positive for strep throat. Six phone calls to the after hours physician, I finally got a prescription for penicillin.

Lord hope you and your loved ones never get sick!

From: Laurie Engel
To: NCIPCBSC (CDC)
Subject: The CDC guidelines meeting
Date: Friday, July 23, 2021 4:13:01 PM

Hello: I have been a chronic pain patient for most of my adult life. Ever since the guidelines were released every month you hold your breath wondering is this the month my meds get taken away. It is a horrible strain on us. The FDA says their is no limits on how much opiate pain medication a patient can have. The limit of 90 mme is not based in fact it is based on very bad science. Please rescind these guidelines.
Regards, Laurie Engel

Sent from my iPhone

From: LAWRENCE FAVERO
To: NCIPCBSC (CDC)
Subject: Comments - Meeting of the NCIPC Board of Scientific Counselors (July 16, 2021)
Date: Wednesday, July 21, 2021 10:16:53 PM

To Board Members and Participants,

I am writing to you today as a concerned caretaker of an intractable pain patient. I am writing to express my extreme concern about the unintended consequences of our country's continuing war on opioid drugs. My wife suffers from a long-term condition that at this time has no cure, that can and often does causes severe intractable pain. She has received tremendous benefit from opioid pain medications that were prescribed, as a last resort, to manage her constant severe pain after all standard pain treatments had been tried and failed to help. By taking these medications, she has been able to get back some semblance of a normal life that she doesn't have without them. As a result of actions taken by the Centers for Disease Control and Prevention (CDC), the Drug Enforcement Administration (DEA), and other regulatory agencies, my wife may soon lose access to the medications that she relies on to manage the pain and have a decent quality of life.

During the past several years, the media has trumpeted that deaths have continued to rise from illicit drug use, even as prescriptions for opioid medications have declined.

"From 2006 to 2008, the number of opioid prescriptions written increased 4.1% annually. From 2008 to 2012 that rate slowed to 1.1% annually, and then from 2014 to 2016, that rate dropped to an annual decrease of 5% per year. Essentially, compared to 2014, prescribers wrote 15% fewer opioid prescriptions this past year, which equates to a reduction of more than 26 million prescriptions. The number of opioid patients per 100 Americans in 2014 was 20.7, whereas at the end of last year it was 19.1. The average MME per prescription dropped as well, from 59.7 in 2006 to 47.1 in 2016."
--Pharmacy Times, April 3, 2018 https://www.pharmacytimes.com/contributor/kimberly-mckeirnan-pharmd/2018/04/cdc-report-highlights-current-trends-in-opioid-prescriptions

Some facts about the death rates from "opioids":
The number of opioids prescribed nationwide sharply dropped in 2010, as did the death rate from prescription-opioid overdoses. The annual growth rate of deaths involving prescription opioids slowed from 13.4 percent before 2010 to 4.8 percent after. This came after authorities went after pill mills and rogue doctors, states began implementing prescription drug monitoring programs and Purdue Pharma released a reformulated version of the painkiller OxyContin that was more difficult to crush and thus more difficult to abuse, though some users found ways around it.
--"Study: Despite decline in prescriptions, opioid deaths skyrocketing due to heroin and synthetic drugs", Washington Post, April 10, 2018 https://www.washingtonpost.com/amphtml/news/post-nation/wp/2018/04/10/study-despite-decline-in-prescriptions-opioid-deaths-skyrocketing-due-to-heroin-and-synthetic-drugs/

--"A White Paper on Prescription Opioids and Chronic Pain", Alliance for the Treatment of Intractable Pain, April 12, 2018

There are two very separate problems going on that involve the same substances:

- The use of medically prescribed opioids to treat painful conditions, and
- The misuse and abuse of illegally obtained opioids often resulting in overdose or death (whether prescription medication obtained via misdirection of legal prescriptions or plain illegal substances like illicit fentanyl or heroin).

These are two very separate issues – the use of prescribed opioids to treat painful, intractable conditions, and the abuse of illicit drugs – The illicit drug use is causing unintended consequences for chronic pain patients. Both chronic pain and addiction are very serious medical problems that deserve compassionate care, but recent efforts to identify and target "pill mill" doctors and pharmacies are causing innocent pain patients to lose the medical care they require.

Please know that a person who suffers from severe pain who has also dealt with discrimination and demeaning treatment from medical professionals, the general public, and sometimes from their own friends and associates. Severe intractable pain conditions are very real and, if untreated or undertreated, can result in physiological deterioration and even death due to cardiac arrest, stroke, or adrenal failure. My wife is a responsible, law-abiding citizen who has done nothing wrong. Despite the fact that she used opioid medications responsibly, never misused or diverted medications, and been stable on her opioid dose for many years, my wife will soon experience the same constant excruciating pain she endured for years prior to finding appropriate medical care. This is the other side of President Trump's opioid public health emergency…the return to horrific suffering of innocent citizens who happen to be seriously ill. As far as I am concerned, deliberate action by our government that results in the withdrawal of readily available and effective pain treatment from a person suffering intractable pain is equivalent to the commission of torture. This is a violation of human rights, an injustice of the highest order that must stop now!

The studies cited by the CDC when creating their 2016 guidelines are based on weak medical evidence at best. Per the ATIP White Paper cited above:

- "The writing group also contained no practicing Board Certified Pain Management specialists who had experience managing patients in community settings. Psychiatrists in addiction management dominated the group. There was no representation by the CDC's own medical ethics group."
- "Even the statistics of the CDC itself have proven to be faulty, over-magnifying what has been called a "prescription opioid crisis". CDC has acknowledged that it has reported as "prescription opioid overdoses", deaths that were in fact due to illegally imported fentanyl and its analogs. They called their reported prescription opioid overdose rate "significantly inflated" over several years. For 2016, this "inflation" amounted to nearly doubling the number of deaths attributed to prescription medications."
- "A 2018 study reported in the British Medical Journal examined outcomes among more than 586,000 patients prescribed opioids for the first time after surgery. Less than 1% continued renewing their prescriptions longer than 13 weeks. 0.6% were later diagnosed with Opioid Abuse Disorder during follow-up periods averaging 2.6 years between 2008 and 2016. Likelihood of diagnosis increased with the length of prescriptions, but rose only modestly as dose levels increased from under 20 to over 120 MMED."
- "A statistic often quoted in popular media is that over 70% of all people with addiction report that their first exposure to opioids was from prescription drugs. So how are these young men and

women exposed to prescriptions? The answer is almost entirely through theft and diversion of unused medications left over after legitimate patients no longer need them. 75% of people with addiction who begin this way never saw a doctor for pain. Few are able to sustain a developing addiction from home supplies. They soon begin purchasing street drugs – either illegal drugs like heroin (often laced with illicitly-manufactured fentanyl), or safer, but diverted, prescription drugs that cost much more."

- "It has also become clear in recent years that overdose deaths only rarely involve a single prescription opioid given by a doctor to a pain patient. When the Commonwealth of Massachusetts did an extensive analysis of two years of overdose-related fatalities, they discovered that in only 9% of 1657 deaths did medical examiners detect an opioid in post-mortem examinations that could be tracked to the State Prescription Drug Monitoring Program."

The facts about the risks of opioid medications when properly used by severe chronic pain patients do not support the actions that have been taken by Congress, Federal agencies, and state agencies. The CDC needs to take action to address this situation on behalf of all these vulnerable Americans. It is clear that the "war" on drugs has become a war on pain patients.

I ask that the 2016 CDC Guidelines Be withdrawn until a major rewrite can occur to correct the errors and biases found therein. A much broader range of field-experienced medical practitioners and patients must be included. The writing process must be transparent and include a significant comment period.

Second, I ask that the CDC support establishment of a program to support "palliative care" patients who are suffering long-term intractable pain from a variety of established and documented disorders. This program must include protections for physicians who are board certified in their discipline and specialized in treating intractable pain patients.

There are people with severe pain all across the country who are suffering at the hands of their physician because of the actions taken by the Congress, CDC and DEA. There are people dying because they were not given warning and were not allowed to properly wean off their medication. We have people with chronic pain who are committing suicide because they simply cannot deal with the pain on a daily basis without the treatment they had been on for a long period of time. I ask that you please act now before my wife becomes the next casualty in the ongoing war on opioid pain medication.

Sincerely,
Lawrence Favero
951-901-3279
Sent from Mail for Windows 10

From: Lori"s Foster
To: NCIPCBSC (CDC)
Subject: CDC opioid recommendations
Date: Wednesday, July 21, 2021 1:18:40 PM

I was made aware through news outlets that the CDC was in the process of once again revising opioid dosage recommendations. With all due respect, lives are hanging in the balance when you restrict opioid prescriptions further. I was an active worker in the retail industry and did kick boxing classes for fun before I developed fibromyalgia after giving birth in 2011. The fibromyalgia caused me to be unable to work, clean house, or exercise. After attempting physical therapy, antidepressants, and muscle relaxers with no relief, Dr. Sandra Landry put me on 4 Norco pills (325 mg tablets) per day. I took those every 4 hours. It saved my life! I was successfully at that dosage for 5 years with no issues.

Then, the CDC guidelines changed and my world fell apart. There was no gradual weaning process. One day the office didn't have my regular paper copy of my prescription ready. I called to address the error only to find out it wasn't an error. My doctor simply wasn't allowed to continue the effective narcotic pain treatment for my fibromyalgia. The label states " do NOT suddenly stop or start this medication without consulting your doctor." We knew the other treatments I had tried were not effective. So, I had to quit my job due to uncontrolled physical pain. I could only attend church 1 or 2 times a month, and when I did attend, I had to go straight home and lie down so I wouldn't pass out from pain and/or exhaustion. Then, I would have to sleep for about 6 hours to recharge myself for the energy to make dinner and shower.

I had to have my mother come help me take care of my daughter and clean my home during the week. I even had to sit on a stool to shower because it is painful to stand up to shower. I became very suicidal. My life is a struggle to do everyday tasks and a constant fight for the desire to stay alive on this Earth for my daughter. I keep telling myself to keep breathing for her...to keep waking up so she can have her mother.

Keep people like me in mind when you propose opioid guidelines. We weren't using opioids to get high or party. We want one more day to hold hands with our children. We want one more night to hear a beautiful symphony. We just want to live to see another sunrise! Thank you for your time.

-Lori Foster
South Carolina

I am Dr. Lewis Hsu, Chief Medical Officer of Sickle Cell Disease Association of America. I am a practicing physician. I prescribe opioids for children with sickle cell and cancer. I applaud modifying the guidelines with attention to pain care. I want to advocate for **implementation** of the guidelines to do better than 2016 for sickle cell pain.

Sickle cell pain is among the most severe pains known and can start from infancy. Even with the best current treatment, sickle cell pain has unpredictable acute recurrences. Therefore opioids are part of the standard of care for sickle cell multimodal pain management. Studies show that sickle cell patients do not have high rates of fatal opioid overdose.

1. Science shows that sickle cell pain pathophysiology is different from other types of pain. Sickle cell pain mgt was put outside the scope of the 2016 CDC Opioid Prescribing Guidelines by a single sentence, referring readers to "***the NIH … Expert Panel Report for management of sickle cell disease (46).***" which by the way should be updated to 2020 sickle cell pain guidelines (*Brandow AM, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv. 2020 Jun 23;4(12):2656-2701.*)
2. As stated earlier by sickle cell advocate Adrienne Shapiro, that single sentence in the 2016 CDC Guidelines was widely ignored by medical systems. Restrictions were misapplied to sickle cell pain and increased suffering by delays in authorization and caps on the number of doses. These implementation and dissemination problems for individuals with sickle cell and cancer are described by an expert panel report (*Schatz AA, et al. Bridging the Gap Among Clinical Practice Guidelines for Pain Management in Cancer and Sickle Cell Disease. J Natl Compr Canc Netw 2020, 18(4):392-9*). We suggest more assessment of Implementation and Dissemination and build in early corrections, do not wait for 5 years to do a reassessment of health equity. Keep the capacity to act on stakeholder feedback by keeping the opioid work group available for a year after the guidelines roll out.
3. We strongly urge more research on effective pain management options that are alternatives to opioids.
4. Collect data on opioid safety when prescribed for pain treatment in chronic disease like sickle cell disease.

From: leonard.jensen@att.net
To: NCIPCBSC (CDC)
Subject: @CDCInjury BSC July 16
Date: Tuesday, July 20, 2021 6:21:09 AM

My Comments Below:

Winning the War on Drugs

The primary reason most controversial issues are never resolved is because the truth has never surfaced, been buried or completely ignored. It's called "politics".

The easy way to fake your initiative, rub your opponent's nose in the dirt, and continually gain popularity and funding

; even though you neither have the political courage nor know a damn thing about the crisis and will never-ever implement a solution.

While statistical experts at the FDA and CDC have continually tried to focus their management on Illegal and Illicit drugs as the major driver (80-90%) of drug overdoses; both CDC and FDA management continue to use the phrase, "Prescription Opiates" in their announcements and publications on drug overdose rates.

It is a statistical FACT that 80-90% of drug overdoses in the U.S. are from ILLEGAL or ILLICIT drugs; NOT from legal prescriptions. I have emails from the statistical experts and management at the CDC that confirm this truth. I am willing to share these resources with anyone that asks.

Because this lie persists, record funding on the so-called "Opiate Crisis" has been provided to the FDA and CDC, rather than to the DEA and peer state and local law enforcement agencies.

The War on Drugs will never be won through the misappropriation of funds and abuse of Texas intractable pain patients; which are mostly Senior Citizens.

As an intractable pain patient myself, I have witnessed the degrading and abuse of real pain patients; some of which committed suicide because of untreated and unrelenting pain.

Most state government agencies, the media and most politicians stigmatize intractable pain patients and fail to protect their senior citizens. They continue to focus on the beating of legitimate patients and their doctors, rather than the criminals that provide illegal drugs. Likely because it is popular and politically advantageous to do so, but especially for the record funding they continue to receive.

Elder Law already exists in most states that could protect seniors that suffer from intractable pain, but most state agencies fail to recognize or utilize those statutes.

As a former certified Texas Guardian, Long-Term Care Ombudsman and hospice volunteer; let me encourage you to maximize the effectiveness of federal funding for the war on drugs by directing it to where it would be more efficient and effective; to reinforce Texas law and drug enforcement agencies and to stop the enormous flow of illegal drugs across our southern border and elsewhere from China and Mexico.

The continued beating you are providing to intractable pain patients is completely unwarranted. There is currently an felonious overkill of Federal, State and local statutes and laws that continue to result in the mistreatment of elderly intractable pain patients. The current rate of suicide or criminal behavior because they were refused treatment adequate for intractable pain is contrary to logic, ethics, morality and should be treated as a felony.

The fake War on Drugs has been totally ineffective and a complete failure because federal, state and local authorities have focused on intractable pain patients while the Chinese and Mexican Cartels continue to smuggle record amounts of illegal drugs into the United States. Over 90% of drug overdoses are from high concentrations of fentanyl laced into other illegal drugs. The majority of overdose deaths are first time users. They had no chance to experiment with illegal drugs . The first dose killed them!

Very Respectfully,
Leonard Jensen
1222 Thistle Hill Trail
Weatherford, Texas 76087
(817)944-1534
leonard.jensen@att.net

https://www2.texasattorneygeneral.gov/seniors/elder-abuse

From: Kerry Kennedy
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:52:55 PM

I have not completely read the updated guidelines but seriously need to express my opinion on the current state of affairs. After 17 years of fighting post incomplete spinalcord injury I feel there IS a need for use of opioids in pain management. P.T. of all varieties , strength training , stretching , injections , holistic approaches have become fruitless in MY case. What can I do to help the medical community help me ??

From: Lisa Kronus
To: NCIPCBSC (CDC)
Subject: Comment for opioid workgroup
Date: Friday, July 23, 2021 8:30:02 AM

Hello
How are we going to make a red alert to physicians, once the guidelines have changed?

Also, please change the definition of palliative care from death within six months to debilitating, degenerative, painful conditions. This will help a lot of patients.

If this is not where I should comment, can you please send me the correct link?
Thank you for your time and consideration
Sincerely
Lisa K Kronus, RN former CHPN. Current CPP
305-797-6730

Sent from lkk

From: Cherie L
To: NCIPCBSC (CDC)
Subject: 7/23 deadline request
Date: Thursday, July 22, 2021 12:20:59 PM

Hi,

Here’s my little paragraph for the minutes:

“Pain can make you wish you were at end-of-life. Allow us to recapture as much life, function, and dignity as possible by not forcing us into that place.
This is not about appearances and politics, it’s rubber-meets-road reality. Ask us about our risks and benefits, and then factor that into yours.”

Thanks so much for all your efforts!

Best,

Lorinda Lee

--
Lorinda Lee
140 W. 69th St, Apt 96B
New York, NY 10023
631-816-4121

From: Lin Lee
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 3:04:39 PM

Hello. Thank you for giving me the opportunity to include my letter for this very important issue on the cdc opioid prescribing guidelines and the urgency for needed changes of the current guideline.

I am a chronic pain patient whose life has been, and continues to be, greatly improved with opioid medications for over 20 yrs. My chronic and painful conditions are the following: a constant, severely painful progressive autonomic small fiber neuropathy, spinal arachnoiditis, spondylolisthesis/unstable spine and with adjacent level breakdown below fused spine with instrumentation, failed back surgery, spinal stenosis, radiculopathy, and fibromyalgia, and sjogrens-like syndrome. These conditions were diagnosed and validated after multiple, repeated, medical objective testings and corroborated by many experts of their fields including in neurology, orthopedic, infectious disease, Neuro-radiology, and pain medicine, and from some of the most prestigious medical centers, as well as from my internal medicine, primary doctor of 30 yrs.

I am that person that does not like to put ‘anything’ in my body that is not natural unless absolutely necessary for my physical and medical well being, and then only after having tried the least of. Over many years, specialists in their fields have tried different medications types and these were either unable to sufficiently treat my severe constant and chronic pain and/or resulted in intolerable effects, including non-opioid medications with dangerous long term use effects (and many not safe for chronic/long term conditions). After all else tried, the opioid pain medication treatment was the only treatment that gave me sufficient relief and without any intolerable side effects like all else tried. I’m able to not only live without excruciating constant pain but able to have a quality of life that would not be possible otherwise. Opioid pain medication has been a Godsend for me.

Over the 20 plus years being treated for my multiple, chronic, severeIy painful conditions, I have never experienced any euphoric or “high” type effect, nor have I ever experienced any addictive-type effects from. Although I have been on opioid pain medication for many yrs, I have been able to reduce greatly the dosage amount and have remained on this same amount for over 3 yrs. I believe that this is partly due to my ability to have had my severely painful conditions appropriately and sufficiently treated for all of this time with opioid pain medication and therefore able to continue much needed healthy exercise and ability to move my body, as well as the overall mental benefits of, including a better sense of well-being that one has back with a quality of life and ability to once again have life experiences with family and friends...and at my age, especially grandchildren. Without my many yrs of successful opioid pain treatment, the resultant insufficient pain control over that time would most assuredly have caused me to continue in an increasing consequential dysfunction and disability and overall physical deterioration with decreased movement, and a life in bed, or laying on a couch, and with increased health/medical issues from such inactivity, as well as the physical consequences of unrelenting severe pain, including high blood pressure, which in itself can cause **stroke, heart attack, heart failure and other heart conditions**; cause damage to your kidneys, memory and vision (https://www.google.com/amp/s/www.hopkinsmedicine.org/health/conditions-and-diseases/high-blood-pressure-hypertension/resistant-hypertension%3famp=true), as well as a deterioration of mental health and well being (which also effects the physical health) for the obvious reasons of one with uncontrolled, severe, constant pain and the loss of function, loss of enjoyment...in everything, isolation and resulting loneliness, decreased sense of worth, *and so much more.

I’m not uninformed, I’m not unable to make wise and necessary, and right decisions for myself along with the educated/trained expertise of my doctors who know and well understand my conditions and medical history. Nobody else should have the right to tell me and my doctors any different. Would you want that if you were in my shoes? Would you want false and/or misleading information and opinions to interfere with your medical treatment needs and to take away your ability to have your intolerable pain made tolerable and able to have a quality of life? How would you feel about such false information and opinions causing the loss of your quality of life being caused by the allowance of such from those who know nothing about your individual medical conditions and history, including any knowledge of all failed and/or intolerable treatments that you have tried over many years, and from those who are not experts in your medical conditions, and from those who are not experts in pain nor pain treatment, and in addition to, from those who have huge conflicts of interests, including receiving large amounts of money to do and therefore untrusting motives to make sure that their big paydays can continue? Even if you or a loved one of yours have never experienced severe pain, whether acute, subacute, or chronic, one day you will, and if you do not do your part to stop the needless suffering of so many lives due to the 2016 opioid guidelines, I assure you that one day you will so badly wish you had.

Please take this seriously and take action to remedy the existing and very troubling current situation that is hurting and causing the unnecessary added suffering of so many innocent people who simply want to be able to live without intolerable pain and to have some quality of life, and without having to endure inadequate medication and/or medication amounts, and without the very real side effects from other medications (including the causing of very ill-causing, and even dangerous and life threatening conditions) that are not appropriate for long term chronic pain amounts. Everyone has a different story, a different history, a different need, and why it’s always been said that every medical case and best and necessary treatment should be INDIVIDUALIZED, and why medical needs and treatment must be between doctor and patient...period. There is of course a means of handling the small % of those doctors and those patients who are not responsible with and/or abusing without hurting the great majority who are legitimate, responsible, and law-abiding treating doctors and their patients who receive great benefit from utilizing opioid pain medications. In addition to this, there is of course, also a means of handling the small percentage of patients who do become addicts from a pain medication prescription (dependence on a medication is NOT the same as addicted to). There are many medications for many conditions where one can be dependent on. Again, this is not addiction. However, not every legitimately opioid prescribed patient even becomes dependent on. But even those who are, what is so wrong with that? It's just something that can naturally occur with so many different types of medications treating many people's lives for many conditions who otherwise would be suffering needlessly. I thank God that opioids exist for myself and others who have had great benefit from.

It's difficult enough living with severe chronic pain, so again, please do your part in correcting the wrongs that have hurt legitimate pain sufferers and their families. One day it could be you or your loved one suffering from severe chronic pain. Every person should have the right to have medication that enables them to have their pain tolerable and quality of life, and with their doctor, the decision of what that treatment/medication should be. Doctors need to again put the needs of their patients first and not put in the position of having to choose between that and fear of their practice ruined. Please don't let this go on deaf ears and nothing done to help all law-abiding legitimate pain sufferers. Do your part to help undo the damage that has been done and make it right. Another day that goes by that this doesn't happen is another day of causing needless suffering for so many.

Sincerely,
Linda Buckley

*
https://www.google.com/amp/s/coloradopaincare.com/chronic-pain-and-heart-disease/amp/
Long term chronic pain can produce severe stress and anxiety, which in turn can elevate blood pressure and pulse rate. Elevated blood pressure and heart rate over a sustained period can damage the heart leading to **cardiac arrest, stroke or death**.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614505/
"Untreated pain has a profound impact on quality of life and can have physical, psychological, social, and economic consequences. Inappropriately managed acute pain can **result in immunological and neural changes**"

https://www.nursingtimes.net/clinical-archive/pain-management/understanding-the-effect-of-pain-and-how-the-human-body-responds-26-02-2018/

“**Pain** therefore increases heart rate, blood pressure and respiratory rate. **If** these physiological responses are prolonged, especially in **a** person with poor physiological reserves, it **can** lead to ischaemic damage (Wei et al, 2014).Feb 26, 2018”

From: Leah LoneBear
To: NCIPCBSC (CDC)
Subject: Follow up comments to CDC Conference 7-16-2021
Date: Friday, July 16, 2021 7:03:40 PM

To the NCIPCBSC ,

As we are here again revisiting the opioid guidelines that were established in 2016,

we remind you that since the inception of guidelines, citizens the nation over, have begged and pleaded for mercy to maintain their quality of life, avoid medical collapse, refrain from going to the street for relief and/or commit suicide. You as a group began this atrocity in 2016 and here in 2021 you have allowed the death and suffering to continue unabated with the idea in mind it may be end of 2022 before you update guidelines?????? That just isn't good enough.

All that your actions have caused is loss of quality of life, medical collapse and death, suicide, destroyed lives and families. You have exponentially increased the black market and the number of patients who will seek it as a last resort. You have exponentially increased the number of people who are no longer able to work and have to turn to disability whereas before they were functioning and working as long as they were medicated for pain. Pain medication has been ripped from patients en masse. I have witnessed speeches by Pediatric Surgeons pleading for you to understand the need for pediatric pain control. You say adverse childhood experiences have to do with whether or not a person becomes addicted. I cannot imagine a more adverse childhood experience than going through cancer surgery and treatment or pancreatitis etc... without adequate pain control so it will be you that created that adverse experience to then turn around and use it as a reason not to medicate pain. How utterly inhumane , barbaric and calloused has this nation become?

We have come to the place where the NPS which is the child of the 2016 Guidelines and were intended to come together, broken down to its simplest form, is basically saying “Stop going to the Dr for your pain. Stay home and deal with it yourself, aka self management all the while the DEA and FDA seek to take away nearly all the natural or alternative treatments people can find for themselves, Kratom being one good example. It is as if, as a group ,all you alphabet agencies have determined that you will take absolutely everything you can take and leave people to suffer.

Pain patients have been stigmatized by the very term “Biopsychosocial” because now any and all pain regardless of its origin is treated as something you can use yoga for, meditate your way through or learn to endure because after all it's all in your head. I can assure you it was nothing in my head that catapulted me through a car window and left me with injuries and missing and broken body parts that cannot be healed. Not only are patients no better off than they were before 2016, they are in fact worse. The number of pain patients committing suicide has exponentially increased, medical collapse and death has exponentially increased, disability has increased exponentially, over doses have increased exponentially. You have accomplished nothing but misery and death.

If you need a vivid, clarion example of that, then hear this. Erin Gilmer was a chronic pain patient and an attorney who worked in health law. She in fact worked with and for Stanford University, PCORI and AHRQ. Due to the insanity of the environment that now surrounds pain medications and pain patients which was created by the lot of you, Erin was unable to obtain proper relief and care for herself and last week when her pain became more than she could bare , She ended her life. Your creation has come home to roost and landed at your own door. You killed one of your own by deprivation induced by your policies.

This IS a human genocide. It violates the Nuremberg Code of ethics, the Belmont Report, 42 US Code 1395 and is a total atrocity that you MUST stop. You yourself have referred to this as deaths of despair. It is despair that you have caused and it is only getting worse. If any of you have even the slightest humanity left within you which at this point appears debatable. STOP the denial and death. Just STOP.

The 2016 guidelines have utterly destroyed the practice of medicine in its entirety and you owe it to the citizens of this nation to change it , starting with changing it back to a biomedical treatment model. You need to get out of people's heads, hearts and personal business and treat their physical ailments. Oh and if we stand a chance at making any of this improve, I would suggest telling the DOJ they need to reign in the DEA who took a guideline and made it into de facto law with which to destroy patients and Drs. You caused that and you need to fix it post haste.

From:	Lyn Marie Rollins
To:	NCIPCBSC (CDC)
Subject:	Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids
Date:	Friday, July 23, 2021 4:26:53 PM

Before May of 2007, here is my life
1.) I was working full time
2.) I was going to college full time for Electrical Engineering
3.) I was very involved with my children & grandchildren
4.) I loved riding my Motorcycle as I was an Abate Member & Patriot Guard Rider
5.) I enjoyed Hunting
6.) I was working on a Hunting Clothing Line to set myself up for my future and the future of my family
7.) I I avoided medication unless it was absolutely necessary

In May of 2007 I was injured at work and found myself fighting to get answers and to be fixed. I soon learned that I had
CRPS. It was something I had never heard of but I would soon learn first hand.

I went through
1.) Stellate Ganglion Blocks
2.) Sympathetic Nerve Blocks
3.) Pain Pump Trial that I fought against as it was too permanent and I still wanted fixed
4.) Acupuncture
5.) Physical Therapy
6.) Opioid Pain Meds
7.) Spinal Cord Stimulator as I was told, last resort
8.) Injections in my head for Occipital Neuralgia
9.) Botox Injections for Chronic Migraines

Let's talk about my first SCS. It was a ST. Jude Eon Mini. It was implanted Sept. 2011 and I immediately started experiencing the following when turned on
1.) My heart started beating so fast I felt as though I was running a marathon
2.) When I least expected it I would get zapped so hard that one time
  A.) By Dec. 2011 I had to have an Ablation to close 7 holes in my heart. Some feel it was related
  B.) I fell and shattered my left wrist
  C.) another time I fell and fractured my nose
  D.) Chronic Migraines and one stemming from my neck at the leads.

I kept telling my Work Comp.Dr. that something was horribly wrong with the SCS and she kept saying there wasn't. By June of 2012 (3 months short of a year) I received a letter from St. Jude stating something like, By now you know that your SCS & Leads were on recall at the time they were implanted. I absolutely DID NOT KNOW. Work Comp. quickly moved to retire me from working and close my case. In 2013 I finally found a Dr. to remove it but the damage had been done. They did implant a new one but said, not sure if it will work as there is so much damage from the first.The 2nd SCS has not worked and now they are trying to force a 3rd. If the 2nd did not work, why would we try a 3rd?

Since 2009, the only thing that did work, was my Opioid Pain Meds. that are slowly being taken away. I expect to have the last few taken away on my next visit as I am refusing a 3rd SCS.

With my Opioid Pain Meds.I had a quality of life. I was no longer Working, going to College, riding my Motorcycle or Hunting but,

1.) My pain was being managed
2.) I was involved with my children & Grandchildren
3.) I was thinking about the possibility of going back to school for design to continue my Clothing Line
4.) Looking at the possibility of riding again

Now in 2021, these people have basically been given Power of Attorney of my life,WITHOUT MY CONSENT

A) CDC
B) Government Officials
C) Many not experienced in Pain Medicine, such as, Andrew Kolodney & PROP
D) DEA

This does not even touch the lives lost to suicide. That wreckage is on those listed above and needs to STOP immediately. The CDC Guidelines must be rescinded and let our Doctors do their job.

From: Leslie Munday
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:45:11 PM

Hello,
Since 2016 my life has not been the same with strict guidelines put in place that affect my entire life. It is EXTREMELY Difficult to get treated for Lifetime Chronic Pain from a Spinal cord Injury that has neurologically sustained my attention completely. I have been seen by 4 pain management Doctors since 2017 and because of the Guidelines from 2016 They are Completely incapable of doing their JOB, which is to help me with Medicine that Subsides my 24/7 Chronic Neurological Pain issue to the point that at least bare minimum I can return to a chapter of my life I last left in 2016 and to enjoy living period!
My Doctor need to be able to do his Job and execute his knowledge base and work with me to make my life and OTHERS as well live again. You have NO idea what we deal with, if shoe was on the other foot you Would understand. So listening is your best option.
Truly Hurting,
Leslie Munday

From: Louis Ogden
To: NCIPCBSC (CDC)
Cc: Kristen Ogden
Subject: Comment on draft updated CDC Guideline for Prescribing Opioids 2022
Date: Friday, July 23, 2021 4:08:44 PM

Rather than update the guidelines, I'd like to see them done away with completely. A doctor's prescription should be treated like any other prescription without government interference. The CDC does not have a medical license and should not be practicing medicine. They do not have guidelines for heart patients or diabetics or any other patients, so why is there a guideline for pain patients? People metabolize opioids differently from each other. Some need a small scrip some need a large one. You should be able to see all the suicides and the low quality of life these guidelines have caused. I started taking opioids for chronic pain during the time period of Pain Patient Bill of Rights and pain as the fifth vital sign. I have done nothing illegal yet now I feel like I'm being treated as a criminal. **SCRAP THE GUIDELINES!!!!** The guidelines have caused me great harm because my dose has been lowered to the point that I no longer have a good quality of life. Thank you for the opportunity to comment.

Louis Ogden

From: Laura Lynn Olinger
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:10:12 PM

Dear CDC:

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

You must understand that these guidelines are followed to the letter by doctors, hospitals and clinicians whether or not it is to the detriment of pain patients. This causes those with pain to seek alternative sources of relief including legal medications, illegal drugs, over the counter remedies, CBD, marijuana, and upon finding no relief, suicide.

I am a chronic pain patient and the CDC guidelines have caused me harm!!

Thank you,
Laura Olinger
10314 236th Ave
Anamosa IA 52205

From: Lysa Ortenzi
To: NCIPCBSC (CDC)
Subject: Abolish the 2016 CDC Opioid Prescribing Guidelines
Date: Tuesday, July 20, 2021 9:20:47 PM

To whom it may concern,

My name is Lysa Ortenzi and I'm a chronic pain patient who has been under the compassionate and responsible care of the same PM doctor since @2005, and continue to see him every month. I was referred to him after my primary could no longer handle my condition which was about an additional 3-4 years previous to that time.

I was grateful for the referral to a specialist that would focus on my pain appropriately. With my primary physician, I tried PT, TENS units, different exercises that I could do on my own in addition to trying several different off label prescriptions for things like NSAID's, muscle relaxers and anti depression meds that a. never helped and b. cause negative side effects that I couldn't tolerate and frankly, didn't want to tolerate. I'm not depressed so taking anti depressants is a recipe for disaster in my opinion and being the kind of person who would rather NOT take any meds if possible, wasn't willing to live with the side effects on the off chance they might provide *some* pain relief. My primary did eventually prescribe opioids for me starting with the lowest dose possible however, after more than a year of adjusting the dosage higher and my constant requests to know if there was anything else I could do to alleviate my pain, he knew he needed to send me to a specialist.

Once referred to my PM, he and I discussed other options available at the time but eventually settled on a regiment of short and long acting opioids and muscle relaxers that gave me a quality of life that was worth living! I had spent so many years in pain, being miserable and my conditions, degenerative disc disease and arachnoiditis, were only getting worse with time and age but with the relief I received from my carefully monitored, appropriate dosages of opioids, my QOL improved even further. After the birth of my youngest in 2007 at age 38 (I voluntarily decreased my dosage to only a fraction of my usual dose during my pregnancy and was miserable the entire time but glad I did it for my child who was born perfectly healthy and happy), I resumed my pre-pregnancy regiment after an appropriate amount of time and was once again living almost pain free. By the time my daughter was 4 1/2, I was hiking 6 miles a day and hitting the gym after each hike for 2 more hours. Staying active in addition to my pain meds is what has always worked best for my conditions and had the added benefit of keeping me healthy and fit and able to keep up with a small child, especially at my age! My dosages did increase incrementally over time as is expected with degenerative diseases however, my pain was managed very well. Until 2016 that is.

During my entire time with the same PM doctor, it is required that I see him once a month to monitor everything about my condition and as is regulated when one is a PM patient. During the past 16 years -
- I have never once missed an appointment
- I have never requested additional/early meds or refills
- I have never seen another doctor for my pain and even when I've had surgeries over the years including an intensely painful elbow surgery, I refused additional pain meds because frankly whatever they were going to give me probably wouldn't have worked, I was already managing my pain with my current prescriptions and I also REFUSE to be called a drug seeker even if it meant additional pain relief

- I've passed every drug test that's been given to me as required as a patient of my PM doctor and my insurance company
- My file has been audited by the DEA on multiple occasions due to the high dosage I received, never once finding anything wrong or misappropriate in my treatment.
- ***I AM A MODEL PAIN MANAGEMENT PATIENT.***

Starting in 2016 with the well intentioned but 100% completely misapplied CDC Guidelines, my health, my pain management and the control over my entire quality of life was stripped from me and my PM doctor. Due to the CDC, the DEA and the greedy insurance companies that take my money but refuse me proper care, I now have very little quality of life. Long gone are the miles of hiking and hours at the gym which gave me so much joy and made me an active participant in my life, the lives of my family members and the world around me. I have had my dosages tapered to a point that leaves me with little pain relief every moment of every day and I'm no longer able to be an active participant in my once full life. My pain WAS being managed at approximately 80-90% but has flipped to only being managed about 20-30%. I'm only 52 and should still be able to exercise and be strong and active. Instead, I am only just barely able to do the most basic of chores like drive my daughter to school and feed my animals. I rarely sleep through the night due to my pain and have recently had to begin getting regular injections in my elbows and hips just to try to get about 30% pain relief in them. ***THIS IS NO WAY TO LIVE!*** Especially when there is a proven safe and effective pain treatment that I shouldn't be denied through no fault of my own!
THIS IS INSANITY AND IT MUST BE STOPPED!

I understand that there were too many so-called doctors and drug seeking people who were abusing the system and these meds before the guidelines came out BUT seriously, the majority of those people have been weeded out now. We have a raging ***ILLICIT FENTANYL AND HEROIN*** epidemic ravaging our country and destroying lives but instead of focusing on those drugs, ***THE ACTUAL CAUSE OF THE VAST MAJORITY OF OD's***, the CDC only focuses on legal prescription takers like myself and hundreds of thousands of other CPP's and you're killing us! ***THIS HAS TO STOP!*** The CDC has done and continues to do irreparable harm and damage to far too many responsible but sick people and too many of those who are NOT a part of the "opioid epidemic" are having their PM's fined out of business and these very sick and fragile people are being left without care and without their life saving meds.

What do you think so many are forced to do because of these terribly written and completely misapplied guidelines once they lose access to care?
ITS YOUR POLICIES THAT ARE CAUSING TOO MANY OF THESE PEOPLE TO SEEK OUT DANGEROUS BUT NECESSARY RELIEF FROM THE STREET OR COMMIT SUICIDE!

I DEMAND THAT THE 2016 AND THE 2022 GUIDELINES BE ABOLISHED! THERE IS NO WAY TO CONTINUE WITH THE CURRENT GUIDELINES AS THEY EXIST OR EVEN REVISED. THEY MUST BE ABOLISHED TO STOP THE INSANITY, THE HARM AND CRUELTY GOING FORWARD!

I also demand that any future guidance is ONLY created by real pain management doctors and professionals and not biased, paid shills who have blatant conflicts of interests and have no business telling anyone how pain management, chronic pain or pain of any kind works when they're nothing more than psychiatrists and rehab counselors who treat addiction! How they ever were chosen to do this kind of work is beyond shocking and irresponsible and whomever at the CDC made the decision to chose these people should also be held responsible for all the harm and deaths caused by the choices they made.

WE ARE REAL PEOPLE BEING MADE TO SUFFER EXCRUCIATING PAIN EVEN THOUGH WE ALREADY HAVE SAFE AND EFFECTIVE SOLUTIONS.

STOP TREATING DEPENDANCE AS ADDICTION!

NOW!

Thank you for your time,

Lysa Ortenzi

From: Lisa Peddicord
To: NCIPCBSC (CDC)
Subject: Opioid guidelines
Date: Sunday, July 18, 2021 11:26:29 AM

To all who work on these guidelines: please know: 1) your guidelines have caused so many deaths and so much suffering. We just lost 3 amazing pain warriors due to undertreated pain. 2) your guidelines are treated as law where doctors are concerned, please stop saying they are suggestions, we know better. No doctor wants to go against anything you say, you are setting rules when you make these guidelines. 3) opioids are the only thing that help many intractible pain patients, many cannot do activities without them because of pain, so saying other things work is not true, we always try other things first before we ever ask for help. 4) if you divide the # of years from 1999 to 2020, you have roughly 50,000 overdose deaths per year, alchohol causes more deaths per year than all opioids combined. There was never a crisis. There was never a reason to take any pain patient's medication away from them, which is what happened; and you caused hundreds of deaths, possibly more. And it did NOT change the # of overdose deaths. But it caused pain patients deaths. 5) I do not believe you should deny people medicine to solve the addiction problem. These past 5 years should have shown you it did not work. 6) the guidelines should be rescinded and efforts put into helping people with addiction. Please leave all pain patients and their doctors alone, no matter how old or how young, pain is a horrible thing to suffer from and we have a way to medically treat it. It is inhumane to let people suffer with chronic or acute pain. 7) doctors did not cause the overdose crisis, there is no specific scientific evidence to prove that. And I want you to know that many of us fear a fall, an accident or need of surgery due to the unprecedented ramifications these guidelines have caused throughout the medical/patient community. We put off any surgery because we know we will not be treated for the pain surgery causes. 8) as a human being first, I beseech all of you to stop and realize the needless suffering you are causing. I do not want my kids, and grandkids to live in a world where people are treated so badly that medication to ease their pain is no longer allowed. This is what your guidelines are causing. 9) regardless of whether I ever get medication for my painful conditions treated again, I want compassionate doctors to treat the people who live after I'm gone. Not cold, uncaring doctors that my grandkids and most people fear. And that's what you are creating with these guidelines. Pain must be treated at all costs, if addiction occurs, then follow the patient and treat it. But please do not keep on telling doctors to not treat pain. 10) again, any medical advice you put out is taken as rules of standard. I have heard doctors myself say they are not going against the CDC guidelines. Please rescind the guidelines before anyone else dies, before any other person is treated inhumanely again. 11) yes I am a pain patient that lost access to my medication 2 years ago, I no longer get to visit much with my grandkids, or even get to shower because of pain. I was on a stable dose of pain and anxiety meds but after the guidelines became the rule here I had to choose which and ended up losing both. I never had a problem with the medications, they continued to work for years before they were taken. But the things above are more important, we cannot let ourselves become a cold and inhumane society.

Thank you
Sincerely,
Lisa Peddicord

From: Lori Ravelli
To: NCIPCBSC (CDC)
Subject: Our voices matter!
Date: Thursday, July 22, 2021 11:07:09 AM

Why is the CDC punishing pain patients and why is my life any less valuable then a drug addicts? Why are the people that see doctors more often, go thru drug/urine screenings and live in daily agony have less of a value and being punished. We are suffering, can no longer get proper treatment when pain medication is our only hope for some relief but can no longer have access to it. Why do doctors not want to treat patients in chronic pain any longer when pain is the number one reason patients visit doctors/hospitals? The doctors fear of the DEA is leaving us…the pain patients to live our days in extreme agony, to search for relief from the streets or sadly end our lives because help from our physicians is no longer available. It has been proven during the past few years, the “opioid crisis” is not patients who regularly see their physicians it is the heroin and fentanyl found on the streets. There has been a huge decline in opioid prescriptions written but the amount of overdoses has risen greatly. There needs to be changes made immediately to help people suffering with painful conditions to have treatments made available to them. Doctors take an oath to “do no harm” but by not providing pain related **when all other options fail** they are doing such great harm. Too many chronic pain patients are choosing suicide because the pain is to great to bear.

“ The MAT trend reflects what physicians must understand: chronic pain patients develop dependency that, in many cases, is as much of a lifetime condition as diabetes. Tapered and abandoned patients with intolerable pain have turned to the tender mercies of the black market, and a great many have died as a result. All suffer unfair stigma. Don't call them addicts, don't diagnose theirs as a use disorder. Most are simply coping as best they can with an iatrogenic condition gone untreated by unfeeling doctors.”

I am a chronic pain patient trying to be a functioning adult. I enjoy working, love my job and sadly without medication I am in too much agony to be able work. I do not want to be forced to go on disability and live on government funds. I do not want to be a burden to my family and want to be able to work as long as I can. With access to some medication I am able to work and provide for my family. I know there are so many people experiencing this lack of treatment and I belong to many chronic pain forums in social media full of people like myself. The pendulum has swung so far in wrong direction and we need change!

Thank you.

Lori S.

Sent from my iPad

From: Lori Ravelli
To: NCIPCBSC (CDC)
Subject: An addition to my previous email....
Date: Thursday, July 22, 2021 10:57:57 PM

My previous email is posted below…
I feel the need to add some information that I did not state in my last email…
I relocated from California to Texas 4 years ago. In California I saw the same doctor without incident for almost 10 years. When I moved to Texas I could not find a doctor to treat me and prescribe the same medication I had been on for the last 10 years. The doctors in Texas saw my test reports and said they see exactly why I am in pain but none would take me on as a new patient nor write me a prescription for pain relief medication. Primary care doctors said I need pain management. I was told by several pain management doctors they would take me on of I would do lumbar spinal injections or a spinal stimulator device but not for medication. I even had doctors tell me if I do not get injections they refuse to have me as a patient at all. I saw in my first 2 years in Texas almost 25 different doctors in search of medical care for my documented chronic ailments. From pain management, orthopedic doctors, neurosurgeons, primary care…I was forced to doctor shop and still could not find adequate care. I was at my wits end, I reached out to my previous doctor in California and explained to home what I was going through. He told me he could care for me until I could find a doctor in Texas that would take me on as a patient. I had to fly back to California from Texas to see my doctor for every medication refill. It was the only way I could ease the pain I suffered from. The few (2 if I recall properly) doctors I saw in Texas that did offer to write a prescription cut down the dose so low it was not helping with pain relief and I was in constant agony. Most doctors blamed the CDC and the DEA and refused to write a prescription and mentioned the 90 mme. I was not even offered a prescription for 90 mme and my medication amounts were dropped with no tapering at all. I was in agony and decided my only option I had was to fly back to my previous

physician in order to be able live with a bit less pain due to the guidelines set by the CDC in 2016. I am so tired of life in agony and being treated like I am a drug seeker. I am just trying to be a productive member of society and with pain medication I am able to do so.

I am a 53 year old professional living in Galveston, Tx. I am begging to ask for a change in attitudes toward people in pain who need improved access to treatments. There are millions of people suffering from chronic pain, cancer and other debilitating ailments that cause severe pain and we are suffering and unable to receive proper medical treatment from our physicians. I am writing to you in hope that you can help with a matter that affects myself and a large number of your constituency.

I need help…I suffer and have suffered for years from severe chronic lower back and coccyx pain that is unbearable. Some of the issues I have been diagnosed with are chronic pain disorder, lumbar spondylosis with narrowing disc space at every level, there are also anterior and posterior osteophytes at all bubbles, hypertrophic set arthropathy at all levels, degenerative disc disease, lumbar nerve root disorder and along with scoliosis (I honestly do not know what all of this means but I know how bad it hurts). I also had a gastric procedure which limits the kinds of medications I am able to take(such as ibuprofen, muscle relaxers, naproxen and nsaids). Long lasting, slow release medications do not work for me because nothing lasts more then 3 hours in my system. I have had multiple appointments with neurosurgeons and other doctors to be told I have too much wrong with my back to have any surgical procedure. It cannot be emphasized enough and I've seen many, many highly-acclaimed surgeons, who are absolutely unanimous in what options I have. They've all said the same thing: Surgery is not an option for me and due to the nature of my conditions I should avoid any invasive procedures as they will make the pain worse. This includes spinal injections, radiofrequency ablation, spinal cord stimulators and pain pumps, to name a few. I have stacks of reports, cds and test results justifying my issues. I have had multiple injections with different medications and in multiple locations to drain my bank account, gain weight and still suffer in agony. Those injections have caused me permanent damage and now I have Adhesive Arachnoiditis. My only option is pain management thru medication and doing physical therapy at home. I can not sit down for any length of time, lying down hurts and I can only stand for so long without my legs giving out. In addition, these days I have shooting pain down my leg when I do sit. Sadly as much as a body needs rest...I can no longer rest comfortably. My quality of life is almost non existent due to the debilitating pain and without access to adequate pain relief I have contemplated if the daily struggle is actually worth it.

My pain has caused me to miss out on daily activities and has become extremely detrimental to my quality of life. I have missed family functions, and important events in my children’s and grandchildren’s lives. I have suffered with this debilitating affliction because I feel that I have been discriminated against by doctors and members of the medical community that have been hamstrung by legislation designed to combat the “opioid crisis”. This crisis made doctors fearful of prescribing medication that significantly improves their patient’s quality of life. There have been cases in which doctors are named in medical malpractice suits or even wrongful death suits based on the prescriptions they wrote for their patients. These outcomes have made even legitimate prescriptions seem like too much of a risk for some physicians. The lack of clear guidelines leads many doctors to become more conservative with pain medication than they need to be. This has caused patients that legitimately need these medications to have their medication dosages decreased or cut off completely. This in turn creates another problem that causes otherwise law abiding citizens to seek illicit drugs from the street and drug traffickers. Doctors have increasingly been tightening their standards for opioid prescriptions as the crisis worsens and more regulations are introduced at state and federal levels. These regulations are counterproductive and have caused many chronic pain sufferers to endure pain or become a criminal in the sight of the law. There are currently no nationwide federal laws regarding opioid prescription regulations. The Centers for Disease Control and Prevention (CDC) has released guidelines for prescribing opioids, but they are just that: guidelines. Enforceable laws about opioid prescriptions are down to individual states, and many of the laws enacted are incredibly restrictive. Refusal to prescribe pain medication leads to unnecessary suffering. It is becoming more commonplace for physicians to under prescribe medication for fear of litigation. I am not the only person caught in this circumstance. I am a member of several chronic pain groups on social media with membership in the thousands just in Texas alone. Chronic pain is something every physician should take seriously without fear of repercussions from the DEA or litigation so their patients can be treated humanely.

When people are not able to get their medication from the proper channels they will seek options from the street with hope of finding some relief. Pain relief is a human right and without relief people will take their lives. Living with debilitating pain you have little quality of life and no desire to wake up in the morning. I am suffering severely and sadly need medication to be a functioning adult. I know I will never be pain free but any relief is welcomed. Please, please for the love of God stop punishing the patients and the medical professionals trying to help them!

Lori R.

Sent from my iPad

From: Lisa Reed
To: NCIPCBSC (CDC)
Subject: Written comment
Date: Friday, July 16, 2021 2:23:50 PM

I have been a CPP for 27 years, the 2016 guidelines have been a nightmare. Pain doctors are retiring or refuse to treat CPPs out of fear of being investigated and/or shut down. I have multiple dx's and live with uncontrolled pain. I have no quality of life without pain medicine to help control my pain. The government needs to be less concerned about CPPs developing addiction and more worried about the CPPs that are dying in agony or suicide because they can't find pain relief. There is an Opioid epidemic going on but it has very little to do with prescription medicine and everything to do with illegal street drugs. The CPPs are needlessly suffering because the government is inhumanely withholding pain medication. One size does not fit all, everybody's body is different and nobody processes medications the same. Pain patients are being demonized and discriminated against because we have legitimate illnesses and need life-sustaining medicine just like anybody else with long-term health issues. The guidelines need to be re-written or done away with altogether. Pain management and opioid prescribing should be left up to the physicians that are treating the CPPs. The guidelines are killing fellow CPPs; they're dying because their bodies can't fight anymore pain, they're dying by suicides because they can't get any help, they're dying by going to the streets to find some kind of pain relief. How many more innocent CPPs have to die in needless suffering before something is done about it?

Thank you,
Lisa S. Reed

From: Lisa Reed
To: NCIPCBSC (CDC)
Subject: CDC.gov opioid prescribing guideline revision
Date: Thursday, July 22, 2021 12:46:09 PM

I've sent in a comment already but one comment about the government killing chronic pain patients is not enough to be heard. When I got hurt 27 years ago my pain was managed. Shortly after getting hurt I became a single mom to 2 young boys. Because my pain was so well managed I was able to be a mom to them and make sure that they were taken care of. I was able to raise those boys, on my own, up until 2016 when the guidelines came out and I was completely cut off all my pain management medicine. After I was taken off my pain medicine, I couldn't be a mom to my kids like I was able to be before. I can no longer drive or do anything with my kids, I can barely get out of bed most days, and that's when I'm having a "good" day. I have a degenerative disease and have tried the healthy lifestyle, exercise, etc, etc and yet my disease is getting worse. Taking OTC pain relievers is for me at this point, like telling an insulin-dependent diabetic to just avoid sugar. I'm not a drug-addict, I haven't stolen or sold everything I own to chase some high. I'm a chronic pain patient with a progressive disease who is dependent on long term opioid therapy higher than the 90 MME to maintain being able to live my life. I depend on pain medicine the way a patient with diabetes depends on insulin, the way someone with high blood pressure depends on their medicine. I didn't ask to be disabled or be in constant horrible pain and to have to depend on pain medicine that other people use to get high. The stigma behind pain medicine and it only causing addiction is accomplishing nothing in stopping the overdoses and deaths. The only thing it is accomplishing is killing more innocent people that live in never-ending unbearable pain and just want some much-needed relief. By taking away pain medicine the government is inhumanely and barbarically torturing and killing chronic pain patients. The 90 MMEs do not work because not every body is different and the same dose that works for one person won't work for another. If all our bodies were the same, they wouldn't ask how much you weigh to calculate how much anesthesia to give you for surgery or dental procedures. The CDC and the government need to get rid of the 90 MMEs and the guidelines before more chronic pain patients die in unbearable, excruciating agony. I am one of those chronic pain patients that have to live in horrible never-ending agony and I don't know how much more strength I have left in me to keep fighting to live. I do hope I'm around long enough to see the CDC and the government realize what a horrible mistake they made and that, because of that mistake, they have the blood of all the chronic pain patients that died in horrific and completely unnecessary pain, on their hands, and that they take into consideration how many more chronic pain patients they'll be condemning to death by not changing the guidelines. I hope I live to see the day the government will start treating chronic pain patients like our pain is valid and we're not all addicts looking for the next fix. The government needs to stop punishing the millions of chronic pain patients because of the opioid crisis and instead turn their attention to the illegal street drugs like fentanyl, that the CDC has admitted is causing most of the overdose-related deaths. Pain medicine and chronic pain patients are not the enemies in the opioid war, WE ARE THE INNOCENT VICTIMS, and I really hope I live to see the government realize this and start protecting me and my millions of chronic pain brothers and sisters instead of condemning us to a life of unspeakable, unbearable pain and eventually death. Chronic pain patients need pain medicine, not because we're addicted to it, because for many of us, that's the life-saving medicine that allows us to raise our families, to work our jobs, to visit with friends and family, and basically live a life that isn't filled with the horrible excruciating pain that we live with every second of every day... We just want to live.

Thank you,
Lisa S. Reed

From: Laura Richard
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 6:58:45 PM

To the powers that be at the CDC,
As a chronic pain patient, and disabled former trauma nurse, I am greatly concerned with the status and changes your recommendations have made to not only myself, but pain patients everywhere.
We are not "cookie cutter" patients. Our pain is real. We are forced to jump thru hoops every month to get our meds. We pay to see a dr, take frequent drug tests, and have had our dosages cut to a 90 mg/day limit that you all deemed fit for all. We have been blamed for the opioid crisis, yet if you watch the "to catch a smuggler" program, it's obvious the opioids are coming in from other countries.
So, why are pain patients the one's that are constantly suffering? If my meds are lowered again, I will be bedridden. I will have basically NO life with living. Why is this not left up to our pain management dr's?
I sincerely hope you all get out of the equation, because you are the one's hurting the people who need these meds in order to have a functioning capability.
Sincerely
Laura E Richard

From: Louise Schwartz
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:52:52 AM

To whom it may concern:

The guidelines continuously use the term sub-acute or chronic pain yet do not give a definition of what they consider chronic pain to be. There are many people who have low back aches, leg cramps, and neck discomfort that they or their physicians call chronic pain. At the same time their are rare conditions such as Complex Regional Pain Syndrome where victims suffer a level of pain that they describe as continuously having boiling oil being poured over their (arm, leg, foot) or red ants crawling through their skin while electricity is coursing through the area. Some victims of this syndrome have flares of this torture while others like myself have this acute level of pain 24 hours a day, 7 days a week. Personally I have had 12 injections a day of nerve blocks in my neck, implantation of devices that course electricity to my spine (SCS), IV medications, nerve medications that are as addictive as opioids(ie. Gabapentin), others medications that gave me side effects ranging from dizziness, double vision, extreme exhaustion, nausea and vomiting, severe headaches and more, mirror therapy, biofeedback, desensitization, and yet the only treatment that actually made the constant acute burning tolerable was opioids. I was on a dose higher than your “ guidelines” but once I got to the dosage that made my pain tolerable I never had to increase it and took the same dose for over 20 years. I was able to work, raise a family, and contribute to society.

Then 2016 your guidelines came out and Insurance and the DEA forced me to reduce my dose. I now spend my nights crying and screaming in horrendous pain. The pain wakes me screaming from sleeping pills that give me a couple of hours of sleep on a good night. I am 69 years old and only want to see my grandchildren grow up. I had 4 doctors recommend the Intrathecal Pain Pump but because of your guidelines Workman’s Compensation Insurance has continuously denied it using a paid “pain specialist “ and your guidelines as evidence that no-one unless they have cancer should have the dosage of opioids they need to make their intractable pain tolerable.

Well according to medical experts through the McGill Pain Scale, my condition, CRPS is more painful than cancer, sickle cell, trauma, or the later stages of childbirth.

I agree that we need oversight to make sure patients aren’t being prescribed opioids for conditions that should get NSAIDS or Tylenol and that due to pharmaceutical companies pushing opioids as non-addictive, they were over prescribed but people like myself who have rare chronic and intractable pain with no cure should be allowed to have treatments they need and are prescribed by pain specialists, even if it is opioids over the arbitrary limit set by the CDC.

From: Linda Silverman
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:52:35 PM

Hello,

I am a 74 year old woman who has been treated for chronic pain for the past 3 years. My pain is due to stenosis and complicated by scoliosis both in my lower spine. Please for just a moment imagine your foot being held over a flame. Now imagine that you cannot take it away from the flame. My injury being so low have led surgeons I have seen to lead me away from surgery. I do have a stimulater inserted in my back which really does not help much. My pain on a bad day maybe goes up to a 6 or 7 on the pain scale.This is with my meds.

Nerve pain is what I have. It radiates from my toes and anywhere else on my legs or low back it wants to go. Due to my medications, I do have better days. Days when it doesn't hurt to watch a movie or sit in the back yard. Days when I can prepare a meal or sit at the computer and write.

I wish my pain would leave me alone but it won't. Wishing doesn't make it so.

Please before making changes to the strength of a medication or perhaps how many times a day a person can take it think about me and all of the other people like me. We see doctors at pain clinics. Speaking for myself I wouldn't know what corner to stand on if I didn't have these medications. We are real people seeing real doctors. I have to be drug tested! How embarrassing is that?

Please before making any changes to the CDC guidelines think of me and the burning pain I would have if you do.

Thank you for your attention,
Linda

From: Laura Stanley
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:14:16 PM

I am writing to tell my story of successful opiate use. It involves conservative, closely supervised dosing from a pain specialist who knows me well and works in close partnership with me and my other physicians.

I suffer from polyneuropathy, meaning both the peripheral and central nervous systems are implicated. It is a consequence of advance Sjogrens disease. The pain is relentless and chronic, and affects me all over my body: skin, hands and feet, legs and arms, hips, face, mouth, and eyes. There was a time that it disabled me so profoundly I wished for death. But that's changed as a consequence of superb pain management, which includes careful dosing of two narcotic drugs, tramadol and methadone. To be clear, I still live in pain. I still have days when I think I can't bear it anymore. But, for the most part, I can enjoy a quiet life that wasn't possible before.

It saddens me deeply that, under the Updated Draft Guidelines released July 16, other pain patients will struggle to find their way to the kind of care that has helped me so much. I am able to use opiates safely because my doctor has helped me understand how these drugs work, and the grave risk I run if I deviate from the protocol I am on. It took the two of us 4-6 months to achieve a regimen that works for me, over which time we learned to listen to and trust each other. Now we meet once a month, to review my symptoms and assess my needs for the coming month. We discuss my lifestyle and life events, overall health, even the weather—anything going on that may be triggering or relieving pain. We have experimented with every complementary and alternative method that I am comfortable trying, including acupuncture and hypnotherapy. My pain specialist is up to date my progress on rheumatological therapy, and has a close working relationship with my neurologist and PCP. The benefits to me are more than physical. I feel seen, heard, and cared for, which is as critical to my survival as any of the medicines I take.

This personalized approach is the opposite of what many—maybe most—pain patients experience. They work with physicians who are not expert in managing pain and cannot, will not, or are not permitted to prescribe opiates as part of a holistic pain management strategy. To deprive these sufferers of care that could make their lives livable—and by this I mean not just the drugs, but the support that can and should go with—is frankly inhumane.

Laura Stanley
84 Norfolk Road
Southfield, MA 01259

From: L Lee taylor
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 5:00:34 PM

You just don't learn! What do call insanity, oh yeah, insanity is doing the same thing over and over again and expecting a different result! You have caused millions of people to suffer unnessiarily and we are still suffering. The CDC has no business dictating the course of pain treatment as pain 8s not a disease. Your quidelines have resulted in patients being stigmatized, denied care, tapered off of or abruptly stopped thier safe and effective medications with not a care or concern in the world for these patients. Doctors lie to and about thier patients. The DEA has adopted and weaponized your guidelines using your rediculis mme equivalents as a hard line. If a Doctor prescribes over that hard limit his office is raided by swat teams of DEA agents, patients records are siezed along with all the Dr's assets as patients cower in fear of being shot by the DEA agents in the waiting room. These patients are immeadilty deemed "drug addicts" and are black balled from all opioid medications by all other doctors for the rest of thier lives. Some are prescribed the addiction drug Suboxone, which does very little, if anything for pain and is 10 times harder to stop. The DEA goes through patient records (hippa be damned!) to see how much medication was prescribed and if they decide 2 tablets a day are enough and you were prescribed 4 you are immeadilty guilty of diverting and abusing your medicine with your doctor guilty of over prescribing.

So by all means let's have more of the same! Let's have people suffer until they can't suffer anymore and commit suicide! YOUR FALACIES ARE LITTERLY KILLING PATIENTS. We don't need more of the same, as a matter of fact, we don't need guidelines or anything else from the CDC. Pain is not a disease RECIND THE GUIDELINES, BACK OFF AND BUTT OUT OF MY DOCTORS OFFICE. CALL YOUR DOGS OFF TOO (DEA). You have done enough harm to patients.

Sincerely, with the utmost discust and dismay,
Another One Who Suffers Needlessly.

From: Linda Turner
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 1:45:57 PM

Hello. Thank you for giving me the opportunity to include my letter for this very important issue on the cdc opioid prescribing guidelines and the urgency for needed changes of the current guideline.

I am a chronic pain patient whose life has been, and continues to be, greatly improved with opioid medications for over 20 yrs. My chronic and painful conditions are the following: a constant, severely painful progressive autonomic small fiber neuropathy, spinal arachnoiditis, spondylolisthesis/unstable spine and with adjacent level breakdown below fused spine with instrumentation, failed back surgery, spinal stenosis, radiculopathy, and fibromyalgia, and sjogrens-like syndrome. These conditions were diagnosed and validated after multiple, repeated, medical objective testings and corroborated by many experts of their fields including in neurology, orthopedic, infectious disease, Neuro-radiology, and pain medicine, and from some of the most prestigious medical centers, as well as from my internal medicine, primary doctor of 30 yrs.

I am that person that does not like to put ‘anything’ in my body that is not natural unless absolutely necessary for my physical and medical well being, and then only after having tried the least of. Over many years, specialists in their fields have tried different medications types and these were either unable to sufficiently treat my severe constant and chronic pain and/or resulted in intolerable effects, including non-opioid medications with dangerous long term use effects (and many not safe for chronic/long term conditions). After all else tried, the opioid pain medication treatment was the only treatment that gave me sufficient relief and without any intolerable side effects like all else tried. I’m able to not only live without excruciating constant pain but able to have a quality of life that would not be possible otherwise. Opioid pain medication has been a Godsend for me.

Over the 20 plus years being treated for my multiple, chronic, severely painful conditions, I have never experienced any euphoric or “high” type effect, nor have I ever experienced any addictive-type effects from. Although I have been on opioid pain medication for many yrs, I have been able to reduce greatly the dosage amount and have remained on this same amount for over 3 yrs. I believe that this is partly due to my ability to have had my severely painful conditions appropriately and sufficiently treated for all of this time with opioid pain medication and therefore able to continue much needed healthy exercise and ability to move my body, as well as the overall mental benefits of, including a better sense of well-being that one has back with a quality of life and ability to once again have life experiences with family and friends...and at my age, especially grandchildren. Without my many yrs of successful opioid pain treatment, the resultant insufficient pain control over that time would most assuredly have caused me to continue in an increasing consequential dysfunction and disability and overall physical deterioration with decreased movement, and a life in bed, or laying on a couch, and with increased health/medical issues from such inactivity, as well as the physical consequences of unrelenting severe pain, including high blood pressure, which in itself can cause **stroke, heart attack, heart failure and other heart conditions**; cause damage to your kidneys, memory and vision
(https://www.google.com/amp/s/www.hopkinsmedicine.org/health/conditions-and-

diseases/high-blood-pressure-hypertension/resistant-hypertension%3famp=true), as well as a deterioration of mental health and well being (which also effects the physical health) for the obvious reasons of one with uncontrolled, severe, constant pain and the loss of function, loss of enjoyment...in everything, isolation and resulting loneliness, decreased sense of worth, *and so much more.

I'm not uninformed, I'm not unable to make wise and necessary, and right decisions for myself along with the educated/trained expertise of my doctors who know and well understand my conditions and medical history. Nobody else should have the right to tell me and my doctors any different. Would you want that if you were in my shoes? Would you want false and/or misleading information and opinions to interfere with your medical treatment needs and to take away your ability to have your intolerable pain made tolerable and able to have a quality of life? How would you feel about such false information and opinions causing the loss of your quality of life being caused by the allowance of such from those who know nothing about your individual medical conditions and history, including any knowledge of all failed and/or intolerable treatments that you have tried over many years, and from those who are not experts in your medical conditions, and from those who are not experts in pain nor pain treatment, and in addition to, from those who have huge conflicts of interests, including receiving large amounts of money to do and therefore untrusting motives to make sure that their big paydays can continue? Even if you or a loved one of yours have never experienced severe pain, whether acute, subacute, or chronic, one day you will, and if you do not do your part to stop the needless suffering of so many lives due to the 2016 opioid guidelines, I assure you that one day you will so badly wish you had.

Please take this seriously and take action to remedy the existing and very troubling current situation that is hurting and causing the unnecessary added suffering of so many innocent people who simply want to be able to live without intolerable pain and to have some quality of life, and without having to endure inadequate medication and/or medication amounts, and without the very real side effects from other medications (including the causing of very ill-causing, and even dangerous and life threatening conditions) that are not appropriate for long term chronic pain amounts. Everyone has a different story, a different history, a different need, and why it's always been said that every medical case and best and necessary treatment should be INDIVIDUALIZED, and why medical needs and treatment must be between doctor and patient...period. There is of course a means of handling the small % of those doctors and those patients who are not responsible with and/or abusing without hurting the great majority who are legitimate, responsible, and law-abiding treating doctors and their patients who receive great benefit from utilizing opioid pain medications. In addition to this, there is of course, also a means of handling the small percentage of patients who do become addicts from a pain medication prescription (dependence on a medication is NOT the same as addicted to). There are many medications for many conditions where one can be dependent on. Again, this is not addiction. However, not every legitimately opioid prescribed patient even becomes dependent on. But even those who are, what is so wrong with that? It's just something that can naturally occur with so many different types of medications treating many people's lives for many conditions who otherwise would be suffering needlessly. I thank God that opioids exist for myself and others who have had great benefit from.

It's difficult enough living with severe chronic pain, so again, please do your part in correcting the wrongs that have hurt legitimate pain sufferers and their families. One day it could be you or your loved one suffering from severe chronic pain. Every person should have the right to have medication that enables them to have their pain tolerable and quality of life, and with their doctor, the decision of what that treatment/medication should be. Doctors need to again put the needs of their patients first and not put in the position of having to choose between that and fear of their practice ruined. Please don't let this go on deaf ears and nothing done to help all law-abiding legitimate pain sufferers. Do your part to help undo the damage that has been done and make it right. Another day that goes by that this doesn't happen is another day of causing needless suffering for so many.

Sincerely,
Linda Buckley

*
https://www.google.com/amp/s/coloradopaincare.com/chronic-pain-and-heart-disease/amp/
Long term chronic pain can produce severe stress and anxiety, which in turn can elevate blood pressure and pulse rate. Elevated blood pressure and heart rate over a sustained period can damage the heart leading to **cardiac arrest, stroke or death**.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614505/
"Untreated pain has a profound impact on quality of life and can have physical, psychological, social, and economic consequences. Inappropriately managed acute pain can **result in immunological and neural changes**"

https://www.nursingtimes.net/clinical-archive/pain-management/understanding-the-effect-of-pain-and-how-the-human-body-responds-26-02-2018/
"Pain therefore increases heart rate, blood pressure and respiratory rate. **If** these physiological responses are prolonged, especially in **a** person with poor physiological reserves, it **can** lead to ischaemic damage (Wei et al, 2014).Feb 26, 2018"

From: Lyn Wall
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:49:46 PM

Many people, like my husband and myself suffer from chronic pain and we have a terrible time getting enough relief to function normally because it is so hard to get opiods and tramadol due to the opiod epidemic. Many of us have used opiods responsibly for many years without addiction, withdrawl or turning to street drugs.

We should not be forced to live with excruciating pain when we have proven ourselves to be responsible and use pain medications appropriately. My heart goes out to people who have been affected by the opiod crisis, but responsible chronic pain sufferers are being victimized by the restrictions.

Doctors should be able to prescribe medication appropriately without worrying about going to jail for helping a chronic pain sufferer.

From: Lea Williams
To: NCIPCBSC (CDC)
Subject: Comment: Updated Draft Opioid Prescribing Guideline
Date: Thursday, July 22, 2021 2:46:37 PM

July 22, 2021

Updated Draft CDC Guideline Comment

Submitted via email to: ncipcbsc@cdc.gov
Date emailed: July 22, 2021

As an individual with years of CHRONIC PAIN I find the new CDC UPDATED GUIDELINE does little if anything in the way of treating a chronic pain patient with opioid medications – the medication for me that was very successful in giving me a quality of life, increased functioning, better mobility, decreased pain under the care of my physician.

Unfortunately, when I relocated a new physician decreased my chronic pain opioid substantially to almost nothing not even taking into consideration that what I had been prescribed NOR did that physician take the time to listen or verify with my previous physician – Medicine At Its Worst. Now, due to the decrease in a medication that works I have constant daily chronic pain, decreased mobility, a loss of quality of life. Instead, a patient is made to feel like they are a drug seeker, a criminal and worse. Alternative therapies have not worked.

The CDC did not discuss NOR INCLUDE the fact of the benefits when opioids are used appropriately (which, by the way I have but have now been reduced to almost no medication). For chronic pain patients to be treated like this is despicable. Chronic pain patients such as myself should not be subjected to treatments/medications that have not worked costing me out-of-pocket monies. It is well known that chronic pain patients are put through treatments that do not work or are not covered by insurance.

There is substantial research that OPIOIDS WORK WHEN USED APPROPRIATELY but the CDC, along with other drug regulatory agencies and state regulatory agencies have induced fear of prescribing to physicians. Many will no longer accept patients with chronic pain, some physicians will tell a new patient outright that they do not prescribe pain medications.

As a result of the guidelines currently in effect many chronic pain patients who have had their medications discontinued have resorted to, unfortunately, illegal street drugs often fatal. Yet, the CDC FAILS to take that into consideration. CDC also FAILS to take into consideration that some chronic pain patients due to no longer being prescribed opioids (which worked well for them & they did not abuse) take their own lives. CDC FAILS, in my opinion, to consider that most opioid abuse is by illegal use/abuse. Instead, CDC has, with bias, targeted the chronic pain patient.

Supposedly, in 2019 the CDC publicly acknowledged the “misapplication” of the guideline and promised to make changes yet pharmacists, physicians and other prescribers have failed to correct the “misapplication of the guideline”. By copy of this comment, I am requesting that the CDC IMMEDIATELY publicize, notify all prescribers as well as the media of the “Misapplication of the Guidelines” in hopes of correcting the wrongs of CDC.

That the CDC makes these biased regulations including those in the UPDATED GUIDELINE is truly horrendous and is a “tremendous detriment” to the patient with chronic pain. CDC a while back stated some of the guidelines were being misapplied. I invite the CDC to tell physicians this in a manner that they comprehend and understand to STOP the bias against the chronic pain patient.

That the CDC makes NO MENTION therapeutic options in the NEW GUIDELINES is reprehensible.

The CDC DRAFT GUIDELINE NEEDS to be written in a such a manner which includes Therapeutic Options as well as having an UNBIASED workgroup. No individual in the group should be biased or have a conflict of interest with regards to opioids.

The CDC needs to ask themselves how they would feel like or “What It Feels Like to be Me Today” when your opioid medication has been discontinued or significantly decreased to the point you suffer with daily chronic pain to the extent of not being able to do anything on any given day, have a low quality of life, decreased mobility, unable to do things that were once a part of what you enjoyed BUT THANKS to CDC are no longer because a physician discontinued/reduced your opioid medication.

I invite all of the CDC and workgroups to experience the CHRONIC PAIN we go through each and every day. I would not wish this on anyone and I’m confident others wit chronic pain are in agreement.

In closing, the CDC should be mandated to be thoroughly transparent with regard to the development of the Updated Draft CDC Guideline including the AVAILABLITY of the entire written Updated Draft CDC Guideline. It is well overdue that the CDC starts listening and taking into consideration all that chronic pain patients have to say instead of being biased against them.

Respectfully submitted,

Lea Williams

Connecticut

From: Lesley X
To: NCIPCBSC (CDC)
Subject: OPIOD WORKGROUP July 16th MTG PUBLIC COMMENT
Date: Sunday, July 18, 2021 7:46:02 PM

I’ve been a Registered Nurse my whole adult life working in all areas of nursing from the elderly, oncology, surgery, critical care, nurse education, home health/hospice and school nursing. I spent years improving my skills and continually learning and was thrilled to finally receive my Masters degree in nursing because this meant I can do more for my patients, hospitals, education and my community. I had high hopes and aspirations. My dreams as a little girl becoming Florence Nightingale had finally come true. Until one fateful day in 2008 when I was caring for a dying woman in a coma and short on help (which wasn’t unusual). I asked my peer for assistance to turn my patient to make her comfortable. We lifted my patient and consequently I suffered bilateral knee injuries. The pain was excruciating. I had 3 knee surgeries soon after and was put on light duty. After about a year of physical therapy and every measure possible to make myself stronger while suffering in pain, I was released back to work. Soon after I unfortunately suffered a second work related injury except this time I shattered two vertebrae and once again I was soon back on the surgery table and another 2 years of healing and strength building. I was never able to return to hospital work and spent the next 13 years disabled and trying to live a quality life while suffering with severe chronic pain and anxiety. During this time I also developed some health issues as most people do with chronic illness.

Fortunately, I've been able to return to work, in some measure, in my community community but still live in pain daily. Without pain management this would not be possible. I also suffer from chronic anxiety and see a therapist twice monthly as well as visit my pain management doctor monthly and my primary doctor every 3 months. I eat healthy, exercise regularly and still just barely make it through my days due to pain.

Since the publishing of the 2016 Guidelines and their subsequent misapplication, my medications have been reduced both by my health insurance prior approval process, as well as the DEA, and state medical board's intimidation of my exceptional pain management physician. I'm fearful that soon my medications will be non existent due to the restrictions and fear from the doctors and pharmacists to relinquish opioids due to this "opioid crisis".

I beg whoever reads this, to please have compassion on those of us who just want to lead ordinary lives, work hard, contribute to society, enjoy our family and friends and not be a burden to our loved ones or the government. To accomplish this, I rely on pain medication. I’ve tried and still do alternate types of pain relief but nothing works as effectively as pain medications. That’s what they were created for. Please don’t treat me and others like me as abusers and addicts. That’s the real problem. Not persons like myself. I challenge you to differentiate between us and don’t treat us as abusers. Your war on opioids has left a stain on all of us who suffer and those that abuse…continue to do so. The problem is not getting resolved in fact it seems worse. Not to mention the suicide rate increasing in those populations of chronic pain patients because they can no longer live with their suffering.

I will not stop writing and educating everyone I can on what the true crime is...our rights to a fair and pain free life because of those that abuse the system and the powers that be not seeing the difference.

Please cancel these CDC guidelines altogether, or at least eliminate the illegitimate, unscientific MME numbers for chronic pain sufferers, and suspend the current guidelines until the revised guidelines are finalized and published.

Please hear our cries and help us. Don’t make us suffer any longer.

In hopes of compassionate changes,
-Lesley C.
CPP (chronic pain patient)
Registered Nurse
Voting U.S. California Citizen

From: lisagoeagles
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:31:46 PM

Despite a diagnosis of Stage Two Breast Cancer, at age 40, I was determined not to let cancer stop me from working, and continued my full time employment throughout six months of chemotherapy.

Approximately 5 years post chemotherapy, my disc degeneration began.

The first 3-4 years of Degenerative Disc Disease, I took approximately 4-5 ibuprofen, several times daily, just to keep working.
...And to avoid prescription pain medication.

After my Assistant Pastor explained to me how he almost died from internal bleeding due to similar doses of ibuprofen, I swallowed my pride and made an appointment with
my doctor about my pain.

What followed was 18 months of trial and failure: Involving 35+ alternative forms of pain management.
- The only effective pain treatment for me, unfortunately, was found to be a prescription narcotic Pain Medication at over "90MME".

I am on Medicare and suffer from Multilevel Degenerative Disc Disease with Radiculopathy. Throughout my entire spine are Bone Spurs. Nearly every Disc, within all 3 levels, is Herniated.

I have been diagnosed as having Severe Forminal Stenosis, Vertebrael fractures, Severe Disc Space/Hight Loss, Scoliosis, Anteriolisthesis, Spondylolisthesis, Cervical Dystonia, and so on, up and down my vertebral/spinal column.

I experience electric-shock-like nerve pain, at random intervals, throughout all 4 limbs.

I am not a surgical candidate due to severe osteoporosis and vertebral degeneration.

I am only 54 years old. My condition will worsen over time.

These current CDC recommendations, to fight addiction to opioids, STILL have not included allowances for people like me.

I've never felt "a high" from my narcotic pain medication, nor the urge to take more than prescribed. It does not make my brain fuzzy like so many other medications tried (Ex: Gabapentin).

I was forced to taper by a new pain doctor after the 2016 CDC letter went out.
I had been working out 3 times a week, prior to the taper, to strengthen my core muscles.
After 3 months of slowly tapering my pain medicine, (still over 90 MME however), I could barely turn over in bed, or make it to the bathroom. The pain was unbearable before the physician would make an exception to those CDC guidelines.

If my Pain Management Specialist/Anesthesiologist is forced to cut my pain medication below 90MME,
my body will become a torture chamber.

A medical doctor should be allowed to use their education and professional judgement in managing a patient's severe degenerative pain.

Please stop the war on pain patients.

Please consider what you would want for your family member, if they were forever in pain.

Sincerely,
Lisa J.
Colorado
U.S.A.

From: melissa adams
To: NCIPCBSC (CDC)
Subject: CDC Guidelines
Date: Friday, July 23, 2021 8:41:51 AM

To whom it concerns,

You guidelines on Medications for pain is harming my quality of life. I have severe stomach issues and now can’t take Motrin and related medications; and Tylenol. I have now lost 31lbs because I can’t eat right without getting sick. I have EDS, get inflammation of my GI track, my right kidney has issues, Chronic Pancreatitis, and already had most of my large intestines out. They might do surgery again because of the pain and issues. Because testing is taking a long time since January. My score is high and many doctors are worried about the score not the pain. My quality of life went from working out, working, and spending tons of time with my family. Now I am stuck in a bed with 4 walls because of pain. If you want to do a study or have me do one on quality of life of those with chronic pain with and without pain medications I can do it or you. Because something has to be done. I already have a published peer review article on Quality of Life of Food Allergic Children. https://pubmed.ncbi.nlm.nih.gov/28017626/. I also have a dissertation Gender Roles and Career Decisions-Making Self-Efficacy in the Civilian Military Spouses. So I have no trouble doing this or you can. I read about people committing suicide due to pain. Stats show it’s the illegal drugs that cause the majority of overdose. I don’t understand on making people with medical information and testing showing they are in pain not having access to medications that would help them feel better and improve their quality of life. Please redo you guidelines.

Melissa Adams PhD.
--
Thank you, Dr. Melissa Adams

From: michelle cowin-gantz
To: NCIPCBSC (CDC)
Subject: pain management
Date: Wednesday, July 21, 2021 5:49:28 PM

I would like to give you a very short background on my issues before I tell you about my pain management or lack there of.
I was born with a genetic disorder named cystic fibrosis.
Cystic fibrosis (CF) is **an inherited disorder that causes severe damage to the lungs, digestive system and other organs in the body**. Cystic fibrosis affects the cells that produce mucus, sweat and digestive juices. These secreted fluids are normally thin and slippery. However with CF they are thick and block organs causing major damage.

When I was born I couldn't breathe and fought for every gasp of breath I could get. At birth my abnormalities were prominent but at that time there was little to no research and depending on where you lived no access to additional health care. So during my childhood I developed multiple cases of bronchitis and pneumonia and terrible, painful GI issues always dismissed as irritable bowels or worse a "schoolitis stomach ache."
Teen years; failure to thrive, unable to gain or maintain normal weight for my height and age. Multiple very painful sinus infections leading to blockage and eventually surgery to remove sinus cavities in the face.
Adulthood pulmonary issues, sinus infections and severe GI DIFFICULTIES. Narcotics prescribed to help with the severe abdominal pain. Surgery to remove my gallbladder that was blocked with mucus. Removal of bilary duct also blocked. Narcotics continued to help control abdominal pain. Chronic disabling pancreatitis. Only treatment nothing eat by mouth for 2-3 weeks, narcotics for pain until the episode passed. Unfortunately, this happened every 4-6 weeks. So years after dealing with this pain and trying to maintain with narcotics with emergency doctors who were unfamiliar with cystic fibrosis and chronic pancreatitis that they often labeled me a drug seeker. So I would continue throwing up and screaming in pain. Finally I sought help from Transplant doctors at VCU. They removed my pancreas, spleen, 1/3 of my stomach and my duodenum. After surgery things actually got worse my kidneys failed, my lungs collapsed and I developed delirium. I was on and off the ventilator and in ICU on IV narcotics for 45 days. Then I was moved to the transplant floor for three more weeks. Since this surgery we have found that I suffered nerve damage, painful internal scarring that can only be treated with narcotics. I lost over 70 lbs and was on TPN (feeding through IV) that continually got infected. Each infection was worse than the one before and my entire body suffered sepsis. I again was in ICU and again on a ventilator. In 2021, after continuing to lose weight it was decided that I would have a feeding tube placed. I had several in the past however since my pancreas was removed and my system being completely modified it was difficult to find a doctor willing to do the surgery. So I continued to have pain. Then a GI surgeon felt he could place the tube using endoscopy. However, he punctured my intestines. For two days I was fed formula through the feeding tube that was actually just laying in my abdominal cavity. Extreme pain and fever developed alerted the staff that they needed to respond quickly. They discovered the punctured bowel and the leakage that now poisoned my entire body and I needed emergency surgery to close the puncture and remove the infection, formula and other liquids. I was placed on a ventilator and my family was told that they should prepare themselves because I may not make it. Luckily by the grace of God I did make it! But I required a lot of antibiotics, pain medication and rebuilding after being hospitalized and bed ridden for nearly three months.
I came home and had developed severe lower back pain. It was thought to be as a result of being inactive for so long. However further testing revealed discitis an infection in the discs in

your spine. I am currently taking oral and IV antibiotics to treat this as well as narcotics to combat the pain. I had to be admitted for over a week to attempt to gain pain control because it is so severe. After leaving the hospital and coming home I developed a fever and low blood pressure and was rushed to the hospital. The diagnosis pneumonia and acute respiratory failure and I was placed on a ventilator. 2 weeks later my blood pressure dropped to 74/53 and I was taken to the hospital with acute kidney failure. I am now home treating all of these issues and the chronic pain. I go to a pain management clinic who prescribes all of my narcotics. I have a home health agency that sends a nurse twice a week to take labs and change dressing and check on my twice a day IV antibiotics. I work with an OT to strengthen my upper body so that I can care for myself more freely. I have a physical therapist twice a week to help rebuild the muscles that have diminished. I also have a nursing aide who comes to help me with a shower and bathing.

I take pain medication every 4 hours to maintain as much pain control as possible.

Now that you have heard my struggles surely you can understand why I might need access to narcotics to maintain my daily living. I ask you to please consider me and others with illnesses like mine when deciding about the availability of narcotics. Know that I was a professional licensed counselor until 2016 when I could no longer work because of my frequent attacks and severe pain. There must be allowances for patients such as myself.

Sent from my iPhone

From: michelle cowin-gantz
To: NCIPCBSC (CDC)
Subject: Re: pain management
Date: Wednesday, July 21, 2021 5:50:56 PM

I apologize I just sent an email without my signature. Michelle Rae Cowin-Gantz 571 274 8380

Sent from my iPhone

> On Jul 21, 2021, at 5:49 PM, michelle cowin-gantz <bargainfamily@icloud.com> wrote:
>
> I would like to give you a very short background on my issues before I tell you about my pain management or lack there of.
> I was born with a genetic disorder named cystic fibrosis.
> Cystic fibrosis (CF) is **an inherited disorder that causes severe damage to the lungs, digestive system and other organs in the body**. Cystic fibrosis affects the cells that produce mucus, sweat and digestive juices. These secreted fluids are normally thin and slippery. However with CF they are thick and block organs causing major damage.
>
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and again on a ventilator. In 2021, after continuing to lose weight it was decided that I would have a feeding tube placed. I had several in the past however since my pancreas was removed and my system being completely modified it was difficult to find a doctor willing to do the surgery. So I continued to have pain. Then a GI surgeon felt he could place the tube using endoscopy. However, he punctured my intestines. For two days I was fed formula through the feeding tube that was actually just laying in my abdominal cavity. Extreme pain and fever developed alerted the staff that they needed to respond quickly. They discovered the punctured bowel and the leakage that now poisoned my entire body and I needed emergency surgery to close the puncture and remove the infection, formula and other liquids. I was placed on a ventilator and my family was told that they should prepare themselves because I may not make it. Luckily by the grace of God I did make it! But I required a lot of antibiotics, pain medication and rebuilding after being hospitalized and bed ridden for nearly three months.

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Sent from my iPhone

From: Janie Cole
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:43:40 PM

To whom it may concern,
I am a chronic pain patient writing to give you my opinion on the CDC guideline of 2016 and the Updated version of the guidelines.
It seems that the benefits of opioid therapy have been overlooked in the prescribing guidelines.
I am a 60 yr old woman with degenerative arthritis in my back and throughout my body. I have an foot and ankle condition that is EXTREMELY painful. A smalk bone on the top of my foot has rotated to the underside of my foot and is a very complicated operative fix. My right knee is beyond bone on bone and needs replaced but due to lymphedema surgery is not an option.
Pain meds give me some relief. I can not imagine cutting my daily dose down from 90 mme to 50. There is no reason to treat legitimate pain patients like addicts. They are two separate medical conditions and should be treated as such. A person with more weight and more pain will need more mme's than a smaller person. It should not be a blanket dose for everyone. That is the equivalent of saying all Diabetics should take a set amount of insulin. That is obsurd.
Please take the well being, quality of life and need for pain medicine into account while making these very life changing guidelines. Suicides among pain patients have increased because of lack of pain relief. I am not ready to die when there is a medically safe medicine to help the quality if my life.
Thank you for your time and consideration
Melissa Jane Cole
Box 675
Council Idaho 83622

From: Mike C
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 3:16:54 AM

I am a RN, CCM and have had AIDS for 25 years with painful peripheral neuropathy, L4-5 disc with impingement, torn Rotator Cuff, C3-5 arthritis that I have managed well with opioid medicines for 20 years. I also have PTSD from my time as a captive of the Ethiopian Resistance when I was volunteering for an NGO in Bele Twene Somalia.

When I become tolerant to these meds we slowly reduce my dosage to zero and take a drug holiday to restart at lower doses. This has worked well for me for 2 decades.

In December of 2020 my anesthesiologist was changed with overprescribing and I was left with no medication. He was subsequently found innocent but no longer writes prescriptions due to fear of further reprisals.

In one day I was left with no access to opioids as my Primary Care Physician was too frightened to help me, as was my Neurologist, my Orthopedist, and my psychiatrist.

Unable to get help I was forced to detox at home, alone, with not even a non opioid medication to help ease the detox. I was talking Methadone and Morphine Q6h and had been on a stable dose for 4 years.

As a result I lay on my bathroom floor for 3 days, sweating, vomiting, abdominal cramping, diarrhea, paranoia, anxiety, indescribable pain, and I was even unable to clean myself, so I lay in my own filth for days. On day two I crawled to my closet, retrieved my shot gun from its locked case and loaded a bullet. I just didn’t think I could take anymore, and lay with it at my side “just in case the forced withdrawal got worse”.

After 72 hours of horrid withdrawal the symptoms began to ease and I could keep down water. Then another 10 days confined to my bed in severe mental and psychological distress. I can’t even begin to describe the following months of inability to care for myself and the unimaginable psychological
and physical pain. This experience subsequently increased my PTSD distress, and I can no longer leave my home except to go to the doctor or pharmacy.

When I was finally able to see a pain management physician he refused to prescribe any medication other than Suboxone every 6 hours. The out of pocket expenses went from $27/month to $347/month, and the Suboxone barely takes the edge off my pan. Living on Social Security Disability I was forced to eat rice and beans and whatever I could find dumpster diving.

I would not wish anyone to have the experiences I have been forced to endure, but that was the end result of legislating opioid doses, instead of letting my medical professionals decide the best course of treatment.

Thank you in advance for taking the time to read my story, and I hope it will, in some way, prevent another Chronic Pain patient from having to go through what was worse than the treatment I received as a prisoner of the Ethiopian Resistance.

Respectfully,
Michael Cummings RN, CCM

Sent from Mikes iPhone

From: Marsha Eddy
To: NCIPCBSC (CDC)
Subject: NEEDS of CHRONIC PAIN PATIENTS
Date: Wednesday, July 21, 2021 10:39:18 PM

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1. HOW - and when - does the CDC plan on addressing care for severe chronic-pain patients who require opiod medications amid this current climate of demonization of narcotic prescriptions, along with those who must rely on them for pain relief and quality of life?

2. CAN, and DOES, the CPC plan on interjections into decisions, made by unqualified politicians, that DENY medically sane pain-control to chronic pain patients?

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Published CDC "guidelines," intense nationwide media coverage, and ambitious politicians -- with a backdrop of high numbers of drug overdoses and deaths -- has created a NIGHTMARE scenario for the millions of Americans who depend upon their physicians to issue Class II narcotic prescriptions for a variety of legitimate medical conditions.

We have not just been ignored; We have been attacked and abandoned.

And we are suffering -- and DYING.

If not from the conditions and injuries that cause our unrelenting pain or from symptoms of withdraw, then from the intense PAIN ITSELF (which can cause strokes and other fatal medical scenarios) or from acts of "self-mercy."

For NO ONE can LONG tolerate ever-present intolerable pain.

We are simply not equipped, or intended, to do so!

Revised or re-written CDC guidelines providing STRONG SUPPORT for issuing tightly controlled and well-monitored Class II narcotic medications to properly evaluated chronic pain patients (as required) and with promising PROTECTIONS of issuing physicians --

which are then WIDELY PUBLICALLY BROADCAST both within and without the medical communities --

would go far in repairing the unintentional damage caused by the earlier (incomplete) CDC guidelines.

From: MARY DONIS FOUGHT
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:08:02 PM

To CDC:

I am writing about the updated guideline for opioids and its features below: In the new guideline there is:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

As a fibromyalgia patient, I know the benefit of opioid pain relief. The Percocet pills I take, and have taken for many years, definitely ease my pain and definitely make my condition bearable. I use my Percocet pills judiciously and do not share them with anyone. I hide them when strangers are in my house. It is not right that my right to pain relief via an opioid drug might be curtailed because other people misuse opioids. Sincerely, Mary Fought

From: MONTY GODDARD
To: NCIPCBSC (CDC)
Subject: FOLLOW ON COMMENT on July 16th OPIOD WORKGROUP MTG
Date: Tuesday, July 20, 2021 6:21:50 PM

To whom it may concern,

Since 1997, my wife, has suffered severe chronic pain due to an incurable progressive bone condition. Since 2003, she has been prescribed opioid medications. Prior to 2016, these pain medications finally provided her a reasonable QOL. With the publishing of the 2016 Opioid Prescribing Guidelines, and their subsequent "misapplication", her medications have been reduced both by my federal employee's health insurance "prior approval" process, as well as the DEA, and state medical board's intimidation of her exceptional pain management physician. She now has no QOL! She is mostly couchbound, enduring constant excruciating pain, and spends too much of her day praying for the "Lord to just take her."

As part of the current updating/revision process, on September 2, 2020, I participated in a one hour long, one on one, OPM facilitated discussion with a CDC representative. With my permission, the discussion was recorded. In it, I provided much factual information about my wife's illness, other pain management protocols she attempted prior to her almost two decade safe and effective use of opioid medications. After being told by the CDC rep, that I could expect the updated guidelines to be published at the end of 2021, I asked for the current guidelines to be suspended, as their existence was causing great harm and suffering to innocent vulnerable pain patients, like my wife. Now, I am hearing the revised guidelines will not be finalized until the end of 2022. WOW!

Please cancel these CDC "Guidelines" altogether, or at least eliminate the illegitimate, unscientific MME #'s for chronic pain sufferers, AND ABSOLUTELY suspend the current "Guidelines" until the revised "Guidelines" are finalized and published.

In conclusion, it is unbelievable, given Dr. Richard Chou's bias AND well documented conflicts of interest, that he is allowed to participate in any meaningful way in this process! You must remove him if you have any hope for credibility.

Thank you,
Francis (Monty) Goddard, CE

From: Michael Hause
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:29:15 PM

Probably my 50th comment ever since the cdc decided to torture millions of us living with life long crippling pain. This will be short. I have several neck, back and feet issues. Surgeries are out of the question due to lack of success.
I was put on opioid therapy almost 20 yrs ago.
I was stable once my dr fount the right.medications and dosages. Don't get me wrong. I TRIED EVERYTHING ELSE UNDER THE SUN TO RELIEVE MY PAIN. NOTHING WORKED.

I WAS FORCED TO TAPER TO A DOSE THAT WAS 20% OF MY STABLIZING DOSE. I AM PRETTY MUSH BEDRIDDEN, I HAVE ZERO QUALITY OF LIFE AND IF I DIDNT GET THE 20% I WOULD PROBABLY NOT BE ALIVE ANYMORE.
WHATS BEING being done to us is criminal and must stop. I BEG OF YOU TO END THIS CRAP.
THANK YOU
MICHAEL HAUSE

From: Malcolm Herman
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:13:10 PM

Sent from Mail for Windows 10

1. Most of the changes in the Updated Guidelines are essentially cosmetic, updating existing language, but making no fundamental changes.
2. There is no change in the scientifically unfounded and arbitrary use of MME dose limits
3. Many physicians have ceased treating chronic pain patients because of the deterrent effect of the guidelines. This will not change.
4. The guidelines fail to rectify or even acknowledge the numerous problems identified by identified by researchers, clinicians, pain management experts, patient advocates, and patients.
5. The guidelines fail to recognize that best practice in pain management is a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options.
6. Drug overdose deaths in the United States rose 29.4% in 2020 to an estimated 93,331, which proves the failure of the CDC approach to drug overdoses. Arbitrarily restricting prescriptions by physicians has clearly failed to solve this crisis.
7. The guidelines penalize chronic pain patients and criminalize physicians, but without a concerted effort to confront recreational drug use, substance abuse in general (including alcohol), the seemingly unchecked flow of fentanyl into this country, the CDC is fulfilling a populist political role but abandoning its medical duties.

From: Maria Higginbotham
To: NCIPCBSC (CDC)
Subject: CDC Opioid Prescribing Guideline Revision-COMMENT-Maria Higginbotham
Date: Wednesday, July 21, 2021 2:29:05 PM
Attachments: cdc letter.docx

To the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) of the Centers for Disease Control and Prevention

Please find attached my public comment regarding the rewrite of the 2016 CDC Opioid Prescribing Guidelines, also written below for permanent records.

Maria E Higginbotham
Vaughn, WA 98394

Honorable members

July 16, 2021

As you know, millions of patients with rare diseases, cancer, hospice and those with medical conditions that cause intractable pain have been adversely effected by laws that regulate the use of opioids to treat pain.

The inception of the 2016 CDC Opioid Prescribing Guidelines brought about significant changes in public policy, insurance regulations and pharmaceutical interventions. These chilling adverse effects have been dubbed “the unintentional harms” by the CDC, the AMA and several other leading medical associations.

Arbitrary limits measured by MME have been adopted by state medical boards, hospitals, pharmacists, and physicians. The DEA has waged an outright war on physicians treating pain patients.

On June 7th and 8th, 2021 the FDA held a workshop named:

“Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions”

https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and

Several prominent physicians and scientists rebutted the efficacy of the utilization of MME to set limits on medication doses. There is no actual scientific proof that MME is an accurate tool. Aspects such as biology and metabolism are important considerations, not valued by a computer calculator.

That tool, MME has taken the lives away from millions of Americans suffering in pain, quite literally causing the deaths of many.

Physicians, so deeply afraid of hostile regulatory malfeasance, are afraid to treat patients with opioids. The DEA has charged, arrested and prosecuted many good compassionate physicians, only because they treated their patients with empathy and compassion by prescribing opioids.

It is agreed, that years ago there were some unethical physicians who operated pill Mills, working the system to benefit themselves financially and contributed to overprescribing and overdoses.

However in the last several years, including those since the inception of the 2016 CDC opioids prescribing guidelines, opioid prescription numbers have gone down, yet overdoses due to illicit drugs continue to rise. Is this not evidence that patients on

opioids are not responsible for the “opioid crisis”?
From the National Institute on Drug Abuse
Overdose Death Rates | National Institute on Drug Abuse (NIDA)
“Figure 4. National Overdose Deaths Involving Prescription Opioids—Number Among All Ages, 1999-2019. The figure above is a bar and line graph showing the total number of U.S. overdose deaths involving prescriptions opioids (including natural and semi-synthetic opioids and methadone) from 1999 to 2019. Drug overdose deaths involving prescription opioids rose from 3,442 in 1999 to 17,029 in 2017. From 2017 to 2019, however, the number of deaths dropped to 14,139”
Even the CDC made a public statement advising against harms created by and due to the Misapplication of their 2016 guidelines
CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain | CDC Online Newsroom | CDC
Quote:
“Misapplication of the Guideline’s dosage recommendation that results in hard limits or “cutting off” opioids. The Guideline states, “When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should… avoid increasing dosage to =90 MME/day or carefully justify a decision to titrate dosage to =90 MME/day.” The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.”
Yet nothing was done to stop the massacre of pain treatment in this country!
The fact is, the CDC’s opioid prescribing guidelines have been nothing more than an absolute failure causing the destruction of pain care to our most vulnerable population.
Our battle with addiction should be against illicit drugs such as heroin and illegal fentanyl. Drug dealers and cartels are responsible for our rise in overdoses. The DEA should refocus its efforts on true criminals. Even the DEA reports that illicit drug activity is presently to blame for the unusual high number of overdose deaths in our country.
Patients, once treated under the ever watchful eyes of their physicians, have been forcibly tapered off their stable doses of opioids, many completely abandoned. These patients were forced to choose to live in agonizing pain, many committed suicide, and others went to the streets for pain relief.
This is unacceptable in the United States of America.
Pain control is a human rights issue. Patients should not have to suffer in such pain.
Even the AMA, the most prestigious medical association in this country refuted the 2016 Guidelines
Stating:
“The AMA called for CDC to remove arbitrary limits or other restrictions on opioid prescribing given the lack of evidence that these limits have improved outcomes for patients with pain. Rather, they have increased stigma for patients with pain and have resulted in legitimate pain care being denied to patients. “Hard thresholds should never be used. Where such thresholds have been implemented based on the previous CDC Guideline, they should be eliminated,” Dr. Madara wrote”
AMA urges CDC to revise opioid prescribing guideline | American Medical Association
The CDC, after 5 years of seeing the harms created by its original guideline, is presently working on a revision, expected to be finalized in 2022.
Unfortunately this comes way too late for many patients.

Just this past week, a prominent civil rights attorney committed suicide due to lack of pain treatment.
We are not expendable humans.
We are loved, and we love.
Most of us have tried every available treatment alternative, after failing, finding relief from our pain through opioids. We sign pain contracts, we submit to UA's which not only test for illicit drugs but verify our correct usage of our opioids. We submit to random pill counts at a moment's notice. We are treated as pariahs, with bias and hostility for only having been blessed with bodies that are diseased and in pain. Lives we did not choose but are forced to endure.
We want quality of life, to be able to pick a flower in a garden, to walk our dogs down a country road, to cook dinner for our loved ones, to volunteer our services in the betterment of life. To be active members of our society. Not forced to watch life pass us by from our beds, hospitals and or doctor's office. Having multiple diseases requires the involvement of many physicians, many doctors' appointments. It takes a lot to keep up with.
You can see from the attached "Observations of the Opioid Workgroup "that the revision of the CDC guidelines is in process.
Ultimately many things, important issues such as MME limits which have created the most harm to patients due to their differences in biology, metabolism and genetics, are being considered for removal.
The AMA again warned of setting limits on dosages:
D-120.932 Inappropriate Use of CDC Guidelines for Prescribing O **|** AMA
I implore you to ACT NOW.
I suffer from multiple rare diseases. They are both aggressive and progressive. I am slowly losing the connective tissue holding my body together. My pain is horrific. I was personally forced tapered from a stable opioid dose after 12 years, to a dosage that barely touched my pain. Luckily, I met a kind doctor who offered to treat my pain. Unfortunately this kind physician has decided to retire. Soon leaving almost 300 pain patients scurrying to find a replacement physician, knowing none are to be found.
It is near to impossible to find a physician in Washington State willing to treat chronic pain patients. We are screened during initial contact and quickly shown the door. I have great fear for the outcome of these patients, mostly in Pierce County.
I implore you to please address the issue of under prescribing pain relief. It is rampant in both physicians' offices and hospitals. I realize you have previously issued an interpretative statement but it had little effect on physicians. This issue needs to be brought to light. They need to see change, to be able to practice medicine again with compassion and empathy utilizing the skills taught them in medical school.
I'm available to speak at any time and with your help, look forward to a brighter tomorrow.
Respectfully,
Maria Higginbotham
P3
253-381-1783

American Medical Association

Inappropriate Use of CDC Guidelines for Prescribing Opioids D-120.932

Topic: Drugs   Policy Subtopic: Prescribing and Dispensing

Meeting Type: Annual	Year Last Modified: 2019
Action: Appended	Type: Directives
Council & Committees: NA	

1. Our AMA applauds the Centers for Disease Control and Prevention (CDC) for its efforts to prevent the incidence of new cases of opioid misuse, addiction, and overdose deaths.
2. Our AMA will actively continue to communicate and engage with the nation’s largest pharmacy chains, pharmacy benefit managers, National Association of Insurance Commissioners, Federation of State Medical Boards, and National Association of Boards of Pharmacy in opposition to communications being sent to physicians that include a blanket proscription against filing prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care. A report is due back to the House of Delegates at the 2019 Annual Meeting.
3. Our AMA affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate.
4. Our AMA will advocate against misapplication of the CDC Guideline for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients’ medical access to opioid analgesia.
5. Our AMA will advocate that no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids.
6. Our AMA: (a) supports balanced opioid-sparing policies that are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing practices, minimize workflow disruption, and ensure patients have access to their medications in a timely manner, without additional, cumbersome documentation requirements; (b) opposes the use of “high prescriber” lists used by national pharmacy chains, pharmacy benefit management companies or health insurance companies when those lists do not provide due process and are used to blacklist physicians from writing prescriptions for controlled substances and preventing patients from having the prescription filled at their pharmacy of choice; and (c) will incorporate into its advocacy that clinical practice guidelines specific to cancer treatment, palliative care, and end of life be utilized in lieu of the CDC’s Guideline for Prescribing Opioids for Chronic Pain as per the CDC's clarifying recommendation.

Meetings | BSC | Injury Center | CDC

https://www.cdc.gov/injury/pdfs/bsc/OWG-Report-of-Recs-1-12-06.30.21-FINAL-508.pdf
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P3
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American Medical Association

Inappropriate Use of CDC Guidelines for Prescribing Opioids D-120.932

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Meetings | BSC | Injury Center | CDC

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From: Misty Hoffman
To: NCIPCBSC (CDC)
Subject: 2016 Guidelines Revision
Date: Tuesday, July 20, 2021 6:43:08 AM

I participated in the CDC Opioid Workgroup Zoom meeting Friday, July 16 and listened with hope that the guidelines will be revised so I and millions of other legitimate intractable pain patients can have what semblance of life we had prior to the 2016 guidelines, back. Opioid pain medication above the 90 MME was definitely not the first course of action in my medical treatment. I have Multiple Sclerosis, trigeminal neuralgia (they call it "the suicide disease"), but most painful is the crushed vertebrae I sustained which was made worse by a botched vertebroplasty. Medical grade cement was inadvertently leaked out into my disc space and next vertebrae, then hardened, essentially leaving a rock in my spine. I have tried EVERY non narcotic treatment possible, to the point of bankruptcy, to quell the 24/7/365 excruciating pain, including a spinal cord stimulator. The only thing that quelled the pain was the 330 MME of pain medication I was judiciously using in 2015. I had complete gastric bypass surgery in 2011 so oral meds are less effective, hence, my doctor prescribed a fentanyl patch. I was not "high", not a proverbial "zombie", nor did I ever take more than prescribed, but I was able to be present as a mother and wife. I at least had that since once I became disabled, I have not been able to utilize my college education I worked so hard and paid for. That was taken away from me when the CDC guidelines were applied as defacto law. I am now bedridden most of the time and unable to even enjoy family and friends, or concentrate long enough to read for my book club I had to quit, as it's hard to even read when pain is so tortuous. It's hard to stand to even shower. I've had an hour zoom meeting with the OWG in September 2020 and had hoped this egregious torture would be rectified by now. It is VERY disheartening to know the draft has not been shared and the revised guidelines aren't expected to be finished until the end of 2022. Time is not a luxury chronic pain patients have. We just recently lost another wonderful chronic pain patient, advocate and Ivy League lawyer to suicide, as she couldn't take the pain any longer. There have been many, and will be many more suicides until this is rectified. I was almost one of those but am hanging on, just barely, like many others. We are NOT addicts and these guidelines have NOT helped those that are addicts. Prescriptions are down and overdoses are up, as we have a mental health and addiction epidemic. Addicts and legitimate pain patients require definitively different healthcare protocols. I - WE - urge you to please not let us suffer another year of this. Please get this fixed before the end of 2022. You now know and have evidence of the harms the 2016 CDC Guidelines have caused and know most overdoses are from illicit drugs and polypharmacy, oftentimes mixed with alcohol. Please stop this torture.

Sincerely,
Misty Hoffman

From: [mark ibsen]
To: [NCIPCBSC (CDC)]
Subject: Fwd: 2020 Drug Deaths Spiked 30%. And Pain Pills Had NOTHING to Do With It | American Council on Science and Health
Date: Tuesday, July 20, 2021 6:25:29 PM

Sent from my iPhone

Begin forwarded message:

> **From:** Mark Ibsen <markmusheribsen@icloud.com>
> **Date:** July 20, 2021 at 4:24:42 PM MDT
> **To:** Cdc Work Group <ncipcbsc@cdc.gov>, CDCInfo <cdcinfo@cdcinquiry.onmicrosoft.com>, Senator Jon Tester <senator@tester.senate.gov>, Elizabeth Warren <elizabeth_warren@warren.senate.gov>
> **Cc:** Rachel Maddow <rachel@msnbc.com>, The Maddow Show <email@mail.msnbc.com>, Governor Gianforte Office <governor@mt.gov>, Richard Lawhern <lawhern@comporium.net>, Thomas Revealed <thomasklinemd@gmail.com>, Claudia Merandi <cmerandi1@cox.net>, Terri Lewis <contactdrterrilewis@gmail.com>, Gary Snook <gsnookolds@gmail.com>, Orlinda worthington <orlindal@msn.com>, Phillip Johnson <p.johnson.spear@gmail.com>, Kate Lamport <Katelamport812@gmail.com>, DrMark406 <DMI@drmark406.com>
> **Subject: 2020 Drug Deaths Spiked 30%. And Pain Pills Had NOTHING to Do With It | American Council on Science and Health**
>
> Dear Cdc Work group.
>
> MarkIbsenMD here.
> I have been in a 8 1/2 year conflict with the Montana State Board of medical examiners. In 2012 several patients came to me at my urgent care having been abandoned by their doctor through one circumstance or another. These were patients who were dependent on opiates after being given hydrocodone or Percocet several times a day for several years. I consider these patients to be opiate refugees.
>
> I considered it to be cruel and harmful to abandon patients who had faithfully agreed to a program instituted by their own doctor. The classic scenario would be the doctor retired the new doctor won’t write the prescriptions and the patients was in my office at 6 PM on a Friday in order to prevent going into withdrawal. I did not consider myself to be treating chronic pain patients, I was treating patients with lost access to their doctor which is a “typical scenario”in urgent care.
>
> I was able to help many of these people wean off their opiates using alternative

methods. Most of these patients were also feeling betrayed and upset with a system that abandoned them.

As an ER doctor for 40 years I had kicked the can of chronic pain down the road much of my career.

I had no intention of chronically following anybody. But my Hippocratic Oath requires me to do no harm and, to interrupt harm when I see it happening. I did a lot of that in my ER career,
And my service in remote and underserved areas, working with Mother Teresa in Calcutta, and the Dalai Lama in the Himalayas of zanskar.

The board of medicine in my state did not agree, they accused me of over prescribing narcotics. I was able to prove with no uncertainty that each of the patients who came to me were not started on medication by me and were put on lower doses of medication by me as I helped them see the writing on the wall.

The more I looked into this circumstance I could see that the writing on the wall is this: forces had taken over medicine they were interested in people coming off of opiates-these two groups include anti-opiate addiction doctors who could only see one part of the anatomical elephant that they were treating. They had concluded that opiates caused addiction, and this of course has been debunked. It was obviously not true even then.
The article I have attached documents this but I knew this in 2012.
80% of my patients were able to come off opiates using alternative methods including cannabis. However, 20% of those patients could find no one to take care of them. I was stuck with them because I had a relationship with them. I could not abandon them myself or I would be vulnerable to the same criticism I had to the rest of my colleagues that they were abandoning people after 10 to 15 years of treating pain as the fifth vital sign.

I immediately began to look into this nightmare and patients were having. I was able to find an article from the Institute of medicine from 2011 entitled pain in America a blueprint for change. This article indicated in no uncertain terms that there are 100 million people in pain in America, with a $625 billion impact on the economy. The impact on the individual has been devastating.

https://www.acsh.org/news/2021/07/19/2020-drug-deaths-spiked-30-and-pain-pills-had-nothing-do-it-15669

When the board of medicine filed a complaint against me I was eager to tell them how my successes with patients could be duplicated across the state.
Sadly the board of medicine considered my resistance to their sanctions as some sort of personality disorder.
We had extensive hearings where I was exonerated, yet the board continued there case against me throwing out my evidence. They ultimately suspended my license. The suspension was overturned by District Court judge James Reynolds. The district court judge instead of dismissing the case against me remanded it to

the board and the board has continued to harass me over the years. The stress of this Battle with the board of medicine led to the closing of my clinic, the board of medicine sent Dea to visit me five different times. I was close to bankruptcy, and my health was and is still affected.

The board has continued to impose sanctions against me that are arbitrary and unfair and based on no evidence.
In fact I have evidence that the board of medicine scrambled my documents in order to make a claim of poor documentation against me.

They always seem to impugn doctors‘ documentation when they have nothing else to threaten them with.

As you can imagine this has become the legacy issue of my life.
I kept looking for reasons for this inquisition to be happening. I found lots of evidence that overdoses were related to illicit fentanyl, not prescription medication‘s. In the years since then my inquiries have born fruit.
The article I include here clearly indicates that cutting back on prescription pain relief for patients has led to an increase in overdose deaths. What is not in this article and hasn't yet been documented is the increase in suicides in patients cut off of their opiates.

I have direct experience in this in that six of my patients died at their own hands after my clinic was shut down.

I have an extensive number of videos and interviews with patients in agony which don't seem to get any traction with anybody who sees them. They're very painful to watch.
There is a great documentary about this:

https://www.painnewsnetwork.org/stories/2020/5/25/pain-warriors-a-civil-rights-movement-for-our-time

I have been documenting all of these events repeatedly through local media and national media.

Doctors seem to be easy scapegoats for blaming an out-of-control drug war on patients and doctors. Now unfortunately doctors are out of the picture in pain is being managed by drug dealers.

Unfortunately, and fortunately, human beings tend to forget the impact of severe pain. If we did not have a mechanism for forgetting pain women would only have one baby.

The CDC has been part of a dismantling of the worlds best pain management system.
The CDC guidelines were formed in secret. They were formed with 48 hours of input from those of us who knew a bait and switch game was going on.

It was obvious to me in 2015 when these guidelines came out that they were going to be disastrous. I was part of a small band of doctors who resisted vigorously. It was evident to me many other doctors and representatives from the Washington law group that some secret unscientific deals were being made.

I even said back then it's very sad to me that the CDC was squandering it's impeccable integrity by selling itself out to profiteers.
Who are these profiteers? Dr. Andrew Kehlani and his group at Propp have a financial incentive to lie about opiates. They are paid handsomely to testify against pharmaceutical companies, and they also profit by their associations with Beckett recognize her who manufactures Suboxone. In addition these addiction doctors were on Board of Directors of addiction treatment centers who without any evidence of benefit charge $30-$60,000 a month for addiction treatment. Their incentive is to illuminate opiate some more people will undergo addiction treatment. The other culprits are the interventional pain physicians. They discovered that they were being paid handsomely for invasive procedures, not paid very well for medical management of palliative care.

Asipp is a professional organization representing these doctors. They found that if people lost access to opiates they were much more willing to undergo invasive unproven non-FDA approved procedures such as epidural steroid injections.

Sadly, the culture and the media jumped on some bandwagon thinking that several of these myths were actually true. The classic myth is that of Johnny the high school quarterback who breaks his collarbone when he's 18 received some Percocet, then died of a heroin overdose seven years later and it must've been the Percocet. Heroin and fentanyl have become abundant and cheap. They are affecting white kids in the suburbs. We didn't care about a heroin addiction in the 1980s when it affects the inner city.
Most of the backers of the anti-opiate Crusaders have lost a child to an overdose due to addiction. Percocet is not the cause.

In order to find a successful response to the scourge of drugs one only need to look towards Portugal. They decriminalize all drugs addiction rates dropped crime dropped an addiction is treated as the medical illness that it is in Portugal.

We have already spent $2 trillion over the last 45 years trying to engage in an unwinnable "war on drugs" which actually turns out to be a war on people.

There is a long vast bibliography provided by the lakes of Josh Bloom, Richard Lawhern PhD, Maia Szalavitz, Judith foreman who wrote a book called A Nation In Pain.
Many other authors have delineated this sad abuse of a national agency designed to protect peoples health and not harm them. The CDC guidelines have done nothing but harm patients. I don't think these consequences are unintended either.

I challenge you to take a look at these guidelines and don't even modify them. Discard them. The CDC had no business sticking its nose into the management of pain. Pain does not operate in epidemic formats. Pain is not contagious. In the last several years we have found that stupidity can be quite contagious however.

I don’t think it any revision of these guidelines is warranted. We need to have congressional hearings in order to document the terrible crime that has been committed towards 100 million Americans in pain.

repeal, do not replace

MarkIbsenMD
Helena Mt
406-439-0752

Sent from my iPhone

From: mark ibsen
To: NCIPCBSC (CDC)
Cc: Senator Jon Tester; Elizabeth Warren; Bernie Sanders
Subject: Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research - PubMed
Date: Friday, July 23, 2021 11:48:39 AM

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100 million Americans in pain, $625 billion impact. Probably $1 trillion today.

https://pubmed.ncbi.nlm.nih.gov/22553896/

Sent from my iPhone

From: mark ibsen
To: NCIPCBSC (CDC)
Cc: Senator Jon Tester
Subject: Care of People with Pain - Relieving Pain in America - NCBI Bookshelf
Date: Friday, July 23, 2021 11:59:19 AM

From 2011.

Paid for by tax dollars.
Why are we ignoring this?

https://www.ncbi.nlm.nih.gov/books/NBK92517/

MarkIbsenMD
Sent from my iPhone

From: Melanie Johnson
To: NCIPCBSC (CDC)
Subject: CDC Opiod Prescribing Guideline revision
Date: Friday, July 23, 2021 1:50:47 PM

Dear Sirs:

The guidelines have deeply affected treatment of care for regional complex pain syndrome.
I was forced tapered and then abandoned by physician of 20 years. I was rapidly reduced which had blood pressure at stroke level. (210/125 for weeks) .

When the 2016 guidelines on mme came out. Dr. feared for his license did force taper when medications were controlling pain.

Then insurance company fought paying for the medication on a privately held group policy. We had to get a loan to pay out of pocket expenses to pay for
The prescriptions exceeding 40k. All of this stemmed from the cdc guidelines. The cdc changed the guidelines and insurance company finally started to pay .
Then Dr retired and could not find a dr willing to prescribe the dosage for my quality of life.

I should not have been included in the category from cdc having a rare disease of complex regional pain syndrome.
And forced to reduce tobelow 90 mme .
All of this occurred because of the guidelines that did NOT take into account chronic pain sufferers.
Totally turned life upside down.

These guidelines need to change for all chronic pain sufferers, we were all put in 1 category and not on a case by case basis.

Mrs. Johnson

From: [Marie Lucero]
To: [NCIPCBSC (CDC)]
Cc: [reeose63@yahoo.com]
Subject: Chronic b patients suffering dying from cdc false narratives n false statistics
Date: Sunday, July 18, 2021 3:04:24 AM

Sent from my iPhone I'm writing to let you know as a anti-opioid individual who worked around chronic pain patients there, are people /patients 107million in US with diseases that only if you have these painful diseases will you grasp severity and know The consequences of that pain n suffering!
Triple suicide rates now
Deaths from illicit fentanyl n heroin quadrupled- 4000 percent now

Stop the torture of cpps
You ruined dr/?patient relations
Important to put a couple stats out first off —-only 1.2% have a prescription drug in thier system at the time of overdose death!!!
so there's a statistic to prove that the epidemic is not caused by prescriptions

1.2% have a prescription drug in system at the time of overdose death
I can't say it enough

—and less than 1% addicts to prescriptions... Period fact !!

Patients now not Being able to work no-more..Due to your reckless false deadly guidelines

I can describe to a female like this try being in labor the rest of your life ! that's what some of the diseases feel like every day ,try being in full-blown labor daily!

or A man get hit in your testicles and then try to live a normal life n function!!

it's the only way to make you understand and this is not a joke or Said out of anger but truth no exaggeration...that's how bad the bones and muscles hurt On a daily

and sleep? Forget it ! There is no rest w that bone n muscle pain In joints
the chronic pain that they go through daily and I didn't know this until I got sick myself with several approximately 14 years ago before that I was so ignorant I didn't understand why people took them for fibromyalgia or arthritis or MS n thought they were addicts or abusing boy was I wrong..I want to state I had six major surgeries three of them times I threw half the script in the trash the other three times when I finished I did not ask for no more and I did not get addicted ever in those six surgeries n times that I had surgery ,like I said three of them times I threw actually more than half the script in the trash
I can tell you from being a nurse tech W patients and having family members that had surgery none of us got addicted so that's false It's a low number w an already addiction Gene to addict to any n all drugs sometimes
Once again—-Less than 1 percent addicts to medication fact!

now As I'm—
suffering n praying for death to come many days N can't hold on much longer Tylenol does not touch pain of many diseases n I tried believe me and from trying that useless medication that did not work I got a horrible ulcer and I'm up in our hospital for the ulcer and many have stated the same thing 18,000 approximately on a yearly level die from NSAIDs that's going to rise!
Opioide medication is at the bottom of list as far as deadly anything from cigarettes to alcohol etc
That number is approximately 5000 to 9000 they believe w other modalities but guess what cdc members it causes

absolutely no harm to organs like NSAIDs none!!'
Safe!!!

U know What else was safe now millions and millions of people with mental issues having to take Xanax and drugs like now can't get it due to your guidelines so we have triple suicides

Millions were on anti anxiety meds n prescription meds safely

Now they hv to choose from prescriptions for pain or mental help? They were on it for years in years millions safely that's a fact you cannot take things away from people because I less than 1% choose to abuse something it's ridiculous then you might as well get rid of hamburgers and cheeseburgers from McDonald's because that kills more people from heart attacks and obesity then prescriptions do a lot more
not one responsible majority that is of Pat died from taking both
do you know who die from taking both people who mix it with alcohol and people who intentionally take 20 Xanax 20 pills for pain but they're not pain patients

Their addicts n get it from internet or street
Because the majority of patients do not sell pills they need them to survive if they want to not bite the bullet
Because the majority of patients do not sell pills they need them to survive if they want to not bite the bullet
They r dying off the mixture these are Aga addicts in that less than 1% but more so addicts from street
Or attics on the street that Has to be undone !! Cdc It will reduce suicide rate anxiety is brutal A killer
Why does it have to impact you or someone you love for you don't have any compassion and just look at the stats and do your homework next time
people are suffering mentally or physically and have to choose which one to suffer from ?
it is barbaric
people have never died off of taking their both medicines n both safely and responsibly never
and I know too many to count Esp as a hospital patient worker
I worked 14 Hour days most of my life to support my children n pay mortgage I never took drugs!!
I learned hard way like I said when I started getting sick
The pain was brutal n I took it until I damaged my back n muscles n could not walk n stand nomore Bc. Because I didn't want to get on medicine at all matter fact I don't even like it because it makes me sleepy but at least it took away the pain and I was able to continue to work and then your guidelines came in in the beginning and right away and I've been barely hanging on by a thread and I'm not gonna hang on to much longer I'm not in God's helping me to stay alive because I know he don't want me to kill myself but you're leaving us no choice this is no life there's no quality of life no function do you know what it's like to get out of bed with that much agony where your bones and your body so tired from the pain u feel drugged from lack of sleep n pain

As stated I was ignorant and anti-opioid!!
Please don't be fooled by these disgraceful antiopiode zealots
They ruined your reputation n allowed n enabled deaths

the suicide rate has tripled Esp among vets due to untreated pain even the local news last year reported the skyrocketing suicides especially among veterans in my state which I already knew before the news reported it..

I also knew and heard neighbors and a couple friends who lost their grown adult sons who were on heroin they were roofers and had hard jobs had many back issues they could not get treated for pain n injury I heard from one parent so they sadly chose to relieve themselves w heroin
Or so they thought the heroin sadly was laced with illicit fentanyl
three men died within a week and a half of each other shocking ? No it's normal now n it's qualdrupled - the deaths on street are to many to comprehend due to illicit for tonight and has been since about 2015 and 16 it was never a prescription drugs ever and I wish to God that you would've fact check did not listen to them lying scamming corrupt fraudulent anti-opioid zealots that came and worked with you and lie to you and to statistics prove there lies the numbers prove them liars while they're trying to push the box and which the way it's doing the same thing that you Illegal fentanyl does it's being abused deverted and sold on the street and people are dying from it ...but it's OK because it makes them money ?
but it's not for patients or pain !!!!!it's for addicts so it should not be pushed on any patient n is harsher than heroin...

Back to what’s causing epidemic!!!! N caused it-illicit fentanyl not medication!!! Again three boys in their mid-30s about the same age all due to pain and getting a drug that they didn’t know was filled with illicit powder china white fentanyl from China and Mexico and three mothers and fathers had to bury three adult sons
but they did take accountability unlike today those parents blaming prescriptions instead of their kids actions N illicit heroin in almost all cases not prescription medication
Facts —-
only 1.2% have a prescription drug in their system at the time of overdose death
and you can check with Dr. Vanilla Sihng who you know ! that statistic
and less than 1% addict to prescription drugs
I know for a fact Illicit fentanyl Is killing people and it’s laced in every drug on the street from marijuana to Xanax to heroin in fact it’s again responsible for almost 93 to 98percent of all deaths
the rest of Deaths are due to the other illicit drugs out here like heroin alcohol mix etc
Again 1.2% only have a prescription im system at the time of death

they also found That those have up to 6 to 11 other drugs in system sometimes
that actually caused the overdose death
and not the prescriptions
I also worked with several overdoses and they were intentional and they were alive to talk to me these are people that took 60 something pill 70 something 40 something 56 I remember and the reason they did not die is because they did not mix it with any other alcohol or other drugs I don’t know how they didn’t die but they didn’t I guess they were not opioid naïve and these were intentional so you see there’s another proof that prescription is not causing no epidemic and all the deaths on the street
you by your reckless actions non fact checking n waiting how many years to undo damage? are killing veterans N cpps you’re killing chronic pain patients n left millions suffering
you left millions abandoned and suffering in bed no longer able to work N now having to get on SS
these are not drug addicts s these are actual patients and now the way they’re being treated in hospitals by Drs even cancer patients are being denied medicine
Post op pain patients are denied pain treatment after major surgery
Nurses that I work with telling me that I worked with telling me what’s going on in the hospitals n patients abandoned n getting lawyers to sue and they’re disgusted n guess who’s always blamed the CDC name keeps coming up that you caused it
how can a bunch of intelligent people caus such a reckless harm n death to humanity? it’s barbaric inhumane
Everyone at the CDC everybody involved in us are human beings and have the potential to get in an accident need surgery get an illness it doesn’t make sense that there’s a prohibition on actual humane medicine that is a godsend to human beings in agonizing pain even vets are complaining that they can’t keep their animals pain control now for fear that person may take the meds are we kidding cigarettes kill half 1 million people a year we’re not taking cigarettes away liquor kills approximately what 90,000 a year we’re not taking alcohol away and neither are we blaming the bottle or the cigarettes like we do medicine this is insanity there’s nothing intelligent or normal here

you have to undo your damage now n step down from medicine
Cdc is sopposed to monitor infectious diseases not medicine!

It’s not your feild of expertise obviously

you have caused millions of deaths and it was definitely your false numbers n statistics and not fact checking and listenIng to anti-opioid zealots like chaun Andrew Kolodny who came with only opinions
no science
no fax
no statistics Or false statistics

no numbers ! Fact everything was in your face telling you what was causing the epidemic you were told right away even William bar recognized it was illicit fentanyl the Attorney General at the time but you still sat on it
Fact everything was in your face telling you what was causing the epidemic you were told right away even William bar recognized it was illicit fentanyl the Attorney General at the time but you still sat on it
They had no science to back up false claims of prescription causing epidemicFact it was never ever do to anybody taking any prescriptions and like I said prescriptions or white down about 85% the overdoses have from what I read

went up 4000% it’s more than quadrupling as we speak it makes the CDC look very bad really bad
Fact it was never ever do to anybody taking any prescriptions and like I said prescriptions or white down about 85% the overdoses have from what I read went up 4000% it’s more than quadrupling as we speak it makes the CDC look very bad really bad
It’s incompetent! All involved were incompetent n reckless
Besides straight lack of human compassion

There’s nothing just their anti-opioid views because they never been sick yet!
that’s what it was literally lies
it was Individuals who are looking for money ...

Non drab phyc Drs playing expert witnesses when they are not experts or doctors in the field of pain management or pain diseases or pain period
like Andrew Kolodny for one
Sadly he Dr. Chow and a lot of politicians were your demise by listening to lies
I don’t even know if you can come back from this because too many lives were lost and are still being lost
I think it’s time to stand down and let the FDA do their job and doctors we need a doctor and patient relationship back and you have torn that apart there is none anymore and you could’ve restored it long ago and you didn’t
Stop the Genocide

From: Marie Lucero
To: reeose63@yahoo.com
Subject: Fwd: Chronic b patients suffering dying from cdc false narratives n false statistics
Date: Sunday, July 18, 2021 10:16:33 PM

Sent from my iPhone

Begin forwarded message:

> **From:** Marie Lucero <reerose63@yahoo.com>
> **Date:** July 18, 2021 at 3:04:13 AM EDT
> **To:** ncipcbsc@cdc.gov
> **Cc:** reeose63@yahoo.com
> **Subject: Chronic b patients suffering dying from cdc false narratives n false statistics**
>
> Sent from my iPhone I'm writing to let you know as a anti-opioid individual who worked around chronic pain patients there, are people /patients 107million in US with diseases that only if you have these painful diseases will you grasp severity and know The consequences of that pain n suffering!
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> —and less than 1% addicts to prescriptions... Period fact !!
>
> Patients now not Being able to work no-more..Due to your reckless false deadly guidelines
>
> I can describe to a female like this try being in labor the rest of your life ! that's what some of the diseases feel like every day ,try being in full-blown labor daily!
>
> or A man get hit in your testicles and then try to live a normal life n function!!
>
> it's the only way to make you understand and this is not a joke or Said out of

anger but truth no exaggeration...that’s how bad the bones and muscles hurt On a daily

and sleep? Forget it ! There is no rest w that bone n muscle pain In joints
the chronic pain that they go through daily and I didn’t know this until I got sick myself with several approximately 14 years ago before that I was so ignorant I didn’t understand why people took them for fibromyalgia or arthritis or MS n thought they were addicts or abusing boy was I wrong..I want to state I had six major surgeries three of them times I threw half the script in the trash the other three times when I finished I did not ask for no more and I did not get addicted ever in those six surgeries n times that I had surgery ,like I said three of them times I threw actually more than half the script in the trash
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Once again—-Less than 1 percent addicts to medication fact!

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suffering n praying for death to come many days N can’t hold on much longer
Tylenol does not touch pain of many diseases n I tried believe me and from trying that useless medication that did not work I got a horrible ulcer and I’m up in our hospital for the ulcer and many have stated the same thing 18,000 approximately on a yearly level die from NSAIDs that’s going to rise!
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Safe!!!

U know What else was safe now millions and millions of people with mental issues having to take Xanax and drugs like now can’t get it due to your guidelines so we have triple suicides

Millions were on anti anxiety meds n prescription meds safely

Now they hv to choose from prescriptions for pain or mental help? They were on it for years in years millions safely that’s a fact you cannot take things away from people because I less than 1% choose to abuse something it’s ridiculous then you might as well get rid of hamburgers and cheeseburgers from McDonald’s because that kills more people from heart attacks and obesity then prescriptions do a lot more
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want to not bite the bullet
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people are suffering mentally or physically and have to choose which one to suffer from ?
it is barbaric
people have never died off of taking their both medicines n both safely and responsibly never
and I know too many to count Esp as a hospital patient worker
I worked 14 Hour days most of my life to support my children n pay mortgage I never took drugs!!
I learned hard way like I said when I started getting sick
The pain was brutal n I took it until I damaged my back n muscles n could not walk n stand nomore Bc. Because I didn't want to get on medicine at all matter fact I don't even like it because it makes me sleepy but at least it took away the pain and I was able to continue to work and then your guidelines came in in the beginning and right away and I've been barely hanging on by a thread and I'm not gonna hang on to much longer I'm not in God's helping me to stay alive because I know he don't want me to kill myself but you're leaving us no choice this is no life there's no quality of life no function do you know what it's like to get out of bed with that much agony where your bones and your body so tired from the pain u feel drugged from lack of sleep n pain

As stated I was ignorant and anti-opioid!!
Please don't be fooled by these disgraceful antiopiode zealots
They ruined your reputation n allowed n enabled deaths

the suicide rate has tripled Esp among vets due to untreated pain even the local news last year reported the skyrocketing suicides especially among veterans in my state which I already knew before the news reported it..

I also knew and heard neighbors and a couple friends who lost their grown adult sons who were on heroin they were roofers and had hard jobs had many back issues they could not get treated for pain n injury I heard from one parent so they sadly chose to relieve themselves w heroin
Or so they thought the heroin sadly was laced with illicit fentanyl
three men died within a week and a half of each other shocking ? No it's normal now n it's qualdrupled - the deaths on street are to many to comprehend due to illicit for tonight and has been since about 2015 and 16 it was never a prescription drugs ever and I wish to God that you would've fact check did not listen to them lying scamming corrupt fraudulent anti-opioid zealots that came and worked with you and lie to you and to statistics prove there lies the numbers prove them liars while they're trying to push the box and which the way it's doing the same thing that you Illegal fentanyl does it's being abused deverted and sold on the street and people are dying from it ...but it's OK because it makes them money ?
but it's not for patients or pain !!!!!it's for addicts so it should not be pushed on

any patient n is harsher than heroin...

Back to what’s causing epidemic!!!! N caused it-illicit fentanyl not medication!!!
Again three boys in their mid-30s about the same age all due to pain and getting a drug that they didn’t know was filled with illicit powder china white fentanyl from China and Mexico and three mothers and fathers had to bury three adult sons but they did take accountability unlike today those parents blaming prescriptions instead of their kids actions N illicit heroin in almost all cases not prescription medication
Facts —-
only 1.2% have a prescription drug in their system at the time of overdose death and you can check with Dr. Vanilla Sihng who you know ! that statistic
and less than 1% addict to prescription drugs
I know for a fact Illicit fentanyl Is killing people and it’s laced in every drug on the street from marijuana to Xanax to heroin in fact it’s again responsible for almost 93 to 98percent of all deaths
the rest of Deaths are due to the other illicit drugs out here like heroin alcohol mix etc
Again 1.2% only have a prescription im system at the time of death
[remainder of message body omitted; too large]

From: Granny and the Grandkids
To: NCIPCBSC (CDC)
Subject: My pain matters
Date: Thursday, July 22, 2021 10:45:14 PM

Attn CDC,
Im writing in hope that I will be heard regarding the fact that I have many chronic health issues and due to your 2016 Guidelines I am now being taken off the pain medications i was on successfully for many years.
I am a 57 yr old mother & grandmother who is now trying to raise 2 of my grandchildren. I have been diagnosed with Fibromyalgia since in my early 30s , found out just this year that I have RA with a chronic inflammatory response that are affecting both my hands which has me almostdisableddue to the severeswellingandpainin both hands.
I have Degenerative disc disease and currently waiting for another surgery to my spine C5C6, i have 2 collapsing discs pinching nerves so severely I can barely move my neck, shoulders and pinches nerves to hands causing severe pain and numbness along with terrible migraine headaches. I have bursitis in both hips & thighs that get so swollen I cannot sleep at night.
I was getting my pain medication from my primary care Dr. but as soon as your 2016 Guidelines came out my pcp sent me to a pain clinic and she took me off my pain medication that i was doing extremely well on and had a much better quality of Life than what i have now.
This pain clinic i started going to here in Wisconsin had me on a good dose of pain meds which was a dose that kept me able to function, along with many anti inflammatory meds, a muscle relaxer, gels , rubs etc. I have been to physical therapy for years, but at this pain clinic I had the most painful experience each monthly visit with injections, injections with no numbing medication, stabbed in back sometimes 30 times to inject just a numbing agent which caused bruising and severe pain for days after , and i told the NP it hurt so badly i don't want to keep doing this, But I had to have these injections done each month in order to keep my pain meds, how absolutely terrible is that, they were just looking to bill out thousands of dollars $$$$ to the insurance companies for what could of been a simple office visit. This was last 4 years but ...as of the past year 2020 to now July of 2021 they have been reducing my pain meds so quickly and want me completely off all pain medication in the next few weeks. Causing severe pain, anxiety and no where to turn for help.
Since they have cut me back on these pain medications I am now left crying in pain, somedays , heck most days now im unable to cook or clean for myself or family and I have terrible painful flare ups that I just can barely function. Both hands i have to sit and ice them for hours. Im losing my quality of Life and it is affecting not just me but my family and especially my 2 grandchildren that Need me here everyday! .
Please revise these guidelines from 2016...the stipulations you put on there has caused Drs to quit prescribing pain medication that is and was helping chronic pain patients for years.
You have the DEA agents closing down pain clinics and Drs scared and afraid of losing their license just to do their job in helping people with terrible painful illnesses.
And yes, I do know for a fact that prescription pain medication is Not causing Overdoses, I have family members and people I knew that have Died , ues Overdoses that were due to Illegal Illicit Fentanyl laced drugs.!
It is this illegal Fentanyl Crisis that is the main opioid crisis. I have spoke with hundreds of people in recovery who Did Not start using prescription pain medication from a Dr. You have to know this by now. 6 years since these guidelines came out and the Overdoses rates still are escalating.. all due to illegal Illicit Fentanyl laced Heroin, Cocaine, and Illicit Fentanyl

pressed in pills sold on the street .

As chronic pain patients are suffering severely daily and it is so unnecessary and extremely harmful to all of us. Chronic pain patients are committing suicide due to extreme pain with no help in sight.

I have seen both sides of this crisis and I just wanted to give my perspective into what I know & how this cutting out and cutting people off all Narcotic pain medication is affecting thousands & thousands of people in the United States. Something has to change Now.

Please contact me anytime for further information and I look forward to hearing from you regarding this matter.

Sincerely,
A chronic pain patient from Wisconsin
Michelle Machkovech

From:	Mike McAulay
To:	NCIPCBSC (CDC)
Subject:	Comments on "Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids"
Date:	Wednesday, July 21, 2021 5:08:23 PM
Attachments:	Comments on Updated CDC Guideline for Prescribing Opioids.pdf

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Please find attached a pdf file named "Comments on Updated CDC Guideline for Prescribing Opioids" that contains my comments related to the recent report "Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids."

Please reach out if you have any questions.

Mike McAulay
224433 NE Marketplace Dr.
O1108
Redmond, WA 98053
(714)-609-0095
Level IV Subject Matter Expert/Senior Developer at Globant

From: M Mendes
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:54:24 PM

I'd like to share my experiences, as a chronic pain patient, with current opioid policies & how medical professionals & pharmacists are reacting to them.

I had been able to obtain safe opioids from my doctors regularly. Now? I'm regularly told "no, we can't do it because of new guidelines".... Medical boards have USED CDC RECOMMENDATIONS as the basis for no longer prescribing opioids for pain. Pharmacists regularly deny prescriptions out of fear of having their license ripped from them by DEA's.... merely for helping people gain access to pain relief. And even if someone is misusing prescriptions? A prescription is WAAAAY safer than street drugs.

Pain is now officially under-treated. Even after getting a 3rd degree tear during child birth I was told by the doctor as I checked out that she refused to prescribe opioids as a general rule to anyone giving vagibal births. So even if a woman is utterly tore up & in debilitating pain (and unable to connect to a new baby, breastfeed a new baby), doctors are refusing opioids.

Why can't you understand that the "opioid crisis" is NOT about prescriptions??? Now the pendulum has swung so far in the other direction we now have pain patients committing suicide for pain relief.

From: Marge Morrison
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 2:59:54 PM

I disagree with the CDC guidelines. There are benefits with reasonable dosage for opioids. Misuse if drugs or even over medicating are usually issues of addiction. Please allow the use of opioids in the medical toolbox. Thank you.

From: Monica Murray
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:00:57 PM

I just read the proposed updated Guideline for opioid patients and am very disappointed in it. It sounds almost exactly like the one proposed in 2016. Do you not have any patients known to u on opioid therapy to weigh in on these proposals or do you just ignore them? Let me share a little of my story please.
I had lumbar pain for most of my 30s and 40s. My doctors at the time believed it was sciatica (not one doc ever mentioned an MRI and I didn't even know what an MRI was to even suggest one). Well finally at age 50 and in excruciating pain, my husband read up on them and suggested it to my then doctor. The doctor agreed to refer me almost reluctantly I might add, and there it was..a hot dog sized tumor inside my spinal canal. I'll spare you all of the details but what I will say is it had chiseled bone off of my spine while growing, it was so attached to L3 that the nerve had to be severed to remove it leaving me with a permanent numb left leg and I had to have a laminectomy and fusion L1-L4. Luckily it wasn't a cancerous tumor but a benign schwannoma (but with all the damage it caused not to mention pain I don't see a huge difference). Anyways, that was in 2014. I have had continued pain ever since. And now 7 years later Everything above and below my fusion has deteriorated and now I'm told I probably need to have my entire back fused plus my neck (herniated C5,6,7). I've been in nonstop pain for years and the opioids I receive are the ONLY relief I receive. I cannot take ibuprofen due to stomach issues I have. Opioids are way easier on my gut. I'm subjected to random drug testing like a recovering addict would be yet I'm a 57 year old woman who has never abused medication. I'm limited as to how much I can get due to the MME law you guys made that makes my pain doc feel he can't go over the 90 out of fear I assume that he'll look like he's giving out too much of it? How did y'all come up with this MME number thing anyways? Did there really need to be a set limit for clinicians? Just like giving 3 days worth of immediate release for surgeries. Why is there a number at all? Why can't doctors decide for themselves an appropriate amount for their patients? You've changed how pain is managed for people without enough thought and doing a monthly quiz on the computer is useless (and stupid I might add). My pain is my pain (and it's a lot). I'm not a number, I'm a person in pain who has to fear going every single month to my pain doctors office, fearing he's eventually going to force taper me. I fear this as I was forced to go off my anxiety medication several years ago in order to stay on pain medication which was a difficult thing to do. I'm so disappointed in how pain management is handled and if you had pain like I do, you would be as well.
Thanks for at least reading this but please know opioids are absolutely needed for people like me and removing some of the hoops we all must go through including pain doctors would be very much appreciated. They are taking those MME limits very seriously to our detriment. The people abusing opioids are NOT most patients!
Thank you,
Monica Murray
6744 Mceachern Lane SE
Owens Cross Roads Al
35763

951-323-3666

Sent from my iPhone

From: marissa perry
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:14:09 AM

I wanted to comment on the proposed new Opioid prescribing guidelines .
I don't see any real difference from the 2016.
It affects people like me with chronic pain by having takin away my medication, my pain relief. Medicine that I had been taking under a doctors supervision for over 25 years as part of how I managed my pain is no longer available to me. Not only that but my primary care Dr will not even discuss my pain with me, afraid that I will ask for pain meds.
I now have one huge less tool in my tool belt to deal with my chronic pain and now have to be concerned with my mental health because of the kind of agony I'm in.
And I can't even turn to my medical team for support.
It's worrisome that that this new draft is basically the same.

Marissa Perry

From: Marcella Respini
To: NCIPCBSC (CDC)
Subject: Letter re Opiod Guidelines to CDC
Date: Friday, July 23, 2021 5:03:26 PM

We need to have a full Congressional hearing as there is a conflict of interest when someone like Roger Chou is hired as an expert to write the guidelines when he has very close connections with the anti-opioid prescribing group PROP Physicians Responsible Opioid Prescribing. He is tied into the funding/payment of these studies that support the guidelines (ex AHRQ) and chooses studies he funds himself to support his own opinions. This is unethical at best and a conflict of interest and puts the entire CDC in question as to their ethics.

I feel that the 2016 guidelines need to be rewritten as so that PERSCRIPTION medications are decided between the doctor and patient without limitations.

I have been on oxycodone and Morphine since 2003 and have been on the maximum legally allowed for a few years now. I have just got an x-ray showing bone on bone & a flattening femur in my hip and severe degenerative disc disease in my lumbar area.

I see the orthopedic doctor next week and expect he will tell me to get surgery. For the last 7 weeks I have been paying $65/twice a week for cold laser/acupuncture treatments that have helped reduce pain a little but it doesn't seem to last; however, it's significant enough that I plan to purchase my own machine for $400 so I can do it myself indefinitely twice a day for longer than the 5 min he does in the office!

Over the years, I have supplemented the opiod pain medicine (which only helps me manage the pain, nothing more) with various alternative modalities such as massage, infrared light therapies, herbals, chiropractic, stem cells, acupuncture, and swimming.

I have gotten worse the last two years and at this point, I cannot walk more than to the mailbox without support and I cannot stand longer than about 5 minutes without burning pain in my low back; therefore, my activity has been reduced to staying home 98% of the time and I just go to the grocery store and doctor apts. The only exercise I can do is swim and light yoga.

I'm very worried about surgery as I hear they cannot give me more than three days of extra medication. That is madness.

I also worry when I hear of people forced to take Suboxone which is another opiod that has worse side effects and can take 6 months to get off. I just read an article where inmates said one 8mg Suboxone is cut in 1/16 parts sold for $20 each!

I was sicken to recently hear Meghan McCain share such misinformation to the public on the View saying that 100,000 people died last year from ooiods blaming it on doctor's prescriptions! This is ABSOLUTE HORSE PUCKY AS NOBODY TAKING LEGITIMATE pain meds for chronic pain would purposely abuse their medicine as then we would run out and a doctor is not going to give us extra.

Doctors have become terrified of losing their license and it is ridiculous to assume they would take the risk of over-prescribing. The Opiods being abused are clearly street drugs like fentanyl, meth and things like that. A person getting pain meds is typically under-prescribed so to think that anything significant could be sold on the black market is another ridiculous stretch of the imagination.

I hope that my letter will help understand from the P0V of a long time chronic pain patient. Btw, I'm female, age 72 with a master's degree in clinical health education and I use to help patients with diet, exercise and stress management. I'm attaching some interesting articles that might be informative.

Sincerely,

Marcella Respini
6950 46th ave N. lot 44
St Petersburg, FL 33709
727-251-7826

https://www.salemnews.com/news/state_news/inmates-warn-about-suboxone-use-in-jail/article_39de3b9b-371a-5a85-840c-1b8bae5ca5e8.html

https://www.buzzfeednews.com/article/scottpham/pittsburgh-suboxone-clinic-crackdown?ref=bffbbuzzfeednews

https://m.facebook.com/story.php?story_fbid=4009666505775855&id=955149807894222
Why are we still worrying about pain pills?

https://www.acsh.org/news/2021/07/19/2020-drug-deaths-spiked-30-and-pain-pills-had-nothing-do-it-1566

Or this link:
https://www.acsh.org/news/2021/07/19/2020-drug-deaths-spiked-30-and-pain-pills-had-nothing-do-it-15669?fbclid=IwAR2L_u9Ztdngsk9zZZJmh3AHzoGMutTShxQXVbayxma8o67WWJCwmmnvmco

Another EXCELLENT article about the CDC, PROP, CHOU this is very accurate written by a Doctor
https://www.pallimed.org/2021/05/props-disproportionate-influence-on-us.html?m=1

From: Michele Ritzman
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:37:32 AM

Hello, I am a chronic pain sufferer for well over 2 decades. The only relief I receive is thru pain medication. I've done bv the meditation, therapy, psychiatric forms of therapy countless times to no avail. If the CDC continues to wage war against pain medications and thereby pain sufferers, you continue to do us a disservice by downplaying our pain. If you think we are only bbn interested in taking these pain medications you are sorely mistaken and lacking in jot only empathy but common sense as well.
I'm a 62byr old woman who endured over 2 decades of daily migraines before geing diagnosed with 3 cerebral aneurysms. Since then I've lived with fibroids causing almost 9 yrs of painful flooding periods.
Fast forward to 2014. Pain that brought me to my knees while walking from sever blockage in my left leg. Of course fem-pop surgery corrected that but with residual pain where portions of my leg died due to lack of blood flow and oxygen. 2 bbn yrs later, 2016, breast cancer. The year after, 2017, fem,-pop failed and after 9 months of not being able to walk, another surgery. This time a graft and coumadin. 2 months later, a gastric hemorrhage which I almost died. 2018 saw 3 more hemmorages, the last being the worst of the 4. Between the 4 episodes, 5 blood infusions.
Now my mind and body are in a state of shock, PTSD, after all I've endured. One constant is the pain. If you continue to deny these life saving medicines, I'm not going to have the life I feel entitled to.
Please consider people like me who have endured more than a body and kind should be subjected to with no relief in sight. What if I was a family member or yourself? Would you suffer or make your family member suffer just for the sake of people who are absolutely taking these meds illegally or in quantities not prescribed by physicians? I would certainly hope not.
A patient in pain asking for relief.
Michele R

From: Pete & Marilu Rudez
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:46:51 PM

Please consider the concerns of the U.S. Pain Foundation and patients in pain, because we are the victims of misguided attempts to control the so-called “opiate crisis” with new guidelines which vary little from the original in 2016. Pain was undertreated before the initial guidelines. A comparison show nothing which will improve the original, but will - when combined with the questionable class action lawsuit against pharmaceutical companies and drug store chains, be the literal final nail in the coffin for many of us who live a reasonably productive life with medication for chronic pain, and those who have no treatment but once had hope.

The result of the crackdown from the introduction of the 2016 “guidelines” is ample proof that taking people off of the medication which enables them to live and contribute to society and their families, leads to death. In our organization, patients have reported being pulled from medication while suffering palliative care for terminal Cancer – “for fear of addiction.” I truly wish this were hyperbolic.
Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

There is a disturbing emphasis upon limited utilization of opiod medication for acute pain only – “if necessary” while many who suffer chronic pain have tried various modalities to treat their illnesses, and found that opiod medication enables us to have dignity and quality of life, as well as making a vital contribution. Imagine having that yanked out from under you, and no hope on the horizon, due to strict guidelines and physicians who refuse to become involved in the red tape, or simple ignorance of how to utilize opiates, so they refuse. Those who do utilize opiates in a limited fashion are hampered by the arbitrary MME dose limitations, and encouragement to taper patients off of all medication or simply stop it dangerously and abruptly.

This is tragic. There is NO MENTION in the CDC guidelines of the positive aspects of Opiod treatment! This safe medication has given the lives back to many who otherwise suffer needlessly, or even commit suicide as there is no alternative left to them. When often used after or with other modalities, opiates have proved to be a safe medication under the very careful monitoring of a physician.

Physicians are capable professionals who can and should monitor patients, give appropriate medication, and expect a pharmacist to fill that prescription as written. It would appear that the CDC has somehow joined the class action suit against those who manufacture medication, and those who both (could) prescribe it, and those who should fill those prescriptions.

Why are we even having this discussion? We have state-wide monitoring systems which do not allow ANY duplication in opiod or benzodiazepine prescriptions. This should lead ANY reasonable person to the conclusion that people in pain are the most strictly regulated people in medicine, and there is no way they can obtain medicine from multiple doctors…So where does the so-called "crisis" originate?

Please do not let the meaning of that statement go unheeded. The "crisis" is not caused by the use of prescription drugs. The "Opiod deaths" which are mentioned are NOT from prescription drugs, although the public – and many doctors believe it to be so, because all deaths from drugs, be they illegal or (rarely) legal are lumped together as another sad death from the plague of opiates flooding the land!

https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html 12/ 17/2020

> Over 81,000 drug overdose deaths occurred in the United States in the 12 months ending in May 2020, the highest number of overdose deaths ever recorded in a 12-month period, according to recent provisional data from the Centers for Disease Control and Prevention (CDC).

> The Covid-19 pandemic period showed deaths by SYNTHETIC OPIOD-INVOLVED DEATHS...NOT PRESCRIPTION OPIODS.
> Of the 81,000 deaths by overdose, please do NOT blame legally

prescribed, life-saving opiates for deaths from illegal, synthetic ultra powerful designer Fentanyl, Cocaine and Meth-Amphetamine, but that is exactly what is being done. There IS a connection however, many who have been dropped from their medicine have turned to designer drugs, in a desperation with fatal results.

Overdose deaths involving cocaine also increased by 26.5 percent. Based upon earlier research, these deaths are likely linked to co-use or contamination of cocaine with ***illicitly manufactured fentanyl or heroin*****.** Overdose deaths involving ***psychostimulants, such as methamphetamine, increased by 34.8 percent. The number of deaths involving psychostimulants now exceeds the number of cocaine-involved deaths.***

THESE ARE ILLEGAL DRUGS WHICH HAVE NO RELATION TO PHYSICIAN PRESCRIBED OPIODS, although they are counted as the “opiod crisis” drugs, and blamed on doctors and patients. Funds should be available to treat these people BUT the TRUE VICTIMS are those in PAIN and their PHYSICIANS. The CDC is waging a campaign to frighten doctors to drop people from the medicine which allows them to live in reduced pain, lead a more productive life with dignity, not in torture, depression and pain-induced futility.

.Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

In closing, if the CDC were as concerned with our health and wellness, it would be advisable to give medicine back to the physician, after allowing them to learn how to use opiates, which now have a black mark, and are considered ‘bad medicine’ by many.

https://www.washingtonpost.com/nation/2021/06/14/2021-gun-violence/

"2020 was the deadliest gun violence year in decades. So far, 2021 is worse." WA POST

6/14

IF the CDC cares, perhaps they will address the manufacture and distribution of GUNS and their manufacturers, distributors and sellers in this country. In roughly the same time period as the figures stated for (illegal) overdoses, 81,000 in one year – we lost approximately 1,250 Americans to gun deaths EACH MONTH – and the figures are grimmer in 2021, but gun manufacturers are big contributors to politicians, and I expect we will live and die in terror and suffering a very long time. Children in school are gun victims – repeatedly, people on the streets, in their homes, theaters, stores…There is nowhere safe from gun violence, yet we are focused on taking medicine from the sick and dying.

I truly hope you will invite physicians, pain specialists, pain patients, and other experts from The U.S. Pain Foundation, and other experts before issuing more guidelines.

Thank you for your kind attention. I - and millions who suffer in silence beg of you to help us stop the madness,

M Rudez

From: Mary Schor
To: NCIPCBSC (CDC)
Subject: Public comment
Date: Friday, July 23, 2021 4:04:02 PM

My name is Mary Schor. I have Complex Regional Pain Syndrome (CRPS) affecting all four of my limbs. It is difficult for someone who does not have CRPS to comprehend what it is like to live with this pain. I have been living with it for almost 18 years. It is there every day of my life. There are many things that I can no longer do, not only because of the pain but because of joint contractures and tissue atrophy (e.g., neurogenic myopathy) that are sequelae of CRPS. I have tried numerous oral medications (e.g., antiepileptics, antidepressants, vasodialators, and other classes), topical medications (e.g., lidocaine, ketamine), and infusions (ketamine, lidocaine, magnesium) as well as nonpharmaceutical therapies (acupuncture, neurofeedback, hyperbaric oxygen, aquatic therapy, MBSR, and others). I am not a candidate for an implantable device (i.e. neurostimulator/neuromodulator). Of all of the pharmaceutical and nonpharmaceutical therpaies I have tried, opioid therapy has been the most helpful for my quality of life and ability to function. I have been on opioid therapy for about 13 years, and my dose is currently just below 90 MME. Despite being below 90 MME, doctors have refused to maintain me on the dose that has been appropriate for me when I moved out of the state and was in search of a pain management doctor to take over my care. I feared that I would lose my ability to function and my quality of life until I was fortunate enough to be accepted as a patient by a knowledgeable and compassionate doctor, Forest Tennant. Sadly, his practice was raided by the DEA in 2017 and he was forced to retire. I was left without a doctor and had no choice but to move back to Maryland. I may have to move out of state for work-related reasons at some point and I fear being left without a doctor that is willing to treat me once again. I implore you, not only for myself but for my friends and compatriots living with debilitating chronic pain due to an incurable condition; please reject the 90 MME recommendation. Please make it clear to pain management doctors that they will not lose their license or face prosecution for prescribing opioid medication to patients like me who live with intractable chronic pain. Even authors of the 2016 CDC guidelines have spoken out about how they have led to unintended harms (please see https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html). The guidelines were intended for primary care physicians, yet chronic pain patients who have been under the care of pain management doctors, sometimes for years, have been adversely impacted. Please understand that each patient is unique, and what is helpful for some may not be helpful for others. Some patients may do well on 90 MME or possibly higher doses. Severe pain is tantamount to torture. The risks vs benefits of various medications must be weighed for each individual patient. If it is possible to relieve pain to some degree with opioids but a pain management doctor does not do so because of fear, then that doctor has violated the first rule of medicine: do no harm. Thank you for your time.

——

Mary Schor
pronouns: she/her/hers
Graduate Student, Rehabilitation & Mental Health Counseling
College of Health Professions, Virginia Commonwealth University

From: Maja Shelley
To: NCIPCBSC (CDC)
Subject: Trying to fill pain medication
Date: Saturday, July 17, 2021 7:12:06 PM

I want you to imagine getting a cancer diagnosis that has less than a 37% survival rate after being admitted to the hospital through the emergency room with severe pain. Now you already had a low dose pain prescription for chronic neck pain. You had laparoscopic biopsy surgery in your abdomen where they biopsied the 6 tumors that were growing as well as numerous other sites. They discharge you with a port implanted so you can start chemo in 2 weeks and a prescription for a stronger dose of pain medication.

You return Home devastated at your diagnosis and in more pain then you originally were hospitalized due to the surgery. Your husband goes to fill your medication prescribed by your oncologist along with other nausea meds. Walgreens tells him it hasn't been 30 days since my refill, even though it's a stronger dose, written by an oncologist with a diagnosis code of cancer pain.

This was the Thursday before a holiday weekend. Friday the oncologist office was closed and by Saturday you're crying because of the relentless pain. Your family are panicked and you call the pharmacy begging them to fill it. You offer to bring up your hospital discharge paperwork confirming your diagnosis, but you are told you are a drug seeker for trying to get it filled within 30 days and you're told that Federal guidelines prohibit them from filling it (blatant lie) You beg them to call the doctor for verification but they refused. By Sunday you are about to go back to the ER as you can't sleep and are now in pain so bad your blood pressure is through the roof. You call your oncologist on their emergency call number and explain the situation. Halfway through, he says they did what??!! Then asked for their number and said he'll fix this. My prescription was ready within 45 minutes.

The point of this story is that it should not be so difficult to get legally prescribed and much needed pain relief. I have never abused my medication, never failed any of my many drug tests throughout the years of taking chronic pain meds. But when faced with the situation above, begging for help, the pharmacy would not help at all!

The CDC guidelines and the training they've pushed out is actively hurting those that need the most help. When cancer patients can't get medication, when newly discharged hospital patients can't get medication, there is something wrong. The CDC has the moral, and legal responsibility to do no harm. The guidelines and rules that they have in place are not stopping illegal opioid use. Instead, they are slowly killing, harming those in need.

Please re-evaluate what you are doing. Please fix it and push guidelines to help us!

Maja Shelley

From: Margaret Spiller
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:23:43 PM

As a pain patient I am concerned about the prevention of access to pain meds. What on earth can be wrong with wanting to lower my pain level which makes it possible for me to work and do basic chores? I think that opioids have been used for these needs for hundreds of years. I have been seeing fentanyl deaths on the news more and more. How many of those lives could have been saved if pain patients had more access to proper pain medicine! Is it possible that these victims were cut off of proper legal pain medicine and became desperate to quell their pain? Just because a doctor discontinues a person’s opioid pain management, doesnt mean that a patient’s pain suddenly goes away. These CDC guidelines cause fear amongst good doctors causing under treatment of pain! Its raciest to use your collective power to turn your back on people who are in pain. I used to be like that until I became a pain victim. I live in fear every month that your guidelines will cause me to lay in my bed with untreated pain because a few individuals decided my fate and decided what my doctor should do. We are human and pain happens. I hope it wont happen to you. Please consider the horrors that many good Americans are going through. I guarantee your fentanyl deaths will go down when pain patients are able to legally obtain proper medical care. Thank you for taking the time to read this letter. Respectfully, Margaret Spiller
Sent from the all new AOL app for iOS

From: mike stevens
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 1:22:56 PM

I was disappointed that the new proposed guidelines are practically the same as the 2016 version which caused immense damage to my quality of life and unnecessary suffering of untold numbers of other legitimate pain patients. A dose of >90mg morphine equivalent that was stable for years and allowed me to function and contribute to my household with some human dignity was first reduced by 66%, then discontinued abruptly. Without warning, I was left nearly bedbound, in extreme pain, and unable to complete the most basic tasks of daily living.

Yes, there are risks to opioid medications and they have been known for centuries and federally addressed for a century. The risks of opioid medications should be evaluated in relation to benefits. The current and proposed guidelines ignore benefits, focusing on only risk. The increase in opioid overdose was, is, and will continue to be the result of illicit opioids and nonmedical polydrug use.

The maximum morphine mg equivalent numbers are arbitrary in light of individual differences in a patient's drug metabolism and pain levels. Each patient should be treated as an individual. A physician working with each patient is the best agent to determine the proper dosage of any medication.

My multiple pain conditions cause constant, excruciating pain. While I have great sympathy for patients with cancer, other chronic, lifelong painful conditions exist. Every human should have the same access to pain care, regardless of which diagnosis one has. A painful disease is a painful disease. This should be quite apparent, but it seems it needs to be stated.

The harm caused by the 2016 Guidelines is horrific and there has been zero benefit shown in reducing adverse opioid events--illicit opioid death rates have continued to rise. The 2016 CDC publication may have been "just a guideline," but it quickly became de facto law. It left patients suffering, physicians afraid to exercise their compassion and clinical knowlege, and had no impact on the ostensible goal of reducing opioid related deaths.   Legitimate pain patients have had their lives ruined with zero benefit to the public health. Combat illicit fentanyl use by means other than punishing citizens who, through no fault of their own, have intractable pain. The original Guidelines were not based on scientific evidence; to basically reinforce them in 2021 is unconscionable.

Sincerely,
Michael Stevens
Louisville, KY

From: Michelle Stifle
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:17:25 AM

Dear Sirs,
My story is much like others you have heard before however, the stories are nightmares.
My name is Michelle.
I have been a chronic/Intractable pain patient for 22 years.

I have had 23 or so orthopedic surgeries to attempt and fix my legs and back. In 1981 I was involved in a severe motor vehicle accident. Which has caused progressive conditions from original trauma.
I have had 5 right total knee replacements and 4 left total hip replacements. Multiple joint infections. Thoracic back infection. Failed ankle fusion.
I also have complex regional pain syndrome, crps a neurological disease. These conditions cause extreme intractable pain daily.

Previous to 2016 we had a ranch and I cared for our family, along with some wonderful foster children. I was able to do most daily tasks with few struggles. Our physician took care of all our conditions including my pain control with pain medication therapy. With her knowledge and plan of care I was able to function.

Then in March 2016 the CDC published arbitrary opioid guidelines and my medication therapy with opioids was discontinued by my physician. I was abandoned.
It took me almost a year to find a pain management physician. I have been with him about 4 years. I am required to take urine drug screens and pill counts. I am turned away from palliative care because I am intractable pain patient. Pharmacies have refused to fill prescriptions and told why in front of other customers.

I can no longer walk. I am in unrelenting pain and have no quality of life. I sit or walk with forearm crutches. On some days I use a wheelchair. We sold our ranch and we live in town. I retired from foster care. I could no longer give kids the care they need to grow. My daily life is confined to my house. Hobbies lay unused in a closet. My guitars sit collecting dust.
I am in pain.

Being a chronic pain patient is the most difficult and degradingly painful experience I have ever encountered in healthcare to date. Finding a medical doctor to just treat my suffering is near impossible because of their fear of governmental attack. The doctor patient relationship is being threatened by draconian control. My doctors care is controlled by fear and therefore my pain is under treated. He follows the CDC guidelines. He was probably told by COPICC they would not support him for malpractice. Other agencies are allowed access to my healthcare with out regards to my privacy. Direct Hippa infractions.

My rights to access evidenced based therapy for my pain is a human right. I am dependent on opioid therapy to live.

Can we find someone to listen for the millions of other veterans, cancer and chronic pain patients suffering?

From: maura thompson
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:38:14 PM

To Whom It May Concern;

I am a 60 yr old, college educated grandmother. I suffer from a "rare" hereditary autoimmune disease, which is progressive & debilitating. I live in severe pain 24/7. Prior to 2016, I owned 2 transportation businesses, I worked, I drove & sent both my children to college, I was in severe pain then, but, it was properly managed & I was able to function.

My life has changed drastically since then, due to my pain NO LONGER being managed. I'm no longer able to work, I am 100% disabled, I CAN'T drive & I am now bedridden 24/7.
I am barely surviving financially, being dependent on SSDI alone.

There is NO CURE for my disease, its dubbed "The most painful disease you've never heard of ". I'm recuperating from a heart attack (once again, due to uncontrolled pain), I'm also recuperating from Sepsis & recently suffered pancreatitis & was NEVER offered pain medication to deal with the absolutely HORRIFIC pain.
In 2018, I required a lengthy neck surgery, to prevent me from becoming a quadriplegic, however, due to the new laws enacted by the CDC, once again, due to lack of adequate pain control, I suffered a heart attack the evening of my surgery.

My disease literally tears all my tendons/ligaments from the bone, effecting EVERY joint in my body. It also attacks ALL my internal organs (heart, lungs, bowels, pancreas etc). Thus far, I've endured 18 surgeries.

I pray every evening prior to bed, that God will take me. I am no longer productive to society. I have become a burden to my adult children, I can no longer even hug my grandchild, I am constantly in & out of the hospital. I have lost all HOPE for living, knowing all my tomorrows will be filled with unbearable pain.

For those of us with debilitating/chronic pain, opioids have always been our LIFESAVER. We DON'T abuse our meds, because without them, we remain bedridden. We DONT use ILLEGAL drugs, because they would only make us more sick. We are 100% compliant with our prescribed medications & have NEVER, EVER purchased "street drugs " ie; illegal Fentanyl (which is the ONLY drug causing the opiod crisis!!!)

It's become apparent to most of us, that the members of the "opiod task force " are NOT pain patients, pain management Doctors, Family members, but, members of the community who enjoy "kickbacks" from various companies. Mr Kolodny is one of such members (that we ALL believe should be "looked into with a fine tooth comb"!!!

As the old saying goes, "Walk a mile in my shoes"....the pain we live with, would bring a grown man to his knees, begging for mercy. Where is YOUR mercy for so many of us suffering every minute of every day, where is YOUR mercy trying to convince a pain patient to NOT COMMIT SUICIDE, to just "give it one more day"? (This is OUR REALITY).

Stop focusing on those in society who are addicted to ILLEGAL drugs & find your

COMPASSION for those of us dealt a lousy hand of having an Uncurable Disease. Any one of us could be YOU, your husband or wife, sister or brother or even your child. Perhaps when it DOES become one of YOUR family members/or, God Forbid.....one of YOU, your outlook will change.

I pray God has mercy on your souls & enables you to REALLY "think " about how many lives you're destroying.

M. Thompson
Florida

From: wrbnyhand@aol.com
To: NCIPCBSC (CDC)
Subject: Fwd: Public comments on NCIPC/BSC
Date: Friday, July 23, 2021 11:51:44 AM
Attachments: Public Comments NCIPC-BSC - IPS Intractable Paid Syndrome.pdf

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-----Original Message-----
From: Mike Uretsky <muretsky@stern.nyu.edu>
To: Wendy Burnett <wrbnyhand@aol.com>
Sent: Fri, Jul 23, 2021 10:54 am
Subject: Fwd: Public comments on NCIPC/BSC

Please forward this to ncipc@cdc.gov

---------- Forwarded message ---------
From: **Mike Uretsky** <muretsky@stern.nyu.edu>
Date: Fri, Jul 23, 2021 at 10:44 AM
Subject: Public comments on NCIPC/BSC
To: <ncipc@cdc.gov>

Wendy R. Burnett
Certified Occupational Therapist
215 West 98 Street
New York, NY 10025

July 23, 2021

Re: BSC/NCIPC Comments

IPS, Intractable Pain Syndrome, is defined by Forest Tennant MD of the Intractable Pain and Education Project of the Tennant Foundation is “Constant Incurable Pain causing measurable cardiovascular, endocrine and autoimmune complications.” One of the syndromes listed as causing IPS is arachnoiditis. I have the misfortune of having an intimate relationship with it and high dose opioids as well as other medical therapies which enable me to control the pain and to function.
My life was inexorably changed in 1972 as the result of an auto accident, when a contrast medium, Pantopaque, was injected into my spinal fluid before surgery. It caused an inflammatory response where the nerves floating in the cauda equina began to adhere together and subsequently to the walls of the dura. Pain in both legs gradually

increased as did the milligrams of hydromorphone and oxycontin needed to control it.

I am fortunate to have an excellent medical team and pain management doctor (Chief of Pain Management at a major NY research hospital) who have managed my care for many years.

Although my medicines are prescribed by and monitored by my physicians, I have periodic problems when dealing with some drug dispensers. As an example, when recently hospitalized with a fractured femur I had a problem when the hospital pharmacy unilaterally refused to dispense the opioids required to control my pain -- presumably fearing that I would overdose. I have had to use an oximeter to make sure that my oxygen level was sufficient.

Every year I am required to have my pain doctor write a letter of medical necessity to justify the high level of opioids that he prescribes to control the pain. I have no idea what my end point is if rigid limitations are placed on use of these drugs. Like all people with IPS, I live with fear everyday -- fear that well-intentioned regulators will establish guidelines that will make it impossible for me to function and have a passable quality of life.

Wendy R. Burnett, OT

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Mike Uretsky
Professor (Ret) - Information Systems
Stern School of Business
New York University
Cell: 917-854-3598
Phone: 570-224-6013
EMail: muretsky@stern.nyu.edu

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From: Michele A. Vines
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:31:55 PM

I am writing to express my sincere concerns regarding the Updated Draft Opioid Prescribing Guidelines and how they have affected my care as a disabled, chronically ill, monitored pain patient.

Over the past 5+ years with the changes made to these guidelines coupled with the past administration's focus on the opioid crisis, needed and necessary access to opioid pain management has been extraordinarily challenging. Simply put: Life altering for many, including myself. A broad brush has falsely painted many pain patients into the corner of their pain management doctors offices where efficacious treatment plans were upheaved and quality of life was diminished with the stroke of a pen—especially for those of us deemed at the lowest risk of addiction and have proven that to be the case. For patients like myself, opioids are important tools in our toolboxes for treatment of our complex health situations. We struggle in our doctor's office where their hands are constrained by these prescriptive guidelines which fail to address the needs of closely monitored pain patients.

I can't begin to tell you what it's like to ration out medication I know effectively helps my intractable pain due to guidelines that hamper my ability to be adequately prescribed what I need to live a fulsome, pain controlled life—a life without unnecessary pain and undue suffering.

Twenty Percocet pills every three months…

…and I always make sure there's one pill left in what should be an empty bottle when pill count time comes at my pain management appointments. I call it my 'just in case things get really, <u>really</u> bad' pill. That one pill is *my* pain safety net.

Please consider the healthcare needs of pain managed patients across our country and our right to live pain controlled lives with adequate access to opioid medications.

Sincerely,
Michele Vines

From: Marty Weiand
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:24:47 PM

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

We hope that in drafting the final Guideline, the CDC takes these views into consideration.
Thank you, a person who has chronic pain for 18 years.

Marty Weiand
Twisted Sister LD
Toads place LD/E1/Crew chief.
please excuseane yapos as im ona
xelluair device.

From: Mary Ann WHEELER
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:53:07 PM

Please, please, please do not take the ability of doctors to prescribe pain medication. I have "Deformity of the Spine. I am in constant pain ranging from 5 15. Yes, I put 15 in the scale as the pain is almost unbearable. I have no quality of life. I do take one Percoset once a day. It takes the edge off for about 2-3 hours. I had to go to a pain clinic as no other of my doctors would/could write a prescription for these pills. People who abuse these will always find a way to find some pills.
Thank you!
Mary Ann Wheeler

From: Thomas Siders
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:36:02 PM

And the MME equivalents are arbitrary at best and do immense harm due to the fact that it is impossible to relate every opioid prescribed to 90 MME’s of Morphine Sulfate. These comparisons do not exist in the manner in which you intend them to be applied.

Sent from my iPhone

From: Margaret Wilson
To: NCIPCBSC (CDC)
Subject: CDC Opioid Guidelines
Date: Thursday, July 22, 2021 11:52:00 PM

The CDC Opioid Guidelines must be repealed! They are based in lies, PROP propaganda, and have harmed and killed patients! ODs from illegal drugs have increased over 50,000!! Clear evidence of the CDC failure!!

Denying legitimate patients access to necessary medications is unethical and against patient rights to bodily autonomy, the right to not be tortured, and the right to life, liberty, and pursuit of happiness!!

Evidence of CDC willfully manipulating data to make false claims of Rx opioids causing addiction or ODs have been demonstrated false so many times the lawsuit against the CDC will be easy to win. And to prove CDC attempted genocide of patients! Beyond the damage to pain patients, we've already seen how CDC misinformation hurt us during the pandemic. The CDC has become completely untrustworthy! How many companies & legislators will continue to support an agency so biased and willing to falsify data and willfully harm and kill Americans?

Repeal these lies! Focus on the actual problem Illegal manufactured fentanyl!! Or how about alcohol that kills 800,000 instead of 70,000 a year! Or NSAIDS which kill more than Rx Opioids. Accidental falls and warfrin kill more people than Rx opioids. Over 100 meds/substances kill far more people than Rx opioids.

It is directly the CDC's fault illegal drug ODs grew by 500+%! By willfully Ignoring illegal drugs and thus encouraging the DEA, Border Patrol, and others to also do so, the CDC caused these overdoses and addictions!
The post office was mandated to institute new policies to decrease illegal opioids arriving by mail. But they have refused. Go after them! Not doctors and innocent patients!

Repeal all CDC Opioid Guidelines NOW!!!

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To: NCIPCBSC (CDC)
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Date: Thursday, July 22, 2021 11:52:00 PM

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Repeal all CDC Opioid Guidelines NOW!!!

From: Margaret Wilson
To: NCIPCBSC (CDC)
Subject: CDC Opioid Guidelines
Date: Friday, July 23, 2021 12:04:45 AM

All CDC Guidelines should be scrapped, trashed, removed IMMEDIATELY! the CDC should issue an apology for harming and killing patients! As well as apologizing for experimenting on humans without consent, without redressing harm, without even collecting data on harm!!
The CDC should demand all attention and federal policies based on CDC guidelines be immediately terminated!
Too many patients have been harmed or killed! Illegal ODs spiked while the CDC lied about Rx opioids and ignored data re illegal drugs!! Stop harming patients and addicts! Destroy the CDC Guidelines re opioids!!!

From: Margaret Wilson
To: NCIPCBSC (CDC)
Subject: MMEs are wrong and harmful
Date: Friday, July 23, 2021 2:11:39 AM

The MME concept in CDC Opioid Guidelines is deeply flawed and harmful. As are doseage caps at any amount but especially 50 and 90MME. Medicine is nuanced and people have varied responses to medicine, especially opioids where metabolism, genes, and pain can all effect disease. This is ignored by the CDC which harms patients!

Although supposedly made for primary care docs, the CDC was and has been definitely aware their Guidelines have been applied across the board to chronic pain patients, cancer, even end of life patients. This caused direct harm, worsening pain symptoms, new health issues including dangerous cardiac issues, led to loss of function, self care, and even employment and loss of life! CDC guidelines and MME have been used by pharmacists to deny necessary Rxs. As well as for insurance companies to deny coverage!
Washington state Medicare has used this harmful process to experiment of human subjects without consent! People with no options but Medicare are being denied neccessary pain medication by Medicare policy and then studied - without and IRB required safety provisions- without consent, without redress of harm, without option to opt out and receive the medication they need. Instead they are lied to, harmed, and in studies 20% of patients force tapered off their Rx opioids died within 1 yr!! No studies show 20% addiction or OD from Rx opioids. Yet many show harm and death from denying Rx opioids! No studies show causation between Rx opioids and addiction. None show correlation either. Data shows NSAIDs kill & harm more people than Rx opioids. Failure to treat acute pain leads to chronic pain. Untreated pain leads to increased pain, decreased function, and even suicide. Studies do not show MME caps prevent or even decrease addiction or ODs. Neither do 3 or 7 day caps on Rxs. They only harm patients. And disproportionately harm people of color, elderly, women, disabled, and those with lower incomes. Intentionally biased policies that harm are unethical and illegal!!

Problems since 2016 CDC Ooioid Guidelines:
-MMEs flawed
-No data supporting causation or correlation of Rx opioids & addiction
-Illegal & unethical harmful policies to populations already harmed by institutional policies
-Illegal Experimentation on human subjects
- Intentional lies about ODs refusing to acknowledge Illegal fentanyl, average 5 or more substances in OD victims, or that most OD victims did not die from Rxs that were prescribed to them but rather were illegally obtained.
-Acute pain patients, trauma & burn victims, surgical patients, cancer patients, end of life patients, and intractable pain patients denied pain management due to CDC Opioid Guidelines.
-Refusal to acknowledge patients harm due to CDC policies
-AMA and many other physicians organizations against MME usage, caps, and denial of neccessary Rx opioids for chronic & acute pain.
-Drastic increase of patients suicides after 2016 CDC Opioid Guidelines
-1000% increase of ODs- due to Illegal drugs since 2016 CDC Opioid Guidelines
-Increased DEA harassment of doctors
-Millions of pain patients lose access to pain management doctors
-Millions of pain patients lose access to primary care doctors
-Horrific increased Illegal fentanyl in the US while the CDC, DEA, CBP ignore Illegal fentanyl instead focusing on Rx opioids per 2016 Guidelines

-Pharmaceutical companies stop manufacturing Rx opioids leaving patients without access

Positives since 2016 Guidelines:
None

The CDC Opioid Guidelines MUST be revoked !!!

From: mark ibsen
To: NCIPCBSC (CDC)
Subject: Comments
Date: Thursday, July 22, 2021 2:31:40 PM

Dear Cdc Work group.

MarkIbsenMD here.
I have been in a 8 1/2 year conflict with the Montana State Board of medical examiners. In 2012 several patients came to me at my urgent care having been abandoned by their doctor through one circumstance or another. These were patients who were dependent on opiates after being given hydrocodone or Percocet several times a day for several years. I consider these patients to be opiate refugees.

I considered it to be cruel and harmful to abandon patients who had faithfully agreed to a program instituted by their own doctor. The classic scenario would be the doctor retired the new doctor won't write the prescriptions and the patients was in my office at 6 PM on a Friday in order to prevent going into withdrawal. I did not consider myself to be treating chronic pain patients, I was treating patients with lost access to their doctor which is a "typical scenario"in urgent care.

I was able to help many of these people wean off their opiates using alternative methods. Most of these patients were also feeling betrayed and upset with a system that abandoned them.

As an ER doctor for 40 years I had kicked the can of chronic pain down the road much of my career.

I had no intention of chronically following anybody. But my Hippocratic Oath requires me to do no harm and, to interrupt harm when I see it happening. I did a lot of that in my ER career,
And my service in remote and underserved areas, working with Mother Teresa in Calcutta, and the Dalai Lama in the Himalayas of zanskar.

The board of medicine in my state did not agree, they accused me of over prescribing narcotics. I was able to prove with no uncertainty that each of the patients who came to me were not started on medication by me and were put on lower doses of medication by me as I helped them see the writing on the wall.

The more I looked into this circumstance I could see that the writing on the wall is this: forces had taken over medicine they were interested in people coming off of opiates-these two groups include anti-opiate addiction doctors who could only see one part of the anatomical elephant that they were treating. They had concluded that opiates caused addiction, and this of course has been debunked. It was obviously not true even then.
The article I have attached documents this but I knew this in 2012.
80% of my patients were able to come off opiates using alternative methods including cannabis. However, 20% of those patients could find no one to take care of them. I was stuck with them because I had a relationship with them. I could not abandon them myself or I would be vulnerable to the same criticism I had to the rest of my colleagues that they were abandoning people after 10 to 15 years of treating pain as the fifth vital sign.

I immediately began to look into this nightmare and patients were having. I was able to find an article from the Institute of medicine from 2011 entitled pain in America a blueprint for change. This article indicated in no uncertain terms that there are 100 million people in pain in America, with a $625 billion impact on the economy. The impact on the individual has been devastating.

https://www.acsh.org/news/2021/07/19/2020-drug-deaths-spiked-30-and-pain-pills-had-nothing-do-it-15669

When the board of medicine filed a complaint against me I was eager to tell them how my successes with patients could be duplicated across the state.
Sadly the board of medicine considered my resistance to their sanctions as some sort of personality disorder. We had extensive hearings where I was exonerated, yet the board continued there case against me throwing out my evidence. They ultimately suspended my license. The suspension was overturned by District Court judge James Reynolds. The district court judge instead of dismissing the case against me remanded it to the board and the board has continued to harass me over the years. The stress of this Battle with the board of

medicine led to the closing of my clinic, the board of medicine sent Dea to visit me five different times. I was close to bankruptcy, and my health was and is still affected.

The board has continued to impose sanctions against me that are arbitrary and unfair and based on no evidence.
In fact I have evidence that the board of medicine scrambled my documents in order to make a claim of poor documentation against me.

They always seem to impugn doctors‘ documentation when they have nothing else to threaten them with.

As you can imagine this has become the legacy issue of my life.
I kept looking for reasons for this inquisition to be happening. I found lots of evidence that overdoses were related to illicit fentanyl, not prescription medication‘s. In the years since then my inquiries have born fruit.
The article I include here clearly indicates that cutting back on prescription pain relief for patients has led to an increase in overdose deaths. What is not in this article and hasn't yet been documented is the increase in suicides in patients cut off of their opiates.

I have direct experience in this in that six of my patients died at their own hands after my clinic was shut down.

I have an extensive number of videos and interviews with patients in agony which don't seem to get any traction with anybody who sees them. They're very painful to watch.
There is a great documentary about this:

https://www.painnewsnetwork.org/stories/2020/5/25/pain-warriors-a-civil-rights-movement-for-our-time

I have been documenting all of these events repeatedly through local media and national media.

Doctors seem to be easy scapegoats for blaming an out-of-control drug war on patients and doctors. Now unfortunately doctors are out of the picture in pain is being managed by drug dealers.

Unfortunately, and fortunately, human beings tend to forget the impact of severe pain. If we did not have a mechanism for forgetting pain women would only have one baby.

The CDC has been part of a dismantling of the worlds best pain management system.
The CDC guidelines were formed in secret. They were formed with 48 hours of input from those of us who knew a bait and switch game was going on.
It was obvious to me in 2015 when these guidelines came out that they were going to be disastrous. I was part of a small band of doctors who resisted vigorously. It was evident to me many other doctors and representatives from the Washington law group that some secret unscientific deals were being made.

I even said back then it's very sad to me that the CDC was squandering it's impeccable integrity by selling itself out to profiteers.
Who are these profiteers? Dr. Andrew Kehlani and his group at Propp have a financial incentive to lie about opiates. They are paid handsomely to testify against pharmaceutical companies, and they also profit by their associations with Beckett recognize her who manufactures Suboxone. In addition these addiction doctors were on Board of Directors of addiction treatment centers who without any evidence of benefit charge $30-$60,000 a month for addiction treatment. Their incentive is to illuminate opiate some more people will undergo addiction treatment. The other culprits are the interventional pain physicians. They discovered that they were being paid handsomely for invasive procedures, not paid very well for medical management of palliative care.

Asipp is a professional organization representing these doctors. They found that if people lost access to opiates they were much more willing to undergo invasive unproven non-FDA approved procedures such as epidural steroid injections.

Sadly, the culture and the media jumped on some bandwagon thinking that several of these myths were actually true. The classic myth is that of Johnny the high school quarterback who breaks his collarbone when he's 18 received some Percocet, then died of a heroin overdose seven years later and it must've been the Percocet. Heroin and fentanyl have become abundant and cheap. They are affecting white kids in

the suburbs. We didn’t care about a heroin addiction in the 1980s when it affects the inner city.
Most of the backers of the anti-opiate Crusaders have lost a child to an overdose due to addiction. Percocet is not the cause.

In order to find a successful response to the scourge of drugs one only need to look towards Portugal. They decriminalize all drugs addiction rates dropped crime dropped an addiction is treated as the medical illness that it is in Portugal.

We have already spent $2 trillion over the last 45 years trying to engage in an unwinnable “war on drugs“ which actually turns out to be a war on people.

There is a long vast bibliography provided by the lakes of Josh Bloom, Richard Lawhern PhD, Maia Szalavitz, Judith foreman who wrote a book called A Nation In Pain.
Many other authors have delineated this sad abuse of a national agency designed to protect peoples health and not harm them. The CDC guidelines have done nothing but harm patients. I don’t think these consequences are unintended either.

I challenge you to take a look at these guidelines and don’t even modify them. Discard them. The CDC had no business sticking its nose into the management of pain. Pain does not operate in epidemic formats. Pain is not contagious. In the last several years we have found that stupidity can be quite contagious however.

I don’t think it any revision of these guidelines is warranted. We need to have congressional hearings in order to document the terrible crime that has been committed towards 100 million Americans in pain.

repeal, do not replace

MarkIbsenMD
Helena Mt
406-439-0752

Sent from my iPhone

From: michowe61@gmail.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:37:37 PM

I’m wondering why the emphasis is on the negative rather than the positive side of Opioid Therapy? Through no fault of my own, I was rendered disabled and suffering from severe chronic pain after nearly dying from a botched surgery. For many years, I tried all kinds of therapies, including Alternative Therapy and I was subscribed different types of pain medication. Due to losing the majority of my GI Tract in the failed surgery, most pills passed through me too quickly without any benefit and I continued to suffer from excruciating pain. The day that I finally decided to go ahead with an Intrathecal Pain Pump was when my life turned around. I was astonished at its effectiveness. For the first time in years, I felt more like my “normal “ self and started to enjoy being alive again.

Chronic Pain is debilitating and can encompass your life. This is not by choice of the sufferer. Nobody chooses to live in this kind of pain and depression that is so severe that 24/7 thoughts of ending your life is running rampant in your brain.

Honestly, I’m not sure that I would still be alive if I hadn’t had the pain pump inserted.

There are many people who are needlessly suffering from Chronic Pain because of the choices that Drug Addicts have made. It’s not right to punish all because of the actions of some.

I’m thankful for my Pain Team who monitor carefully and help provide pain relief with the least amount possible.

Please do not allow the actions of those addicted to decide the fate of the people who are truly suffering. One size doesn’t fit all.

Thank you for listening,

Michele H

Sent from my iPhone

From: Nora Bookless
To: NCIPCBSC (CDC)
Subject: Pain meads
Date: Wednesday, July 21, 2021 2:08:54 AM

Nora Bookless
I am a person that is disabled for 4 years been
On pain meads it's been
Hard dr can't help much
So I have sufferd my husband to he is a veteran
They instantly took him off
Instantly no tapering he has really sufferd pain is
Invisible you can look at someone can't tell. I have been taking pain meads I have not aboused them
I don't run around looking for them don't get me wrong I wish my dr can get me bedder pill to help the pain I can't really do anything I vacuumed last week now I am in a lot of pain can't move so I have to give up on everything my quality of life sucks it could be better but those drug attic's that take fentanyl it's being brought in from different countries that don't apply to the ones that are in a lot of pain we need are medecin exactly if you have cancer or elderly you should be able to get pain meds no question. Thanks

From: NORMAN CLEMENT
To: NCIPCBSC (CDC)
Subject: Request to speaker for 3 minutes
Date: Friday, July 16, 2021 3:43:45 AM

SINCE WHEN HAS IT BECOME THE JOB OR THE ROLE OF LAW ENFORCEMENT (DEA) TO DICTATE, TREAT AND RE-DEFINE MEDICAL PROCEDURES and PROTOCOLS:

https://youarewithinthenorms.com/2021/07/13/since-when-has-it-become-the-job-or-the-role-of-law-enforcement-dea-to-dictate-treat-and-re-define-medical-procedures-and-protocols/

THE PHARM.D PHYSICIAN WANT TO BE

‘THE MOST DANGEROUS TYPE OF PHARMACIST’

The truth is that overprescribing has no definition, is not a medical term, and has not been proven that substance exposure alters any aspect of the “opioid crisis.” In fact, patients on long-term opiate therapy for pain stabilization are the least likely to overdose on their medications.

The practice of the “uncomfortable pharmacist” in withholding treatment of a patient by altering or denying medications is both dangerous and unacceptable in the field of medicine; it has resulted in patients’ suicide.

However, what makes these Pharmacists even more dangerous is their opinions and reasoning are base on the foundation of CDC’s flawed Unscientific Opioid prescribing Guidelines which were developed under unreliable data.

A PHARM.D PHYSICIAN WANTS TO BE!!

Exposing “The Uncomfortable Pharmacists”

Furthermore, pharmacists’ attitudes have their etiology in a belief that they have a corresponding responsibility which in fact requires them to operate within the field of medicine in giving a second opinion; thus undermining the diagnosis and treatment plan of the prescribing practitioner.

Its origins have further become grounded in positioning hospital medical politics, “power-hungry egos” to elevate the pharmacy profession out from images of just being in the basement of a hospital dispensing and compounding to a clinical role on the healthcare team.

In these cases, the pharmacist acts by using no materials to support their “uncomfortable foundation.”

1. The pharmacist does no physical examination on the patients.
2. The pharmacist reviews nor orders any lab work.
3. The pharmacist reviews nor orders additional radiographs and views no progress report.
4. The pharmacist further fails by **entering nothing into writing**as to the decision of how they determine the prescription(s) to be illegitimate and why they’ve interjected themselves into the practitioner-patient relationship by withholding or denying patients their medications.

> *“ The American Medical Association strongly supports a pharmacist carrying out his or her corresponding responsibility under state and federal law, but the past few years are rife with examples of patients facing what amounts to interrogations at the pharmacy counter as well as denial of legitimate medications”*

JOSEPH L.WEBSTER, SR., MD, MBA, FACP, BS. PHARMACY:

The respective regulatory bodies, including the various "Boards" of Pharmacy, Medicine, Dentistry, Nursing, etc., clearly outline the 'scope of practice' for each of those disciplines.

The orderly flow of a prescription "from" the doctor to the patient – via the Pharmacist – clearly outlines where the 'diagnosis' has to come from. It is statutorily the purview of the pharmacist to 'inspect and assure' that the drug that is being given is safe and has no known incompatibilities with the patient and its holistic environment.

It is not the purview, nor is the pharmacist trained to 'challenge the physician's diagnosis and to do so verbally or otherwise with the patient. It erodes the 'doctor-patient' relationship and destroys the 'confidence' of the patient in his/her physician. At the very least it is 'unethical' and may very well be a HIPPA violation and beneath the standard of care as a pharmacist.

Any healthcare provider that is licensed to 'prescribe' is governed by the set of conditions and circumstances under which a prescription can be written.

Thus it is illegal to prescribe for a person that the prescriber has not conducted the ‘chain of authority that would qualify them to write a prescription: history and physical examination, formulation of a diagnosis, and discussing such with the patient as well as the proposed manner of treatment in a culturally sensitive and ethically appropriate manner; and provision of an opportunity for the patient to ‘question and discuss alternative forms of treatment; etc.

Once the provider has met all of the aforementioned and other ‘requirements to write a prescription, then and then ONLY should a healthcare practitioner write a prescription. Furthermore, as stated above, a pharmacist IS NOT AUTHORIZED TO WRITE A CONTROL PRESCRIPTIONS by any of the health regulatory boards.

It is my professional opinion that the pharmacist in question had ‘no reason and more importantly the pharmacist had ‘no power’ to question or interrogate each provider on ‘each prescription’ that is received as long as the ‘safety, efficacy and convenience’ of the medications being prescribed meet the standards of

Medication Dispensing.

Any given medication can be and certainly will be given for multiple different diagnoses and it is not even feasible for the pharmacist to ‘contact and question’ each and every diagnosis.

THE AMERICAN MEDICAL ASSOCIATION WROTE ON JUNE 16, 2020:

While the AMA understands that the apparent goal of the Centers for Disease Control (CDC) Guideline was to reduce opioid prescribing, we believe the proper role of the CDC is to improve pain care. Therefore, it follows that a dedicated effort must be made to undo the damage from the misapplication of the CDC Opioid Guidelines.

We are concerned that such a careful approach to identifying the precise combination of pharmacologic options could be flagged on a prescription drug monitoring program as indications wrongly interpreted as so-called “doctor shopping” and cause the patient to be inappropriately questioned by a pharmacist. The AMA strongly supports a pharmacist carrying out his or her corresponding responsibility under state and federal law, but the past few years are rife with examples of patients facing what amounts to interrogations at the pharmacy counter as well as denials of legitimate medication.”

From: NORMAN CLEMENT
To: NCIPCBSC (CDC); NCIPCBSC (CDC)
Cc: AMA Opioid Task Force
Subject: I have previously request to speak I
Date: Friday, July 16, 2021 10:25:58 AM
Attachments: pastedGraphic.png

My name is Norman J Clement I am a Pharmacist and Dentist I am the owner of Pronto Pharmacy which was target by the DEA I wish to speak at this forum and have been unable to register as a speaker. I write the blog youarewithinthenorms.com which takes a critical loog a flawed DEA, CDC Opioid Guidelines which have failed healthcare.

I wish to submit my response on MME

Josh Bloom:

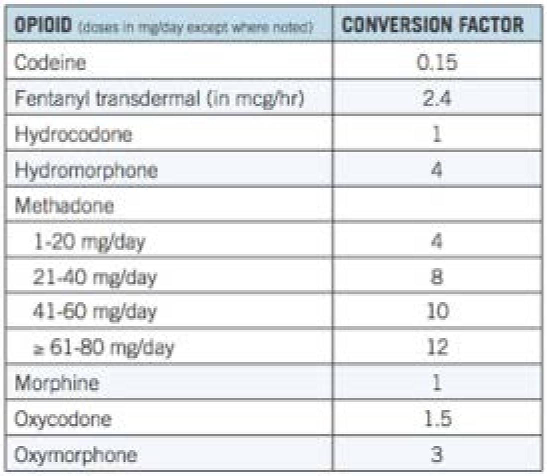
The CDC MME chart, in fact, the entire concept of morphine milligram equivalents may be convenient for bureaucrats but because of differences in the absorption of different drugs into the bloodstream, half-life of different drugs, the impact of one or more other drugs on opioid levels, and large differences of the rate of metabolism caused by genetic factors, is not only devoid of scientific utility, but actually causes far more harm than help by creating "guidelines" that are based upon a false premise. When a policy is based on deeply flawed science, the policy itself will automatically be fatally flawed. It cannot be any other way.

In today's anti-opioid climate a "one-size-fits-all" mindset has become the foundation of government-dictated medicine. And it's very bad medicine. The deeply flawed policies that are being enacted as law all over the country are based on the "one-size-fits-none" concept of morphine milligram equivalents (MME) - the maximum amount of an opioid medication than is permitted per patient per day.

While MME values are touted as useful predictors of the total "opioid load" that a patient can receive, they are nothing of the sort. And MME-based policies don't just fail because of differences in the size of patients; they fail for multiple reasons.

1. Flawed science yields meaningless results

Morphine is normalized to 1.0 and the conversion factor reflects the relative potency of other opioid drugs. So, if the daily MME - the maximum dose of drug allowed - is 90 mg. This assumption could not be less accurate. Once we see the profound differences in the properties of the drugs and the difference between individuals who take them it becomes clear that not only is the CDC chart flawed, but the MME is little more than a random number.



OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

Table 1. MME equivalents. Source: CDC

2. Not all opioids are created equal, especially in the body

Anyone with even a passing knowledge of pharmacology would immediately be skeptical of data in the chart. Bioavailability
One of the many pharmacokinetic properties required to establish how a drug will fare within the body is called bioavailability - a critical determinant for whether a drug will be effective if taken orally.

3. **Bioavailability** which is a measure of the how well a pill will be absorbed in the gut and subsequently enter the bloodstream.

4. Half-life and metabolism

Although critical, bioavailability is far from the only measure of an oral drug's effect on people or animals is primarily metabolized by two different cytochrome P450 enzymes called 3A4 and 2D6.

The difference in metabolizing enzymes itself is a substantial concern when comparing two different drugs, but it becomes even more so when other drugs are part of the picture. The only certainty is uncertainty

From: NORMAN CLEMENT
To: NCIPCBSC (CDC)
Cc: WALTER CLEMENT; Beres Muschett
Subject: Re: CDC GUIDELINE ARE BOTH WRONG AND DANGEROUS NOW TELL THAT TO doj/dea
Date: Monday, July 19, 2021 10:51:49 PM

WE SUBMIT THIS REPORT FOR INPUT AND FEED BACK: AS PER REQUEST BY DR. DEBORAH DOWELL OF THE OPIOID WORK GROUP THE GUIDELINES ARE WRONG AND MUST BE ABANDON AND REPUDIATED.

DEA Suspension Orders & Show Cause Orders

When the DEA takes action to suspend or revoke a DEA registration, it must first serve an order to show cause on the registrant. In certain "emergency" situations, **if the DEA finds there is an "imminent danger to the public health or safety," the DEA may suspend any DEA registration simultaneously with the issuance of an immediate suspension order and order to show cause.**

When a Pharmacist is Black, that individual is automatically a threat and a danger to the public. Being black is a cause of harm, imminent danger and a direct threat to the republic.

The DEA has the authority to immediately determine, based on the color of one's skin to show cause to revoke and or suspend a Black Pharmacist licenses with or without cause.

The DEA has this authority because Black people are a biological danger to society. Their appearance as pharmacist is a false, superficial and artificial

appearance of an educated man or woman.
The show cause order requires you to show why your DEA registration should not be revoked, suspended or denied. The order will contain a statement of the legal basis and reason(s) for issuing the order along with a summary of the facts and law asserted. Much like action taken by state medical boards, the registrant has the right to request a hearing with an administrative law judge (ALJ) to challenge the facts alleged in the DEA's order to show cause.

The registrant has 30 days from the date the order is served to file a request for a hearing. Failure to file the request within 30 days will be deemed a waiver of your right to a hearing, and the DEA may request that final action be taken.

Therefore, it is important that you contact an attorney immediately upon receiving an immediate suspension order or show cause order, so that we may preserve your rights and prepare your defense to protect your DEA registration.

DEA Show Cause Hearings

Show cause hearings are held before a federal administrative law judge. Each party has an opportunity to present their arguments. You may admit evidence and present witnesses to support your case. The DEA has the burden of proof to show by a preponderance of the evidence that a violation occurred. The ALJ will determine whether it is inconsistent with the public interest for the registrant to maintain a DEA registration.

Following the hearing, the ALJ will issue a recommended decision, which is then submitted to the DEA Administrator. If the registrant or DEA disagrees with the ALJ's recommended decision, they may submit exceptions. The DEA Administrator will issue a final decision either adopting, modifying or rejecting the ALJ's recommended decision.

The DEA considers the following factors when determining whether a DEA registration would be “inconsistent with the public interest:

1.

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    1. Failure to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels
    2. Failure to comply with applicable state and local laws
    3. Prior federal or state convictions relating to the manufacture, distribution or dispensing of controlled substances
    4. Lack of experience in the distribution of controlled substances
    5. Other factors relevant to and consistent with public health and safety.

If the registrant is unsatisfied with the final decision, they may appeal the decision to the U.S. Court of Appeals.

From: NORMAN CLEMENT
To: NCIPCBSC (CDC)
Subject: Public comment to CDC
Date: Monday, July 19, 2021 10:59:14 PM

From: youarewithinthenorms.com

The North Star Pharmacist Group

WE SUBMIT THIS REPORT FOR INPUT AND FEED BACK: AS PER REQUEST BY DR. DEBORAH DOWELL OF THE OPIOID WORK GROUP THE GUIDELINES ARE WRONG AND MUST BE ABANDON AND REPUDIATED.

The Deceptive Enforcement Agency lacks the ability to rationalize within the agency the distinctive difference between a criminal drug dealer and a licenses pharmacist. This agency has charged a known drug dealer and licenses pharmacist with the same federal violation 21 U.S.C. §§ 841(a)(1) (possession with the intent to distribute and distribution of oxycodone and hydromorphone and 21 USC 846 (conspiracy to do the same) and 843 (fraud/deception regarding the same).

The Solidarity, or fellowship arising from common responsibilities and interests. This a common feature of the Deceptive Enforcement Agency subculture. The high degree of social cohesiveness and solidarity among the officers causes the acceptance of community and the culture of corruption.

Just think, if a drug dealer and a licenses pharmacist are charge with the same crime, is this a laughable joke of an agency? Or is this a common element of corruption?

The Diversion Investigator (Richard James Albert)from the transcript of his court testimony January 28, 2020, Tampa Florida did absolutely No investigation had know understanding of Pharmacy neither did he have to any investigation or have knowledge or for that mater need knowledge of anything off anything his mission was that of The Sambo the one who is kept ignorant to keep watch over the others especially those are learned and knowledgeable in their trade. He mission is

Dowd may have thought he was helping the DEA however he expose the critical flaws in that the raid on Pronto and the warrant was a racially motivated fraudulent event. In his response Dale Sisco clearly pointed out the flaws in Albert’s testimony and Judge Dowd chose to ignore these important findings with <u>DEA's fraudulent investigation</u>. They knowingly falsified the warrants because there was no investigation by DEA Diversion Investigator Richard James Albert. Richard James Albert's mission to accomplish the goals of his handlers John Beerbower, and Susan Langston, aim to destroy Pronto Pharmacy economic well being. When one examines at the DEA's methodology in handling black-owned pharmacies, they used similar patterns of investigation to remove the Federal certificates.

Let it further be clear, patients being treated for chronic pain who travel to a Black-owned pharmacy are "RED FLAGS" to the DEA and these pharmacies are classified as imminent dangers to the "Public Health.

norm dds

From: NORMAN CLEMENT
To: NCIPCBSC (CDC); Lindley, Tonia (CDC/DDNID/NCIPC/OD); AMA Opioid Task Force
Cc: Richard Lawhern; Jay K Joshi MD; Josh Bloom; Jack Folson; Dale Sisco; Bradley Davis Barbin; Rich SHULMAN; Keith Shulman; Douglas, Kate; Lewis Ladson RPh; HOPE.GOINS@mail.house.gov; Benny Thompson; Daniel Smith; jacqui.kappler@mail.house.gov; jack.dimatteo@mail.house.gov; Beres Muschett; WALTER CLEMENT; Aaron Howard; Epharims Riggins; Robert L Thomas Sr; Dr Scrivens; JULIE Killingworth
Subject: Re: CDC GUIDELINE ARE BOTH WRONG AND DANGEROUS NOW TELL THAT TO doj/dea
Date: Monday, July 19, 2021 11:37:41 PM

On Jul 16, 2021, at 12:29 PM, NORMAN CLEMENT <ywtn@umich.edu> wrote:

> On Jul 16, 2021, at 12:24 PM, NORMAN CLEMENT <ywtn@umich.edu> wrote:
>
> > On Jul 16, 2021, at 12:06 PM, NORMAN CLEMENT <ywtn@umich.edu> wrote:
> >
> > WE SUBMIT THIS REPORT FOR INPUT AND FEED BACK: AS PER REQUEST BY DR. DEBORAH DOWELL OF THE OPIOID WORK GROUP THE GUIDELINES ARE WRONG AND MUST BE ABANDON AND REPUDIATED. IMPROVING ON THEM IS AN ATTEMPT TO IMPROVING THE TASTE OF DOG OR CAT FECES.
> >
> > Both Board member Dr. Grant Baldwin and Dr Deborah Dowell presentations represent the incompetence and their failure to
> >
> > *Previous*

comprehend the Pathophysiology of pain. These presentation were horrifying as they represent a Federal Government and Federal Government policy the American public is in serious danger.

1. WHERE DID THESE GUYS GO TO MEDICAL SCHOOL????

While most of the people on the are good people they are both clinically and academically incompetent and should resign from the Board.

An extensive report was sent to Dr. Dowell June 16, 2020 she has not obviously read it nor understood it. The July 16, 2021 virtual meeting of the CDC Board of Scientific Counselors sadly exposes the complete incompetence which serves on this Federal Government Panel. Im am glad I had a chance to register and participate as a witness to Federal Government Incompetence of the CDC.

THE PATHO-PHYSIOLOGY OF THE CDC GUIDELINE IN THE NEURO TRAMISSION OF PAIN

IS JUST WRONG!!!!!!!

THE CONGRESS REALLY NEEDS TO INVESTIGATE THE AMERICAN PUBLIC IS IN REAL TROUBLE

READ THE WORK OF YOUAREWITHINTHENORMS.COM

THE STORY OF KATHERINE ROTHENBURG-DOUGLAS, “A WORKING REPORTER FOR THE CHICAGO TRIBUNE:

https://youarewithinthenorms.com/2021/07/15/the-dangerous-practice-of-when-your-pharmacist-decides-to-withholds-your-pain-care-i-dont-feel-comfortable-the-story-of-katherine-rosenburg-douglas-a-chicago-tribune-reporter-who-had-broken-he/

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HERINE ROSENBURG-DOUGLAS’S STORY AND THE DRUG
H WITHHOLDS PAIN MEDICATION PRESCRIBED BY YOUR
DOCTOR

demn the opioid epidemic, emember those of us in pain who need help.

ATHERINE ROSENBERG-DOUGLAS

BY

THERINE ROSENBERG-DOUGLAS

O TRIBUNE |JUL 12, 2019 AT 7:34 PM

ollerblading when I was 21. After three
ge 30, I’ve recovered enough that I’ve gone on
al life. I’m a married mother of twin 4-year-
ressed, but fortunately, I’m otherwise relatively

*“These agencies have failed to recognize a
people’s chronic disease conditions of intractable*

pain, while further failing to understand or comprehend human suffering, the science of clinical medical treatment and the value of human life.”

tch delivering slow and steady pain relief to
n get out of bed, and morphine for
life requires more of me than merely getting
e who has ever had a 4-year-old knows each
ng than that. Just driving my kids to school or
minutes at a time is a struggle.”

osenberg-Douglas undergoes a spinal injection procedure on July 2, 2019, at
Rosenberg-Douglas has faced increasingly onerous regulations in managing her
e opioid epidemic. (Erin Hooley / Chicago Tribune)

CIDE IF YOU NEED IT, PHARMACISTS DO!!!

ıglas writes:

ff a prescription before I started work at 7 a.m. armacist said she’d need to speak to the ldn’t get it until Monday. I had my doctor izing hours passed before I called and she told me there were “great distances ddress, the doctor’s office, and where I was e weekend — although they’re all about a 45- dard for Chicagoland.”

d.

EEL COMFORTABLE”

MACIST MADE ME FEEL LIKE DRUG ADDICTS

ıarmacist told me she wasn’t comfortable with ıyl and morphine because, “It’s a lot of pain

R., MD, MBA, FACP, BS. PHARMACY:

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atches but would not fill the morphine. When
ame pharmacy chain for much of the past 10
an easily accessible log of my prescription
to look. She said she had.”

T WITHHOLD TREATMENT FOR PAIN WITH CANCER

en to you, I would lose my license, not your
entioned that without the morphine I’d taken
ing me in a more perilous situation than if she
‘But I have the right to refuse to fill any
on, and I choose not to fill this for you.” Then
o a rival pharmacy chain’s store.”

RELIEVING PAIN IS A PAIN

KATHERINE ROSENBURG-DOUGLAS CHICAGO TRIBUNE REPORT WRITES:

“*The doctor I chose is about 30 miles from my home. He tells me it’s troublesome keeping up with his patient load as other area doctors leave the specialty. Thankfully, many pill mills have been shut down, but even good doctors have closed up shop as keeping up with ever-changing restrictions imposed by legislators has become increasingly arduous, my doctor told me.*

CHICAGO TRIBUNE REPORTER KATHERINE ROSENBURG-DOUGLAS

Among the most asinine of guidelines pushed by various plans to end the opioid epidemic: A pain doctor’s records should show he or she is trying to reduce the number of medications and the dosage patients are on. If your formerly high cholesterol returned to a healthy level with a certain dosage, can you imagine your doctor cutting the dose in half on your next visit?

It’s not clear to me what purpose the every-30-day visits serve, other than to pick up my written prescriptions — controlled substances can’t be called in. But just as these rules unnecessarily hurt those of us in real pain, they also won’t deter those battling addiction who want a fix.“

THE DEA AND UNITED STATES ATTORNEY GENERAL’S OFFICE GONE ROGUE

There is an equally disturbing trend within the medical/pharmaceutical community wherein medical practitioners are targeted. Law enforcement agencies have conducted raids and arrested medical personnel for dispensing legally prescribed medications to the community.

The DEA approach to chronic intractable pain disease and to narcotic addiction disease disorder fails to address clinical issues; a 360-degree view of life, requiring treatment. If addiction is a disease process, then how does law enforcement become the primary healthcare provider to treat a clinical disease process?

DEA focuses is that of law enforcement, linear thinking, unidirectional, at best a duality, binary of good versus evil, good vs. bad, black vs white. The law enforcement approach is designed to keep one in their place to deny your rights and to instill fear. Most importantly their role is to maintain “THE DRUG INDUSTRIAL COMPLEX.”

**LESEDI CULTURAL VILLAGE,
GAUTENG, SOUTH AFRICA**

The DEA has become a rogue agency that must be disbanded. These agencies have failed to recognize a people’s chronic disease conditions of intractable pain while further failing to understand or comprehend human suffering, the science of clinical treatment, and the value of human life.

It is the single most heinous governmental agency whose tactics have led to the increased cost of medications and healthcare across America by misinterpreting the purpose and roles of medications needed to treat acute, chronic, neuropathic, and psychological pain.

MAINTAINING THE ELEMENTS OF THE DRUG INDUSTRIAL COMPLEX

The DEA has waged misinformation to persuade the public that these medications are dangerous drugs whose dosages are “RED FLAGS,” indicating abuse and trafficking, contributing to the so-called opioid crisis in America.

The DEA has become a rogue agency **that has lost their mission,** using threats and intimidation such as;

1. Tactics of no-knock raids and arrest,

2. Forfeiture,

3. Threat of prison time

4. 3 strikes you are out, hands up don’t shoot

5. Economics of Employment: Judges, Bail Bondsman, Barb wire and Prisons

These agents lacking in both knowledge and understanding of **Opioid** Pain receptors come armed with “BADGES, GUNS AND PROFOUND STUPIDITY.” They impose their will on the medical profession (nurses, pharmacists, physicians, dentists, especially drug wholesalers) and their

RELIEVING PAIN IS A

PAIN

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Among the most asinine of guidelines pushed by various plans to end the opioid epidemic: A pain doctor’s records should show he or she is trying to reduce the number of medications and the dosage patients are on. If your formerly high cholesterol returned to a healthy level with a certain dosage, can you imagine your doctor cutting the dose in half on your next visit?

It’s not clear to me what purpose the every-30-day visits serve, other than to pick up my written prescriptions — controlled substances can’t be called in. But just as these rules unnecessarily hurt those of us in real pain, they also won’t deter those battling addiction who want a fix.“

THE DEA AND UNITED STATES ATTORNEY GENERAL’S OFFICE GONE ROGUE

There is an equally disturbing trend within the medical/pharmaceutical community wherein medical practitioners are targeted. Law enforcement agencies have conducted raids and arrested medical personnel for dispensing legally prescribed medications to the community.

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LESEDI CULTURAL VILLAGE, GAUTENG, SOUTH AFRICA

The DEA has become a rogue agency that must be disbanded. These agencies have failed to recognize a people’s chronic disease conditions of intractable pain while further failing to understand or comprehend human suffering, the science of clinical treatment, and the value of human life.

It is the single most heinous governmental agency whose tactics have led to the increased cost of medications and healthcare across America by misinterpreting the purpose and roles of medications needed to treat acute, chronic, neuropathic, and psychological pain.

MAINTAINING THE ELEMENTS OF THE DRUG INDUSTRIAL COMPLEX

The DEA has waged misinformation to persuade the public that these medications are dangerous drugs whose dosages are “RED FLAGS,” indicating abuse and trafficking, contributing to the so-called opioid crisis in America.

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DEA'S RED FLAGS OF DISTORTION

"***stigmatizes the disease state and traumatizes the afflicted"***

When, returning to the United States from Johannesburg on Air France flying to Paris, and I came across TED.com lectures and specifically with the lecture of a Ghanan Professor Sangu Delle concerning the view of mental health in many African countries, in which he says;

"…when it comes to mental illness our ignorance eviscerates our empathy,…… we stigmatize the disease and traumatize the afflicted……"

Professor Delle elaborated, according to in a study done by Arboleda-Flores, when directly asking people about the causes of mental illness the result were staggeringly sad;

4. 34% sited drug mis-used

5. 19% Divine raft of will of God

6. 12% sited witch craft and spiritual possession

Professor Delle summarizes mental health includes our emotional, psychological, and our social well-being. Unfortunately, most people ignore or fail to understand the causes of mental illness, including genetics, social, economic status, war, conflict, or losing a loved one.

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The DEA uses malicious law enforcement tactics to seek greater power and authority in which they “stigmatize the disease state and traumatize the afflicted.” These tactics are the RED FLAGS OF MEDICAL REDLINING, targeted toward licensed professional people of color and the patients in their care. Patients who pay by cash, credit, or debit card do so because they are either uninsured or their pharmacy does not except insurance. As a result, they become “RED Flagged” and deemed abusers and criminals by the DEA.

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From:	Norman J Clement
To:	JULIE Killingworth; kerry@theurbanconservative.org; Richard Lawhern; Rich SHULMAN; jacqui.kappler@mail.house.gov; Daniel Smith; HOPE.GOINS@mail.house.gov; Benny Thompson; Jay Joshi; opioidtaskforce@ama-assn.org; jack.dimatteo@mail.house.gov; Josh Bloom; Dale Sisco; Bradley Davis Barbin; Lewis Ladson RPh; Jack Folson; Kate Douglas; Beres Muschett; Keith Shulman; WALTER CLEMENT; NCIPCBSC (CDC); Lindley, Tonia (CDC/DDNID/NCIPC/OD)
Subject:	BLOOD MONEY: "THE GREAT OPIOID CRISIS QUACKERY," WHY MEDICAL SCIENTISTS, CHRONIC PAIN PATIENTS, INDUSTRY WAGE A CAMPAIGN OF TRUTH AGAINST SETTLEMENTS, DEPRIVING HEALTHCARE, WHILE EXTORTING BILLIONS OF DOLLARS FROM DRUG MANUFACTURERS
Date:	Friday, July 23, 2021 10:05:44 AM

The USDOJ AND DEA campaign to shift the so called OPIOID crisis is based on a foundation of junk science known as mme or morphine milligrams equivalent developing a flawed algorithm used in an attempt to standardize the strength of morphine to other medications of the phenathrene ring. The problem is no one of any drugs behaves the same in a living species and conclusion asserted from such a technique has caused the death of many patients and destruction of our health care system.

I suggest folks to read the work of JOSH BLOOM PHD and Jeff Singer MD then and only then you will believe youarewithinthenorms.com

Then read The war against patients in pain perhaps then Congress will open an investigation hearings on the DEA.

For Now youarewithinthenorms.com

https://youarewithinthenorms.com/2021/07/23/blood-money-the-great-opioid-crisis-quackery-and-why-medical-scientist-chronic-pain-patients-and-walmart-are-waging-war-against-the-dea-doj-from-extorting-billions-of-dollars-from-drug-manufacturer/

Sent from my iPhone

From: Norman J Clement
To: NCIPCBSC (CDC)
Subject: LISTEN TO THE BLACKMAN: THE WHITENESS IN THE “OPIOIDS CRISIS SCANDAL” AND WHY CONGRESS MUST END THE MISSION OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION
Date: Friday, July 23, 2021 12:50:34 PM

Comment on cdc forum
https://youarewithinthenorms.com/2021/06/03/listen-to-the-blackman-the-whiteness-in-the-opioids-crisis-scandal-and-why-congress-must-end-the-mission-of-the-united-states-drug-enforcement-administration/

Sent from my iPhone

From: Norman J Clement
To: NCIPCBSC (CDC)
Subject: THE GREAT OPIOID CRISIS HOAX, EXPOSING THE CORRUPTION AND DANGERS OF MISGUIDED CDC OPIOID GUIDELINES THAT HAVE UNDERMINED PATIENT PAIN CONTROL CARE: WHY CONGRESS MUST ACT NOW!!!!!
Date: Friday, July 23, 2021 12:51:49 PM

Submit for comment
https://youarewithinthenorms.com/2021/05/15/the-great-opioid-crisis-hoax-and-the-dangers-of-misguided-cdc-opioid-guidelines-which-has-undermined-patient-pain-control-care-why-congress-must-act-now/

Sent from my iPhone

From: Norman J Clement
To: NCIPCBSC (CDC)
Subject: THE "REEL" REASON UNITED STATES DRUG ENFORCEMENT ADMINISTRATION (DEA) WAS FORMED, THUS EXPLAINING THE ATTACK ON BLACK-OWNED PHARMACY BUSINESSES (LIGHT)
Date: Friday, July 23, 2021 12:52:48 PM

Submit for comment
https://youarewithinthenorms.com/2021/05/13/the-reel-reason-united-states-drug-enforcement-administration-dea-was-formed-thus-explaining-the-attack-on-black-owned-pharmacy-businesses-light/

Sent from my iPhone

Inches, Centimeters, and Yards

Overlooked Definition Choices Inhibit Interpretation of Morphine Equivalence

Nabarun Dasgupta, PhD, Yanning Wang, MS,† Jungjun Bae, BS,‡§*
*Alan C. Kinlaw, PhD,||¶ Brooke A. Chidgey, MD,#***
Toska Cooper, MPH, and Chris Delcher, PhD‡§*

Objective: Morphine-standardized doses are used in clinical practice and research to account for molecular potency. Ninety milligrams of morphine equivalents (MME) per day are considered a "high dose" risk threshold in guidelines, laws, and by payers. Although ubiquitously cited, the "CDC definition" of daily MME lacks a clearly defined denominator. Our objective was to assess denominator-dependency on "high dose" classification across competing definitions.

Methods: To identify definitional variants, we reviewed literature and electronic prescribing tools, yielding 4 unique definitions. Using Prescription Drug Monitoring Programs data (July to September 2018), we conducted a population-based cohort study of 3,916,461 patients receiving outpatient opioid analgesics in California (CA) and Florida (FL). The binary outcome was whether patients were deemed "high dose" (>90 MME/d) compared across 4 definitions. We calculated I^2 for heterogeneity attributable to the definition.

Results: Among 9,436,640 prescriptions, 42% overlapped, which led denominator definitions to impact daily MME values. Across definitions, average daily MME varied 3-fold (range: 17 to 52 [CA] and 23 to 65 mg [FL]). Across definitions, prevalence of "high dose" individuals ranged 5.9% to 14.2% (FL) and 3.5% to 10.3% (CA). Definitional variation alone would impact a hypothetical surveillance study trying to establish how much more "high dose" prescribing was present in FL than CA: from 39% to 84% more. Meta-analyses revealed strong heterogeneity (I^2 range: 86% to 99%). In sensitivity analysis, including unit interval 90.0 to 90.9 increased "high dose" population fraction by 15%.

Discussion: While 90 MME may have cautionary mnemonic benefits, without harmonization of calculation, its utility is limited. Comparison between studies using daily MME requires explicit attention to definitional variation.

Key Words: opioids, milligrams of morphine equivalents (MME), definitions, epidemiology, Prescription Drug Monitoring Programs (PDMP)

(*Clin J Pain* 2021;37:565–574)

Morphine-standardized analgesic doses are calculated in clinical practice and research routinely. And, in support of safer opioid prescribing, clinical guidelines suggest limits or cautions above 90 mg of morphine equivalents (MME) to prevent respiratory depression. Yet, subtle variations in MME per day calculations have been overlooked.[1] Therefore, we sought to quantify the practical impact of definitional variants to provide clarity.

Equianalgesic conversion factors between opioids were intended to guide dosing when switching patients by accounting for potency.[2,3] Conceptually, an equianalgesic dose is that at which 2 opioids provide the same pain relief. Contrary to conventional wisdom, conversion values are not based on pharmacologic properties. Instead, they arose 60 years ago from small single-dose clinical studies in postoperative or cancer populations with pain score outcomes; toxicologic effects (eg, respiratory depression) were not evaluated.[4]

Amid concerns about opioid overdose, the concept of equianalgesic potency resurfaced.[5] In 2016, the US Centers

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Received for publication November 3, 2020; revised February 26, 2021; accepted April 23, 2021.

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N.D., B.A.C., and C.D.: conceptualized the analysis. N.D., C.D., Y.W., J.B., and T.C.: contributed to study methodology. Y.W. and J.B.: analyzed individual-level data and generated base tables, and conducted quality assurance. N.D.: conducted meta-analyses and sensitivity analysis and created the figure, and was responsible for study integrity. A.C.K.: contributed code and wrote the statistical equations. T.C.: was responsible for all aspects of project management and dissemination.

Supported by FDA and BJA. US Food and Drug Administration, Silver Spring, MD (HHSF223201810183C) funded the efforts of N.D., B. A.C., and T.C. The US Department of Justice, Bureau of Justice Assistance, Washington, DC (2017-PM-BX-K038) funded the efforts of Y.W., J.B., and C.D. The BJA is a component of the Department of Justice's Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, and the SMART Office. Funding agencies had no involvement in study design, analysis, interpretation, or decision to publish. N.D. is a part-time methods consultant to the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS) System of Denver Health and Hospitals Authority, a political subdivision of the State of Colorado. RADARS System had no knowledge of or involvement in this analysis. N.D. has no relationship with any pharmaceutical manufacturer or distributor. The remaining authors declare no conflict of interest.

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Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website, www.clinicalpain.com.

DOI: 10.1097/AJP.0000000000000948

for Disease Control and Prevention (CDC) issued a guideline for chronic noncancer pain management including strong cautions above 90 daily MME based on population-level mortality studies.[6] The CDC Guideline formalized a shift in the MME concept from antinociception to toxicology. The 90 daily MME recommendation was not absolute; however, some state laws, policies, and insurance requirements now invoke the threshold explicitly. For example, the State of Maine prohibits "any combination of opioid medication in an aggregate amount in excess of 100 MME of opioid medication per day."[7] CDC recognized this misapplication with a statement softening the "hard limits" inferred.[8] The American Medical Association has expressed similar concerns.[9]

Definitional issues in opioid management[10,11] and MME criticism are longstanding.[1,12–19] Studies used by CDC to establish the 90 mg threshold employed approaches to calculating daily MME that differed silently. Total MME can be divided by days supply to calculate the average daily MME *per prescription*. However, the CDC Guideline does not address measurement *per patient*. Therefore, we quantified how daily MME definitions impact clinical practice, as well as interpretation of the evidence base.

METHODS

Sources of Definitions

Because of their considerable impact on opioid prescribing and frequent citation in the literature, we examined the 27 studies cited in the CDC Guideline to identify definitions of daily MME, based on our previous review.[20] Despite documentation challenges, we identified 4 distinct approaches among 18 studies[1,21–37] and applied them to dispensing data from California and Florida. Supplemental Digital Content 1 (http://links.lww.com/CJP/A783) contains verbatim extracts from the original studies. Other approaches were identified,[38–40] but described inadequately or infrequently.

In demonstrating how to calculate MME, the online continuing medical education module associated with the CDC Guideline[41] presents the following clinical scenario, to which we added an additional prescription for illustrative purposes.

A patient receives 30 mg extended-release oxycodone twice a day for around-the-clock pain for 30 days (60 tablets), and one 5 mg oxycodone twice a day as needed for breakthrough pain for 7 days (14 tablets). Both prescriptions are dispensed on the first day of a 30-day month, with no subsequent dispensing. Assume 1.5 as the conversion factor for oxycodone-to-morphine.[42]

Alarmingly, for this simple scenario, 4 definitional variants return daily MME inconsistently: 75.8 or 93.5 or 31.2 or 105 mg/d.

Definitions

Total MME for the first prescription equals (60 tablets) × (30 mg per tablet) × (1.5 conversion factor from oxycodone-to-morphine),[42] resulting in 2700 mg. For the second prescription (14 tablets) × (5 mg per tablet) × (1.5 conversion factor) results in 105 mg. Total MME across both prescriptions is 2805 mg, appearing as the numerator in the first 3 definitions. Formulas are provided in Supplemental Digital Content 2 (http://links.lww.com/CJP/A783).

Definition 1—Total Days Supply

This common definition appears in studies[1,26,43] cited in the CDC Guideline and elsewhere.[44,45] The numerator is the sum of MMEs across all prescriptions (2805 mg), and the denominator is the sum of days supply across all prescriptions (37 d), for 75.8 mg/d. The same day may contribute multiple times to the denominator (ie, prescriptions overlap), allowing the denominator to potentially exceed the number of unique calendar days.

Definition 2—On-therapy Days

Consistent with standard practice in pharmacoepidemiology, this definition identifies on-therapy days to account for overlapping prescriptions. This method is used in studies[33,37] cited in the CDC Guideline and elsewhere.[46] The numerator is the sum of MMEs across all prescriptions, and the denominator is the total unique person-days explicitly exposed according to days supply, counting overlap days once. No gap allowances are made for early refills. Applying this definition, 2805 is divided by 30 days, resulting in 93.5 mg/d.

Definition 3—Fixed Observation Window

This common definition from early studies[23,25,30] cited in the CDC Guideline often reference an even earlier study,[47] and is still used.[48,49] The US Department of Health and Human Services Office of the Inspector General recommends this method, which is one of the only definition sources with adequate documentation to allow replication.[50] The numerator is again the sum of MMEs across all prescriptions, and the denominator is days elapsed during follow-up, hospital stay,[51] or beneficiary enrollment.[52] Although 90-day observation windows are most common,[23,25] 180 days[43] and 365 days[30] were also used in studies supporting the CDC Guideline. Applying this definition 2805 divided by 90 days results in 31.2 mg/d.

Definition 4—Maximum Daily Dose

Toxicologic framing identifies the highest single-day MME exposure, irrespective of days supply or opioid tolerance. This definition appears to underlie the calculator in the CDC Opioid Guideline mobile app.[53] Prescriptions dispensed *pro re nata* are assumed to be consumed immediately, regardless of how long the prescription is written for. Yet, paradoxically, the "maximum" does not conceptually include consumption for intentional self-harm. This method was used by studies[24,28,32,35] cited in the CDC Guideline and may be most relevant for prescriptions to patients who are opioid naive. The first prescription is 30 mg×2 (twice per day)×1.5 (the conversion factor) for 90 MME, plus the second prescription with 5 mg×2×1.5 for 15 MME, resulting in 105 mg/d.

Medication Dispensing Data

Our study used deidentified data from Prescription Drug Monitoring Programs (PDMPs) in California and Florida, which we had analyzed previously.[54,55] Inclusion criteria were any complete opioid analgesic dispensing record for state residents aged 18 years and older in California (adult population: 30,571,507) and Florida (adult population: 17,071,450) from July 1, 2018, to September 30, 2018.[56] To minimize left-censoring, we included fractional prescriptions dispensed before the observation period which continued past July 1. A short time period was chosen to limit seasonal variation, secular trends, and to allow stabilization of dispensing after earlier changes in Florida law to limit days supply and require checking of the PDMP.[57,58] Solid oral and transdermal formulations of opioid analgesics were included (detailed in Supplemental Digital Content 2, http://links.lww.com/CJP/A783).

Primary Analysis

Descriptive statistics were calculated under the standard assumption of consumption exactly and completely as directed. We applied the 4 definitions separately to identify the prevalence of patients who would be considered "high dose" (>90 daily MME), such as would be conceptualized in a hypothetical policy evaluation. We stratified into 3 mutually exclusive subgroups: (1) patients receiving only immediate-release or short-acting opioids, generally used for acute pain, initial management, or titration of persistent pain (hereafter *immediate-release*); (2) patients receiving only extended-release or long-acting opioids labeled for chronic pain (hereafter *extended-release*); and (3) patients receiving both immediate-release and extended-release opioids contemporaneously within the 3-month observation period (eg, including, but not limited to, patients with chronic pain receiving opioids for breakthrough pain or during taper). From continuous models of daily MME, we report arithmetic means and medians by subgroup. Data management was conducted in SAS 9.4 (SAS Institute Inc., Cary, NC); code available at www.opioiddata.org.

Meta-analyses

Applying a Food and Drug Administration (FDA) method for opioid measurement dilemmas,[59] we used meta-analytic techniques to quantify how much heterogeneity would have been observed across hypothetical state-comparison studies, each applying one of the 4 variants on the same sample (fixed effects). In preliminary analyses, Florida generally had higher opioid use than California, presumably due to an older population,[56] scope of practice legislation,[58,60] and other factors.[61] Conceptualized as a comparative surveillance study, we evaluated differences between the 2 states: (1) daily MME as categorical comparing the proportion of "high dose" patients, and (2) calculating mean differences in milligrams as a continuous variable, stratified by the 3 opioid categories from subgroup analyses. To quantify heterogeneity between definitions, we computed Higgins and Thompson I^2 metric[62] and χ^2 statistics in Stata/MP 16.0 (Stata Corp., College Station, TX). Code and annotated output are provided in Supplemental Digital Content 3 (http://links.lww.com/CJP/A783).

Sensitivity Analysis

We explored the impact of inconsistency at the threshold borderline: Some studies use >90 daily MME (eg, 91 and higher), while others use ≥90 daily MME. Like the primary analysis, the outcome was the proportion of patients considered "high dose" with prevalence differences. The corresponding number needed to harm (NNH) represents the number of patients seen before one would be misclassified as "low dose" who should have been considered "high dose."

Ethics Statement

The study was approved by the University of Kentucky Institutional Review Board.

Patient Involvement

The Opioid Data Lab (www.opioiddata.org) is a collaboration between the authors' 3 institutions; professional representation by patients with chronic pain and people who use drugs is a core organizational tenet. Representatives review the portfolio of research projects, providing guidance from study conceptualization to findings dissemination. The definitional and clinical nature of this particular analysis elicited limited input from representatives, mostly on clinical plausibility and impact.

RESULTS

Descriptive Findings

The analytic sample contained 9,436,640 opioid analgesic prescriptions (California, n = 5,677,277 and Florida, n = 3,759,363) dispensed for use between July and September 2018, encompassing 3,916,461 unique adult residents (California, n = 2,430,870 and Florida, n = 1,485,591). The 3-month rate of opioid dispensing was lower in California at 7.9 per 100 adult residents than in Florida with 8.7. The prevalence of prescriptions with overlapping days supply was 39.0% in California and 44.9% in Florida, corresponding to 23.0% and 27.4% of patients, respectively. Total MME per prescription was heavily right-skewed, with divergent arithmetic means and medians. In California, average MME per prescription was 1547 mg (95% confidence interval [CI]: 1540-1554), but median was 300 (25th and 75th percentile: 100 to 1275). In Florida, total MME per prescription was higher at 2146 mg (95% CI: 2138-2154), and median 382 mg (25th and 75th percentile: 113 to 1818). Arithmetic means and medians convey dramatically different perspectives on population-level prevalence of "high dose" patients.

Primary Analysis of Definitional Variants

The 4 definitions yielded a 3-fold range of MME: 17 to 52 mg/d in California and 23 to 65 mg/d in Florida (Table 1), on the same sample. The 2 states had 2.4 and 2.9-fold differences in the number of "high dose" patients >90 daily MME (Fig. 1), respectively. In California, the 4 definitions resulted in a range of 3.6% (n = 86,407) to 10.3% (n = 249,471) of opioid recipients identified as "high dose." In Florida, the range was 5.9% (n = 87,295) to 14.2% (n = 211,429) having >90 daily MME. In both states, Definition 4 (maximum daily dose) identified the highest number of "high dose" patients. However, in California, Definition 3 (fixed observation window) returned the fewest patients with >90 daily MME, whereas in Florida Definition 1 (total days supply) provided the least.

Subgroup Analysis

We found that 92.2% of adult opioid patients were treated only with immediate-release opioids, nearly identical to national estimates.[59] In addition, 78.3% of patients with extended-release opioids also received concurrent immediate-release opioids.

We next analyzed the impact of definition choice among mutually exclusive opioid patient subgroups: immediate-release only (n = 3,611,856), extended-release only (n = 66,077), and any combination of extended-release and immediate-release (n = 238,528). Patients receiving only extended-release opioids showed the least variation, with about 2-fold relative differences between the highest and lowest definitions (Table 1).

At a clinical level, the definitional variants led to different conclusions. If assessing whether a single patient was receiving a "high dose" of opioids, on average some definitions would say yes, others no. For patients receiving only extended-release, 2-out-of-4 definitions returned an average dose >90 daily MME. For patients receiving both extended-release and immediate-release opioids, 3-out-of-4 variants returned average dose >90 mg/d.

TABLE 1. Definitional Variation in MME by Type of Pain Medication

	Average Daily MME		Daily MME, Median (IQR)	
Definition	**California**	**Florida**	**California**	**Florida**
All patients on opioid analgesics (mg)				
Total days supply	33	39	25 (18, 40)	30 (20, 45)
On-therapy days	38	46	25 (18, 40)	30 (20, 46)
Fixed observation window	17	23	3.3 (1.1, 13.9)	4.2 (1.2, 19.8)
Maximum daily dose	52	65	30 (20, 50)	33 (20, 60)
No. patients	2,430,870	1,485,591	2,430,870	1,485,591
Average on-therapy days (d)	30	34	13 (5, 56)	17 (3, 69)
Immediate-release only (mg)				
Total days supply	30	34	24 (17, 38)	30 (19, 40)
On-therapy days	31	35	25 (18, 38)	30 (19, 43)
Fixed observation window	10	13	2.7 (1.1, 10.2)	3.3 (1.1, 13.0)
Maximum daily dose	40	45	30 (20, 45)	30 (20, 50)
No. patients	2,273,028	1,338,828	2,273,028	1,338,828
Average on-therapy days (d)	27	30	10 (5, 46)	12 (3, 58)
Extended-release only (mg)				
Total days supply	90	87	60 (30, 120)	60 (30, 120)
On-therapy days	104	97	62 (31, 121)	63 (32, 120)
Fixed observation window	73	67	42 (15, 90)	41 (14, 90)
Maximum daily dose	154	143	90 (45, 180)	90 (55, 180)
No. patients	40,038	26,039	40,038	26,039
Average on-therapy days (d)	61	60	75 (30, 89)	73 (29, 89)
Extended-release and immediate-release (mg)				
Total days supply	74	83	55 (38, 90)	66 (44, 108)
On-therapy days	144	160	100 (63, 172)	123 (75, 210)
Fixed observation window	123	133	82 (42, 151)	98 (51, 181)
Maximum daily dose	251	268	173 (105, 300)	200 (120, 345)
No. patients	117,804	120,724	117,804	120,724
Average on-therapy days (d)	74	74	88 (63, 92)	88 (67, 92)

IQR indicates interquartile range; MME, milligrams of morphine equivalents.

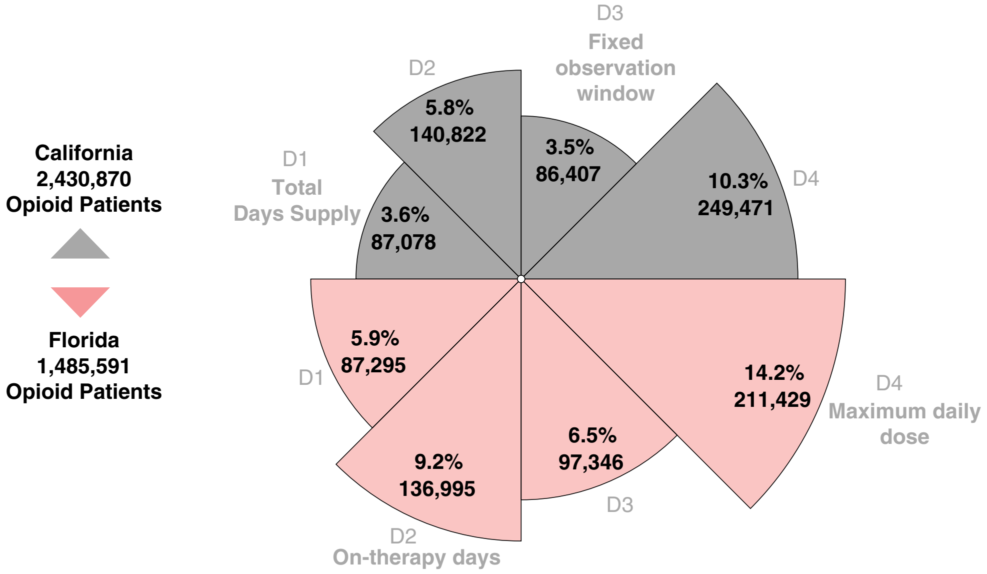

FIGURE 1. Inconsistency in identifying "high dose" patients on opioids. The proportion of patients on opioids considered "high dose" (> 90 mg of morphine equivalents [MME]/day) varies by definition alone, from July to September 2018. Four definitions were identified from the literature and clinical tools. Total days supply (D1) divides the sum of MMEs by the sum of days supply, allowing the denominator to be longer than the prescribed duration. On-therapy days (D2) divides total MME by the number of calendar days. Fixed observation window (D3) uses a fixed denominator, typical 30 to 90 days in research studies. Maximum daily dose (D4) identifies the day with the highest total possible exposure.

TABLE 2. Meta-analytic Comparison of MME Definitional Variants

Relative Proportion More "High Dose" Patients in Florida (vs. California)	
	More "High Dose" Patients, % (95% CI)
Daily MME definition variant (n = 3,916,461)	
Total days supply	64.0 (62.5-65.5)
On-therapy days	59.2 (58.0-60.3)
Fixed observation window	84.3 (82.7-86.0)
Maximum daily dose	38.7 (37.9-39.4)
$I^2 = 99.91\%$	
Test of heterogeneity: $\chi^2 = 3257$, 3 *df*, $P < 0.0001$	
Mean difference in daily MME in Florida (vs. California)	
	Difference in MME (95% CI)
Immediate-release only (n = 3,611,856) (mg)	
Total days supply	3.7 (3.3-4.1)
On-therapy days	3.5 (3.1-3.9)
Fixed observation window	2.2 (2.2-2.3)
Maximum daily dose	5.1 (4.6-5.6)
$I^2 = 98.63\%$	
Test of heterogeneity: $\chi^2 = 219$, 3 *df*, $P < 0.0001$	
Extended-release only (n = 66,077) (mg)	
Total days supply	−3.3 (−1.8 to −4.8)
On-therapy days	−6.8 (−4.9 to −8.7)
Fixed observation window	−5.9 (−4.4 to −7.4)
Maximum daily dose	−10.6 (−7.7 to −13.6)
$I^2 = 86.38\%$	
Test of heterogeneity: $\chi^2 = 22$, 3 *df*, $P = 0.0001$	
Both extended-release and immediate-release (n = 238,528) (mg)	
Total days supply	8.8 (8.3-9.3)
On-therapy days	16.7 (15.0-17.3)
Fixed observation window	10.4 (9.2-11.5)
Maximum daily dose	17.2 (15.1-19.3)
$I^2 = 98.34\%$	
Test of heterogeneity: $\chi^2 = 181$, 3 *df*, $P < 0.0001$	

CI indicates confidence interval; MME, milligrams of morphine equivalents.

Meta-analyses

In the first meta-analysis, we compared the proportion of patients receiving "high dose" (> 90 daily MME) opioids between California and Florida. MME formula was the only source of variation. While Florida consistently had more "high dose" patients, the magnitude of the difference varied solely on how daily MME was calculated: 64% or 59% or 84% or 39%. A hypothetical surveillance study or policy evaluation would reach different conclusions based on which definition was used. Meta-analytic metrics confirmed very high heterogeneity ($\chi^2 = 3257$, 3 *df*, $P < 0.0001$), with I^2 of 99.9% (Table 2).

In the second meta-analysis, we calculated mean differences in milligrams of MME per day between states. Heterogeneity was very high overall based solely on definition choice, with the extended-release only group showing the least ($I^2 = 86\%$), while the other 2 subgroups had $I^2 > 98\%$ (Table 2). A similar pattern was found using χ^2 statistics, with extended-release only showing lower relative heterogeneity arising from definition choice ($\chi^2 = 22$), followed by concurrent extended-release and immediate-release ($\chi^2 = 181$), and immediate-release only showing greatest impact from definition choice ($\chi^2 = 219$). The heterogeneity in the latter subgroup appears to be driven by Definition 3 (90-d fixed observation window) which was markedly lower than other variants (Table 1). Patients receiving extended-release and immediate-release concurrently in Florida had consistently higher average doses than in California, however, the effect size was ambiguous: from 8.8 mg (95% CI: 8.3-9.3) to 17.2 mg (95% CI: 15.1-19.3). Definition 1 (total days supply) showed the least difference between states among patients receiving both immediate-release and extended-release opioids, but the second-highest difference in the immediate-release only subgroup. Definition 4 (maximum daily dose) consistently returned the most exaggerated result. The remaining 3 definitions changed in rank order. Further complicating the picture, patients in Florida receiving *only* extended-release opioids had lower mean MME (range: −3.3 to −10.6 mg/d) than in California. In epidemiologic terms, a claims data study using the standard incident new user design to evaluate extended-release opioids might return the opposite results to a prevalent user design.[63,64]

Sensitivity Analysis

Both states showed boundary effects when comparing > 90 daily MME to ≥ 90 daily MME, with a disproportionally large increase in prevalence for 1 additional milligram of MME (Table 3). Solely including the borderline unit interval: 90.0 to 90.9 increased the "high dose" proportion by 15.4% (95% CI: 15.2% to 15.7%) on average. Definition 3 (fixed observation window) was most robust to misclassification at the 90 mg borderline. With this variant, the NNH for one misclassification was 1 in 2430 in California, and 1 in 1244 in Florida. Definition 4 (maximum daily dose) was most susceptible to boundary inclusion decisions with NNH for misclassification of 1 in 67 and 1 in 30, respectively.

Data Sharing Statement

Data processing code used to construct each definition is available at www.opioiddata.org. Individual-level PDMP records are governed by state laws and requests must be made directly to those authorities; the authors are not permitted to transfer individual-level data to third parties. However, all aggregate data and code used for statistical analyses are publicly available at www.opioiddata.org and institutionally archived at the Carolina Digital Repository (https://doi.org/10.17615/zst5-nc25).

DISCUSSION

Over the past decade, MME have been accepted into clinical practice and adopted for opioid safety studies with limited critical assessment. The computational ease and the evocative lure of molecular fundamentals collide in an optimal level of cognitive complexity to engender MMEs with an unsubstantiated aura of immutability. Our analysis revealed definitional inconsistencies that have been overlooked. There are implications for clinical care, policy, and epidemiology, and the potential to capriciously impact many thousands of patients.

Our findings preclude a universal MME formula which suits all clinical practice. The practical utility of MME in opioid management has been questioned.[12,16] Our study further suggests that when patients are handed-off between prescribers, measurement variation could lead to inconsistent experiences for patients requiring pharmacotherapy for pain relief. MME calculations are incorporated in many clinical decision support systems, yet software interfaces and

TABLE 3. Sensitivity Analysis of Boundary Inclusion at ≥ 90 mg

Definition	Patients > 90 Daily MME, n (%)	Patients ≥ 90 Daily MME, n (%)	Rate Difference Per 1000 (95% CI)	Number Needed to Harm*
California				
Total days supply	87,078 (3.6)	106,240 (4.4)	7.9 (7.5, 8.2)	1 in 127
On-therapy days	140,822 (5.8)	155,254 (6.4)	5.9 (5.5, 6.4)	1 in 169
Fixed observation window	86,407 (3.6)	87,407 (3.6)	0.41 (0.07, 0.75)	1 in 2430
Maximum daily dose	249,471 (10.3)	285,807 (11.8)	15.0 (14.3, 15.5)	1 in 67
Total adult opioid patients	2,430,870			
Florida				
Total days supply	87,295 (5.9)	113,998 (7.7)	18.0 (17.4, 18.6)	1 in 56
On-therapy days	136,995 (9.2)	157,794 (10.6)	14.0 (13.3, 14.7)	1 in 72
Fixed observation window	97,346 (6.6)	98,541 (6.6)	0.80 (0.22, 1.4)	1 in 1244
Maximum daily dose	211,429 (14.2)	261,335 (17.6)	33.6 (32.7, 34.5)	1 in 30
Total adult opioid patients	1,485,591			

*Number of patients seen before one would be misclassified as "low dose" who should have been considered "high dose" by using 90 mg instead of 91 mg as a threshold.
CI indicates confidence interval; MME, milligrams of morphine equivalents.

clinical practice rarely allow space for probing definitional nuance.[65]

MMEs homogenize opioid exposure. On a policy level, the lack of definitional consensus makes it difficult to assess compliance with legislative mandates and third-party payer requirements. For example, an opioid reduction schedule was implemented by Arkansas Medicaid where beneficiaries with ≥ 250 MME per day were required to be tapered to ≤ 90 mg during an 18-month period by 50 mg intervals.[66] Since these patients are clearly not opioid naive, on-therapy days or fixed observation window may be more appropriate than the exaggerated exposure from maximum daily dose (Table 4). Without a standardized definition in this setting, choice of definition will directly impact the course of a patient's therapy arbitrarily.

At the medicolegal interface, our work has implications for law enforcement and prescriber communication.[67] MME alert thresholds are incorporated in "doctor shopping algorithms" and automated proactive reporting, routinely devoid of diagnosis.[68] Some law enforcement use daily MME to target prescribers,[69] yet we have little reason to believe that definitions are applied with fidelity. In light of our findings, penalizing clinicians solely on the basis of 90 MME limits is problematic.[70]

Of concern to epidemiologists, long-term intervention evaluation may be subject to an overlooked form of bias. This is because definition choice impacts immediate-release and extended-release opioids differentially. If the proportion of these 2 formulations changes over time, daily MME will produce biased time trends. For example, between 2012 and 2019 the number of extended-release prescriptions decreased quicker than immediate-release; the reduction was even more pronounced for extended-release opioids with properties intended to deter tampering.[59] Definition 1 is of particular concern as it exaggerates the difference in daily MME between these 2 types of formulations: Definition 1 returned one of the highest daily MMEs for immediate-release opioids, but for the lowest for extended-release. For evaluation studies with trends over time, Definition 3 may have utility since it was the most robust to misspecification, including due to overlapping prescriptions, by formulation, and at the 90 mg inclusion boundary. The mean-median inequality also challenges assumptions in average-generating statistical models; median or geometric (eg, log-transformed) averages may be a more accurate representation because they are less prone to influence by outliers.[71] The mean is not always the message; policymakers reading PDMP reports based solely on MME averages are in danger of making decisions based on metrics that are artifactually inflated. Medians and ranges may convey a more accurate picture in these scenarios.

There are standard assumptions and limitations inherent to database studies of medication use[72,73]: perfect specification and completeness, generic equivalence,[74,75] absence of counterfeits,[76] no external sources (eg, out-of-state, leftover, diverted, or illicitly manufactured).[77] However, these are of less concern in our study because we were not associating with biological outcomes and are independent of definition. To relax assumptions of perfect adherence, we are exploring novel parametric methods.[78] Dispensing data do not necessarily reflect actual consumption. About 60% of patients prescribed opioids retain unused medication.[79] Therefore all definitions assuming medication completion systematically overestimate biological exposure. We did not have enough information to determine how unused medications would impact each definition differently. Each definition is dependent on days supply, which is subject to variations when calculated at pharmacies; we are investigating this separately. Converting transdermal formulations to oral MME can be tricky due to dosing units measured in hours, leading to prescriber, pharmacist, and researcher variation.[80] No definition considered pain etiology or tolerance. We were not able to observe social determinants of health[81] or unfilled prescriptions,[82] and could not differentiate cancer pain. Finally, we note the debate about specific conversion factors between opioid molecules.[16,19] We did not evaluate the impact of equianalgesic multipliers in a bid to reduce analytic complexity. Finally, the toxicologic framing of MME may have limited application for opioids where fatal toxicity does not involve respiratory depression (eg, serotonin depletion with tramadol), in the presence of atypical mu-opioid receptor agonism (eg, tapentadol, buprenorphine), or when consumed in the presence of synergistic nonopioid central nervous system depressants.

TABLE 4. Recommendations on Equianalgesic Definitional Variants

1. *Total days supply:* The least complicated calculation appears best suited when immediate-release opioids are prescribed for short discrete times. It consistently underestimated MME per day when overlapping prescriptions were present or when immediate-release and extended-release opioids were prescribed concurrently, as with 78% of patients with chronic opioid use
2. *On-therapy days*: Provides a smoothed measure useful in studies of dose-dependent adverse effects, including opioid-induced constipation or overdose in patients with opioid tolerance or who have been stable on opioids. The metric is time-varying and affords the greatest flexibility to define medication gap periods and leftover/unused medications to improve pharmacoepidemiologic studies
3. *Fixed observation window*: Most suitable for studies with a known or suspected duration of risk during which adverse events are expected to occur, such as incidence of opioid use disorder. This definition may be useful when prescriptions are filled at irregular time intervals on a as-needed basis (*pro re nata*). The definition consistently had the lowest milligrams per day for immediate-release opioids. This is the definition recommended by the Department of Health and Human Services Office of the Inspector General.[43] It is the most robust to misspecification, amenable to transformations, and has the least noise when constructing continuous functions.[40] However, since it assumes uniform exposure/risk within a window, there is less scope for time-varying adjustment
4. *Maximum daily dose*: A toxicological perspective may be appropriate for opioid naive patients with no tolerance and in the presence of comorbidities for respiratory depression. It appears to be best suited for immediate dose-dependent toxic effects, such as respiratory depression in opioid naive patients. This definition may have limited use if it includes opioids where fatal toxicity does not involve respiratory depression (eg, tramadol) or have atypical mu-opioid receptor agonism (eg, tapentadol, buprenorphine). The definition assumes uniform risk of adverse outcomes regardless of time on-therapy. More so than the others, this definition is prone to influence from early refills, unused medication, and how the 90 MME threshold is operationalized. This definition underlies the algorithm embedded in the CDC Opioid Guideline mobile app.[51] There may be difficulty reconciling findings with studies using the other definitions because it returns a MME per day that is significantly higher

CDC indicates US Centers for Disease Control and Prevention; MME, milligrams of morphine equivalents.

Our recommendations (Table 4) will benefit from collective iteration. Definition 2 appears to have face validity with routine clinical practice. Definition 4's toxicologic focus might be useful for new opioid patients with simple regimens at risk for respiratory depression but carries the highest risk of overestimating daily MME. It remains to be seen if shifting clinical definition choice between patients may provide more practice autonomy and better patient outcomes. At a minimum, clinical guidelines, legislation, PDMP vendors, and clinical decision support systems should make formulae, conversion tables, and code explicit. Research studies should consider sensitivity analyses by definition choice, and treating MME exposure as a transformed continuous variable.[83] Our findings may have implications for other drug classes (eg, benzodiazepines[84] and stimulants) and the World Health Organization defined daily dose for opioids.[80,85,86]

The sensitivity analysis showed that 15% of patients were right on the 90 to 91 mg borderline. While our study was not designed to assess prescribing motivations, the strong clustering effect suggests that this threshold might be used as a cap to appear in compliance with external mandates. There is no particular clinical reason we could identify for patients to otherwise cluster at 90 MME per day outside of policy, health system, and payer requirements. We speculate that patients who might have otherwise received higher doses are subsumed under this threshold. Definitional choices have consequences.

Despite variation in underlying definitions, the studies cited in the CDC Guideline consistently found an increased risk of fatal overdose ≥ 90 daily MME. The simplest explanation is an artifact of turning a continuous metric into one that is categorical: All but 2 studies[30,33] we reviewed categorized MME exposure using 90 to 120 mg as the lower bound for the highest stratum. However, for fatal overdose, not all opioid molecules exhibit a dose-dependent correlation.[87] Still, our study supports FDA's contention that overdose risk with opioid analgesics is a continuous function.[88] Historically, the transition of the MME concept from pain relief to toxicology ignored the clinical concept of differential tolerance.[89] With opioid dose escalation, analgesic and unintended effects emerge asynchronously. While 90 MME may have cautionary mnemonic benefits in the midst of broad societal concern, a renewed emphasis on opioid tolerance and definitional harmonization (for daily MME and long-term therapy[11,90]) seems overdue.

The overlooked inconsistency among daily MME definitions revealed by our study calls into question the clinical validity of a single numerical risk threshold. When measuring with inches, centimeters, and yards, the absolute number of units is arbitrary. The mix of clinical and research metrics used to calculate the 90 MME threshold is similarly convoluted. As providers, we struggle to do what we feel is right for our patients in the midst of increasing outside pressure with serious ramifications. Our findings call into question state laws and third-party payer MME threshold mandates. Without harmonization, the scientific basis for these mandates may need to be revisited. As the CDC Guideline is revised, and clinical decision tools are developed, it is critically important to reassess the evidence base in light of this previously unknown MME definitional variability.

ACKNOWLEDGMENTS

The authors thank Maryalice Nocera, MS (Project Manager, Injury Prevention Research Center, University of North Carolina) and LaMonda Sykes (Budget Analyst, Office of the Vice-Chancellor for Research, University of North Carolina) for project management and actuarial support. They are also grateful to the California and Florida PDMPs for providing de-identified data access.

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Supplement 1. Verbatim MME calculation methods from studies cited in the CDC pain Guideline[1], identified from a previous methods review.[2]

Inches, Centimeters, and Yards: Measurement Variations Inhibit Clinical Interpretation of Morphine Equivalence

Clinical Journal of Pain

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Full documentation available at OpioidData.org

Tennant et al.[3] (1982): mean daily dose reported but methods not specified

Ralphs et al.[4] (1994): The dose of opiates was converted to morphine equivalents using locally developed standard drug conversion tables.

Allan et al.[5] (2005): milligrams of morphine equivalents (MME) not used

Reid et al.[6] (2002): MME not used

Cowan[7] (2005): MME not used

Banta-Green[8] (2009): MME not used

Dunn et al.[9] (2010): We then calculated the average daily morphine equivalent dose dispensed for 90-day exposure windows by adding the morphine equivalents for the prescriptions dispensed during the 90 days and then dividing by 90. For each 90-day exposure window and each person, we calculated the average daily opioid dose dispensed and divided these into 5 categories: none, 1 to 19 mg, 20 to 49 mg, 50 to 99 mg, and 100 mg or more. We included opioid dose as a time-varying covariate, estimated for continuously updated 90-day exposure windows. Participants could be classified as either exposed to opioids (at any of 4 dosage levels) or unexposed on any given day, on the basis of their average daily opioid dose during the previous 90 days, including the event date.

Sullivan et al.[10] (2010): Opioid dose per day supplied was calculated by adding the total morphine equivalents for the three major opioid groups and dividing by the sum of the total days supply (assuming maximum authorized use as calculated by the dispensing pharmacist). If the total days supply exceeded the number of days in the period (180 days), suggesting concurrent use of different opioid types, the daily dose was calculated by dividing the total dose dispensed by 180 days.

Wild et al.[11] (2010): MME not used

Bhonert et al.[12]: Next, each patient’s total maximum daily dose for each day of the study observation period was calculated by adding the daily doses of all fills that covered that particular day. The specific daily dose contributed by each fill was determined by dividing the total morphine-equivalent milligrams dispensed in that fill by the number of days supplied. This measurement of dose reflects the maximum daily dose prescribed and not necessarily the actual amount consumed. Morphine-equivalent maximum daily dose was converted into a categorical variable with the values of 0 mg, 1 mg to less than 20 mg, 20 mg to less than 50 mg, 50 mg to less than 100 mg, and 100 mg or more. In addition, a time-varying indicator of whether patients were prescribed a regularly scheduled opioid plus a simultaneous as-needed opioid was coded for each day of the study observation period that a patient had at least 1 opioid prescription using the following 3 mutually exclusive categories: 0, only regularly scheduled opioids; 1, only as-needed opioids; or 2, both a regularly scheduled opioid and as-needed opioid prescriptions.

Gomes et al.[13] (2011a): The dose of opioid was calculated as the number of tablets dispensed multiplied by the strength of the pills (in milligrams) for each prescription. The average daily dose for each of these prescriptions was then calculated as the dose (in milligrams) divided by the number of days’ supply for which the prescription was written, converted to morphine equivalents using morphine equivalence ratios used by the Canadian National Opioid Use Guideline Group.

Gomes et al.[14] (2011b): For each individual who received at least one opioid prescription in a given calendar year, we calculated the mean daily dose dispensed (mg) of oral morphine, or equivalent, on the basis of the person's first 90 days of opioid therapy. If the supply of drug dispensed for a prescription in that interval extended beyond 90 days, we excluded the excess. The adjusted total amount of morphine equivalents dispensed over the 90 days was divided by 90 to obtain the mean daily dose for the period.

Naliboff[15] et al. (2011): Opioid medication dosages were taken from the computerized pharmacy record and were converted into morphine equivalents per day in order to have a standardized unit for reporting opioid amounts across different drugs.

Cicero et al.[16] (2012): MME not used

Paulozzi et al.[17] (2012): we calculated the dosage of opioid prescribed in MME per day in three different ways. The single peak dosage was the highest amount per day in any single opioid prescription. The total peak dosage was the highest dosage per day at any time during the exposure period after summing dosages from all overlapping opioid prescriptions. The average dosage was the average daily opioid dosage during the entire study period from all opioid prescriptions combined. For regression analysis, we categorized each measure of daily dosage into 0–40, >40–120, and >120 MME/day.

Mitra et al.[18] (2013): All patch dosages were recalculated to morphine equivalent to an equipotent dose using a widely applied guide "DUROGESIC® [sic]: Simple Dosing Guidelines."

Baumblatt et al.[19] (2014): To calculate the mean daily dosage, all opioid prescriptions were combined and converted to MMEs and divided by 365 days. We categorized mean daily dosage into less than 20, 20 to 40, 41 to 80, 81 to 100, 101 to 200, 201 to 400, and more than 400 MMEs/d and defined high risk as a mean of more than 100 MMEs/d for a year.

Edlund et al.[20] (2014): Average daily dose was measured in morphine equivalents and grouped as none (0 mg), low dose (1–36 mg), medium dose (36–120 mg), and high dose (120+mg).

Zedler et al.[21] (2014): For each opioid prescription dispensed during the baseline period, the product of the number of units dispensed and the opioid strength per unit (milligrams) was divided by the number of days supplied. The resulting opioid daily dose dispensed (milligrams per day) was then multiplied by a conversion factor derived from published sources to estimate the daily dose in morphine equivalents (MED). The maximum prescribed daily MED during the baseline period was calculated for each patient by summing the daily MED for all opioid prescriptions dispensed to the patient during those 6 months. It reflects the maximum prescribed daily dose and not necessarily the actual amount consumed.

Dasgupta et al.[22] (2015): The average daily MME per individual in 2010 was calculated by taking the total milligrams and dividing by the days supply, taking into account overlapping prescriptions.

Jones et al.[23] (2015): MME not used

Liang et al. [24] (2015): To calculate the 2 time-varying opioid therapy measures, all filled Schedule II or III prescriptions for opioid analgesics (excluding injectable formulations) were identified from claims in 6-month intervals starting with the first prescription. The total MED was computed from all opioids dispensed in a 6-month interval multiplied by strength (in milligrams) and then multiplied by a morphine equivalent conversion factor derived from published data, conversion tables on the Internet, and drug information resources. When opioid prescriptions spanned two 6-month intervals,

the total MED was allocated proportionate to the time in each interval. We consulted with a clinical pharmacist to review these calculations. Finally, the total MED was summed for all opioid prescriptions filled in the same interval. We calculated the mean daily MED for filled opioid prescriptions for each 6-month interval by dividing the total MED by total days' supply covered by all these prescriptions. Based on categories used in other studies,
0, 1 to 19, 20 to 49, 50 to 99, and ⩾100 mg. Because other studies have not examined total dose in relation to the risk of drug overdose, we examined quartiles of nonzero total MED. When an overdose event occurred in a 6-month interval, both daily MED and total MED were computed from the 6 months exactly preceding that event.

Miller et al.[25] (2005): To assess and control for the effect of the opioid dose, we con- verted each opioid agent to the morphine-equivalent dose following the method of Von Korff et al. We computed the morphine-equivalent mean daily dose by dividing the total quantity prescribed by days' supply and converted the daily dose thus calculated into a corresponding morphine-equivalent dose. After the conversion, prescriptions in morphine-equivalent mean daily doses were categorized as 1 mg to less than 20 mg, 20 mg to less than 50 mg, 50 mg to less than 100 mg, and 100 mg or greater.

Park et al.[26] (2016): Maximum morphine-equivalent daily opioid dose was modeled as time-varying and recoded into the following categories: 0 mg, 1 to <20 mg/d, 20 to <50 mg/d, 50 to <100 mg/d, and >100.1 mg/d. These dosage categories were chosen to allow for comparison with other published work on unintentional overdose as well recent recommendations that caution against prescribing more than 90 to 100 mg/d. To avoid double-counting dosage, opioid fills that seemed to be continuations of the same treatment plan (ie, were the same opioid formulation and dosage) were assumed to not start until the end of the days' supply of the previous fill. Also consistent with the Bohnert article, for each day that an individual had at least 1 opioid prescription, a 3-level time-varying indicator of opioid fill type was calculated to reflect schedule, with the categories of: only regularly scheduled opioids; only pro re nata (PRN) opioids; or both regularly scheduled opioid and PRN opioid prescriptions.

Gaither et al.[27] (2016): MME not used

Turner et al.[28] (2015): The total MED was computed by summing the MEDs for all opioid prescriptions within a given 6-month interval. The mean daily MED in a 6-month interval was calculated by dividing the total MED by days' supply for all prescriptions in that interval, excluding overlapping days. We examined five categories for the mean daily MED (i.e., 0, 1– 19, 20–49, 50–99, and ≥100 mg), similar to other studies. For the first overdose, the mean daily MED was based on data from exactly 6 months before that event

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Supplement 2. Equations for calculating milligrams of morphine equivalents

Inches, Centimeters, and Yards: Measurement Variations Inhibit Clinical Interpretation of Morphine Equivalence

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Full documentation available at OpioidData.org

Dispensing Data Processing

Outpatient pharmacies are legally required to submit detailed information on dispensed controlled substance prescriptions to state-controlled databases. These data were made available in de-identified format masking the identity of individual patients. In Florida, multiple prescription fills by the same individual are linked using name, date of birth, and other information by the database vendor (Appriss Health, Inc., Louisville, KY); one-way hashed unique patient, prescriber and pharmacy identifiers allow for longitudinal observation. In California, a custom fuzzy string matching and network building algorithm identifies patient matches across prescriptions, using name and either a) the same date of birth and zip code, or b) the same street address and city. Prescriptions dispensed from federal institutional pharmacies, inpatient facilities, and methadone clinics were not systematically included, nor were prescriptions dispensed in other states to Florida or California residents. We analyzed opioid analgesic dispensing records for state residents aged 18 years and older in California (adult population 30,571,507) and Florida (adult population 17,071,450), intended for use from July 1, 2018 to September 30, 2018. Only days supply for use during this period was retained if prescriptions originated before or extended beyond these dates. All solid oral and transdermal formulations of opioid analgesics were included. Liquid injectables were excluded because of widespread scientific disagreement on conversion factors and relatively low volume. We used National Drug Codes to identify opioids and excluded codeine and hydrocodone cough syrups, and buprenorphine-containing products, because the CDC conversion tables claim: “Buprenorphine products are listed in this file but do not have an associated MME conversion factor. Buprenorphine products are partial opioid agonists prescribed for pain and as part of medication assisted treatment for opioid use disorder. Buprenorphine doses are not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.”

Equations

Prepared by Alan Kinlaw

Version-controlled UNC institutional repository for equations: https://doi.org/10.17615/zst5-nc25

In demonstrating MME calculations, consider the following clinical scenario:

A patient receives 30mg extended-release oxycodone twice-a-day for around-the-clock pain for 30 days (60 tablets), and one 5mg oxycodone twice a day as needed for breakthrough pain for 7 days (14 tablets). Both prescriptions are dispensed on the first day of a 30-day month, with no subsequent dispensings.
The four definitional variants result in daily MME of: 75.8, 93.5, 31.2, or 105 milligrams per day.

To daily MME, notation is as follows:

q_{ij},	quantity (units) dispensed for prescription j for person i
m_{ij},	strength per unit in milligrams for a given prescription j for person i
c_{ij},	equianalgesic potency conversion factor for medication in prescription j for person i
d_{ij},	days supply on a given prescription j for person i
s_{ij},	start (dispensing) date of prescription j for person i
w_i,	start date of observation window for person i
l_i,	length (in days) of observation window for person i

g_{ik}, date of follow-up day k during observation window for person i

For each prescription j that occurs for each person i, we calculate o_{ij} as the number of days supply that overlap the relevant observation window:

$$\begin{aligned} o_{ij} = {} & \{d_{ij}\}\{I[s_{ij} \geq w_i]\}\{I[(s_{ij}+d_{ij}) \leq (w_i+l_i)]\} + \\ & \{w_i+l_i-s_{ij}\}\{I[s_{ij} \geq w_i]\}\{I[(s_{ij}+d_{ij}) > (w_i+l_i)]\} + \\ & \{s_{ij}+d_{ij}-w_i\}\{I[s_{ij} < w_i]\}\{I[(s_{ij}+d_{ij}) \leq (w_i+l_i)]\} + \\ & \{l_i\}\{I[s_{ij} < w_i]\}\{I[(s_{ij}+d_{ij}) > (w_i+l_i)]\} \end{aligned}$$

Of the four mutually exclusive terms that are summed to calculate o_{ij}, only one can return a non-zero value. This is a result of the indicator functions (e.g., $I[s_{ij} \geq w_i]$), which return a value of 1 if the stated inequality is true, else 0.

Stated in spoken words, the windows are:

o_{ij} = "prescription starts and ends during window" +
"prescription starts during window and ends after window" +
"prescription starts before window and ends during window" +
"prescription starts before window and ends after window" +

Stated in SAS code to calculate o, the windows are:

```
if s ge w and (s+d) le (w+l) then o = d;
else if s ge w and (s+d) gt (w+l) then o = w+l-s;
else if s lt w and (s+d) le (w+l) then o = s+d-w;
else if s lt w and (s+d) gt (w+l) then o = l;
```

Of the four mutually exclusive terms that are summed to calculate o_{ij}, only one can return a non-zero value. This is a result of the indicator functions (e.g., $I[s_{ij} \geq w_i]$), which return a value of 1 if the stated inequality is true, else 0.

To ensure that MME calculations for each prescription were based only on days supply that elapsed within the relevant observation window, we calculated f_{ij}, a scaling factor for that prescription's relevant days supply:

$$f_{ij} = \frac{o_{ij}}{d_{ij}}$$

The range of f_{ij} is (0,1]. When prescriptions elapse entirely within the observation window, $f_{ij} = 1$. This scaling factor was applied to the traditional MME calculation (quantity) × (strength) × (equianalgesic conversion factor) to calculate a_{ij}, a prescription's MME occurring within the observation window:

$$a_{ij} = (qmc)_{ij}\frac{o_{ij}}{d_{ij}} = (qmcf)_{ij}$$

The MME calculations for the above example are as follows, for patient i=1. The MME for the first prescription, $a_{i=1,j=1} = (qmcf)_{i=1,j=1}$, which is equal to (60 tablets) × (30mg per tablet) × (1.5 conversion factor from oxycodone to morphine)[17] × (1 scaling factor for relevant days supply), resulting in 2,700 MME. For the second prescription for this patient, $a_{i=1,j=2}$, the MME is equal to (14 tablets) × (5mg per tablet) × (1.5 conversion factor from oxycodone to morphine)[17] × (1 scaling factor for relevant days supply), resulting in 105 MME. Therefore, the total MME across both prescriptions for this patient, $a_{i=1} =$

$\sum_{j=1}^{2} a_{i=1,j} = a_{i=1,j=1} + a_{i=1,j=2}$, results in 2,805 MME. This total MME for the patient is the numerator in the first three definitions of the daily MME, as shown below.

Definition 1 – Total days supply

The numerator is the sum of MMEs across all prescriptions for patient i:

$$\sum_{j=1}^{n} a_{ij} = \sum_{j=1}^{n} (qmcf)_{ij}$$

The denominator is the sum of all days supply across all prescriptions for that patient that overlap the observation period. Therefore, similar to the scaled MME (a_{ij}) that is applied toward the numerator, it is necessary to use o_{ij} values in the denominator for this calculation. Although o_{ij} may be equivalent to d_{ij} (i.e., when the first mutually exclusive term in Equation 1 is triggered), this should not be assumed outright; otherwise there may be irrelevant days supply that count toward the denominator and tend to bias the daily MME value downward. According to Definition 1, we calculate x_i, the daily average MME for patient i, as:

$$x_i = \frac{\sum_{j=1}^{n} a_{ij}}{\sum_{j=1}^{n} o_{ij}} = \frac{\sum_{j=1}^{n} (qmcf)_{ij}}{\sum_{j=1}^{n} o_{ij}} = \frac{\sum_{j=1}^{n} (qmc)_{ij} \left(\frac{o}{d}\right)_{ij}}{\sum_{j=1}^{n} o_{ij}}$$

Note that this approach allows the same day to contribute multiple times to the denominator (i.e., when prescriptions overlap with each other), and it allows the denominator to potentially exceed the number of unique days in the observation window. Applying this definition to the example scenario:

$$x_{i=1} = \frac{\sum_{j=1}^{2} a_{i=1,j}}{\sum_{j=1}^{2} o_{i=1,j}}$$

$$= \frac{(qmcf)_{i=1,j=1} + (qmcf)_{i=1,j=2}}{\begin{array}{c}\{[(d_{i=1,j=1})(1)(1) + (w_{i=1} + l_{i=1} - s_{i=1,j=1})(1)(0) + (s_{i=1,j=1} + d_{i=1,j=1} - w_{i=1})(0)(1) + (l_{i=1})(0)(0)] + \\ [(d_{i=1,j=2})(1)(1) + (w_{i=1} + l_{i=1} - s_{i=1,j=2})(1)(0) + (s_{i=1,j=2} + d_{i=1,j=2} - w_{i=1})(0)(1) + (l_{i=1})(0)(0)]\}\end{array}}$$

$$= \frac{(qmc)_{i=1,j=1} \left(\frac{o}{d}\right)_{i=1,j=1} + (qmc)_{i=1,j=2} \left(\frac{o}{d}\right)_{i=1,j=2}}{(d_{i=1,j=1}) + (d_{i=1,j=2})}$$

$$= \frac{(60)(30)(1.5)\left(\frac{30}{30}\right) + (14)(5)(1.5)\left(\frac{7}{7}\right)}{30 + 7} = \frac{2{,}805\ MME}{37\ days\ supply} = 75.8\ daily\ MME$$

Definition 2 – On-therapy days

During the observation window l_i for patient *i,* we consider each date g_{ik}, where k indexes the day during follow-up such that $k = g - w + 1 = \{1, \ldots, l_i\}$. To classify each date g_{ik} as whether the patient had medication supply for each prescription j, we assign a binary indicator, h_{ijk}. For each prescription, $j = 1$ to $j = n$, for each patient i on each day, $k = 1\ to\ k = l_i$, during their observation window*,* this medication supply indicator is:

$$h_{ijk} = I[s_{ij} \leq g_{ik} \leq (s_{ij} + d_{ij})],$$

which returns a value of 1 if the date on observation day k falls during the patient's exposure to prescription j based on days supply, else 0. For each patient i, each unique day k (or alternatively, each person-date g_{ik}) can then be classified as exposed or unexposed, by assigning it the maximum value of h that was observed across all prescriptions j that may have overlapped that person-date. This person-day binary exposure summary variable is:

$$u_{ik} = \max_{\mathrm{i}k}\left(h_{i,j=1,k}, \dots, h_{i,j=n,k}\right),$$

which returns a value of 1 for each patient *i* on each day k if they had at least one available medication based on days supply from any of their prescriptions $j = 1\ to\ j = n$, else 0.

Finally, the denominator for the daily MME for patient i is the sum of all their exposed person-days during the observation window, $\sum_{k=1}^{l} u_{ik}$.

According to Definition 2, we calculate x_i, the daily average MME for patient i, as:

$$x_i = \frac{\sum_{j=1}^{n} a_{ij}}{\sum_{k=1}^{l} u_{ik}} = \frac{\sum_{j=1}^{n} (qmcf)_{ij}}{\sum_{k=1}^{l} u_{ik}} = \frac{\sum_{j=1}^{n} (qmc)_{ij} \left(\frac{o}{d}\right)_{ij}}{\sum_{k=1}^{l} u_{ik}}$$

Contrary to Definition 1, this approach does not allow the same day to contribute multiple times to the denominator (i.e., when prescriptions overlap with each other), and it does not allow the denominator to potentially exceed the number of unique days in the observation window. Applying this definition to the example scenario:

$$x_{i=1} = \frac{\sum_{j=1}^{2} a_{i=1,j}}{\sum_{k=1}^{l} u_{ik}} = \frac{(qmcf)_{i=1,j=1} + (qmcf)_{i=1,j=2}}{\sum_{k=1}^{l} \max_{\mathrm{i}=1,k}\left(h_{i=1,j=1,k}, h_{i=1,j=2,k}\right)}$$

$$= \frac{(qmcf)_{i=1,j=1} + (qmcf)_{i=1,j=2}}{\max_{\mathrm{i}=1,k=1}\left(h_{i=1,j=1,k=1}, h_{i=1,j=2,k=1}\right) + \dots + \max_{\mathrm{i}=1,k=60}\left(h_{i=1,j=1,k=60}, h_{i=1,j=2,k=60}\right)}$$

$$= \frac{(qmc)_{i=1,j=1}\left(\frac{o}{d}\right)_{i=1,j=1} + (qmc)_{i=1,j=2}\left(\frac{o}{d}\right)_{i=1,j=2}}{\max_{\mathrm{i}=1,k=1}\left(h_{i=1,j=1,k=1}, h_{i=1,j=2,k=1}\right) + \dots + \max_{\mathrm{i}=1,k=60}\left(h_{i=1,j=1,k=60}, h_{i=1,j=2,k=60}\right)}$$

$$= \frac{(qmc)_{i=1,j=1}\left(\frac{o}{d}\right)_{i=1,j=1} + (qmc)_{i=1,j=2}\left(\frac{o}{d}\right)_{i=1,j=2}}{u_{i=1,k=1} + u_{i=1,k=2} + \dots + u_{i=1,k=59} + u_{i=1,k=60}}$$

$$= \frac{(60)(30)(1.5)\left(\frac{30}{30}\right) + (14)(5)(1.5)\left(\frac{7}{7}\right)}{1 + 1 + \dots + 0 + 0} = \frac{2700 + 105}{1(30) + 0(30)} = \frac{2{,}805\ MME}{30\ days\ supply} = 93.5\ daily\ MME$$

Definition 3 – Fixed observation window

This common definition derives from early studies cited in the CDC Guideline often referencing an even earlier study, and is still used. The US Department of Health and Human Services Office of the Inspector General recommends this method, which is one of the only public sources with explicit description. The numerator is the sum of MMEs across all prescriptions, and the denominator is days elapsed during follow-up, hospital stay, or beneficiary enrollment. Although 90-day observation windows are most common, 180 days and 365 days were also used in studies supporting the Guideline. Applying this definition 2,805 divided by 90 days results in 31.2 milligrams per day.

First, we scale the MME calculation (quantity) × (strength) × (equianalgesic conversion factor) to calculate a_{ij}, a prescription's MME occurring within the observation window:

$$a_{ij} = (qmc)_{ij}\frac{o_{ij}}{d_{ij}} = (qmcf)_{ij}$$

Note that care should be taken to match the length of the observation window, l_i to the desired specification when calculating o_{ij} and subsequently, a_{ij}.

According to Definition 3, we calculate x_i, the daily average MME for patient i, as:

$$x_i = \frac{\sum_{j=1}^{n} a_{ij}}{l_i} = \frac{\sum_{j=1}^{n}(qmc)_{ij}\left(\frac{o}{d}\right)_{ij}}{l_i}$$

Applying this definition to the scenario, where no additional prescriptions are observed in the next 2 months, and using 90-day prespecified observation window (l_i):

$$x_{i=1} = \frac{\sum_{j=1}^{2} a_{i=1,j}}{l_{i=1}} = \frac{(qmcf)_{i=1,j=1} + (qmcf)_{i=1,j=2}}{l_{i=1}}$$

$$= \frac{(qmc)_{i=1,j=1}\left(\frac{o}{d}\right)_{i=1,j=1} + (qmc)_{i=1,j=2}\left(\frac{o}{d}\right)_{i=1,j=2}}{l_{i=1}}$$

$$= \frac{(60)(30)(1.5)\left(\frac{30}{30}\right) + (14)(5)(1.5)\left(\frac{7}{7}\right)}{90} = \frac{2700 + 105}{90} = \frac{2{,}805\ MME}{90\ days\ window} = 31.2\ daily\ MME$$

Definition 4 – Maximum daily dose

Toxicologic framing identifies the highest single day MME exposure, irrespective of days supply or opioid tolerance. This definition appears to underlie the calculator in the CDC Opioid Guideline mobile app. This method was used by studies cited in the Guideline, and may be most relevant for prescriptions in patients who are opioid naïve. However, "maximum" does not include what could be consumed in cases of intentional self-harm. The first prescription is 30mg × 2 (twice-per-day) × 1.5 (conversion factor) for 90 MME, plus the second prescription with 5mg × 2 × 1.5 for 15 MME, resulting in 105 milligrams per day.

For each prescription, $j = 1\ to\ j = n$, for each patient i, we assume that the prescription is apportioned evenly across the prescribed days supply (i.e., no unmeasured dose reductions). We calculate y_{ij}, the average prescription-specific MME per day for that prescription during the observation window, as:

$$y_{ij} = \frac{a_{ij}}{o_{ij}} = \frac{(qmcf)_{ij}}{o_{ij}} = \frac{(qmc)_{ij}\left(\frac{o_{ij}}{d_{ij}}\right)}{o_{ij}} = \frac{(qmc)_{ij}}{d_{ij}}$$

Then, as in Definition 2, each person-day should be classified as exposed or unexposed depending on whether the patient had at least one prescription that overlapped that date based on days supply. For each prescription, $j = 1\ to\ j = n$, for each patient i on each day, $k = 1\ to\ k = l_i$, during their observation window*,* the average prescription-specific MME per day is:

$$p_{ijk} = (y_{ij})(h_{ijk}) = (y_{ij})\ I\big[s_{ij} \leq g_{ik} \leq (s_{ij} + d_{ij})\big],$$

which returns that prescription's contribution to that daily MME if the date on observation day k falls during the patient's exposure to prescription j based on days supply, else 0.

For each patient *i*, each unique day k (or alternatively, each person-date g_{ik}) can then receive a value for total MME across all prescriptions, $j = 1\ to\ j = n$, as:

$$z_{ik} = \sum_{j=1}^{n} p_{ijk}$$

According to Definition 4, we calculate x_i, the maximum daily dose for patient i across all of their observation days, $k = 1\ to\ k = l_i$, as:

$$x_i = \max_{\mathrm{i}}\big(z_{i,k=1}, \dots, z_{i,k=l}\big)$$

Applying this definition to the example scenario, we first calculate the average prescription-specific MME per day for that prescription during the observation window, for each prescription:

$$y_{i=1,j=1} = \frac{(qmc)_{i=1,j=1}}{d_{i=1,j=1}} = \frac{(60)(30)(1.5)}{30} = 90\ MME\ per\ day\ for\ j = 1$$

$$y_{i=1,j=2} = \frac{(qmc)_{i=1,j=2}}{d_{i=1,j=2}} = \frac{(14)(5)(1.5)}{7} = 15\ MME\ per\ day\ for\ j = 2$$

Given that prescription $j = 1$ was issued on day $k = 1$ and it had 30 days supply, and prescription $j = 2$ was issued on day $k = 1$ and it had 7 days supply, we deduce each component of z_{ik}:

$$p_{i=1,j=1,k\ni\{1,2,3,\dots,30\}} = \big(y_{i=1,j=1}\big)\big(h_{i=1,j=1,k\ni\{1,2,3,\dots,30\}}\big) = (90)(1) = 90$$

$$p_{i=1,j=1,k\ni\{31,32,33,\dots,60\}} = \big(y_{i=1,j=1}\big)\big(h_{i=1,j=1,k\ni\{31,32,33,\dots,60\}}\big) = (90)(0) = 0$$

$$p_{i=1,j=2,k\ni\{1,2,3,\dots,7\}} = \big(y_{i=1,j=2}\big)\big(h_{i=1,j=2,k\ni\{1,2,3,\dots,7\}}\big) = (15)(1) = 15$$

$$p_{i=1,j=2,k\ni\{8,9,10,\dots,60\}} = \big(y_{i=1,j=2}\big)\big(h_{i=1,j=2,k\ni\{8,19,10,\dots,60\}}\big) = (15)(0) = 0$$

We can identify three day ranges between $k = 1\ to\ k = 60$ that carry unique values of z_{ik}. The first is days $k = 1\ to\ k = 7$, when days supply for both prescription $j = 1\ and\ j = 2$ are available. The second is days $k = 8\ to\ k = 30$, when days supply for prescription $j = 1$ is available. And the third is days $k = 31\ to\ k = 60$, when no prescriptions have available days supply. These are represented below:

$$z_{i=1,k\ni\{1,2,3,\dots,7\}} = \sum_{j=1}^{2} p_{i=1,j,k\ni\{1,2,3,\dots,7\}} = p_{i=1,j=1,k\ni\{1,2,3,\dots,7\}} + p_{i=1,j=2,k\ni\{1,2,3,\dots,7\}} = 90 + 15 = 105$$

$$z_{i=1,k\ni\{8,9,10,\dots,30\}} = \sum_{j=1}^{2} p_{i=1,j,k\ni\{8,9,10,\dots,30\}} = p_{i=1,j=1,k\ni\{8,9,10,\dots,30\}} + p_{i=1,j=2,k\ni\{8,9,10,\dots,30\}} = 90 + 0 = 90$$

$$z_{i=1,k\ni\{31,32,33,\ldots,60\}} = \sum_{j=1}^{2} p_{i=1,j,k\ni\{31,32,33,\ldots,60\}} = p_{i=1,j=1,k\ni\{31,32,33,\ldots,60\}} + p_{i=1,j=2,k\ni\{31,32,33,\ldots,60\}} = 0$$

$$x_i = \max_{\mathrm{i}}\left(z_{i,k=1}, \ldots, z_{i,k=60}\right) = \max_{\mathrm{i}}(\{105,90,0\}) = 105\ MME\ maximum\ daily\ dose$$

Supplement 3.

Daily MME Meta Analysis

Adapting a method recently developed by FDA to analyze a related opioid methods question, we used meta analytic techniques to test the impact of the four definitions in the real-world. The general set up is to compare opioid use in FL vs. CA across the 4 definitions of daily MME. We previously observed that Florida had higher unadjusted levels of opioid use, presumably an interaction with an older population and the enactment of clinical pain management legislation. We took two approaches, 1) treating daily MME as categorical by comparing the proportion of "high dose" users among opioid recipients, and 2) comparing means of daily MME between the states in a continuous manner, stratified by medicines used for acute versus chronic pain.

In [7]:

```
di "Stata MP"
version
di "Notebook generated on $S_DATE at $S_TIME ET"
```

```
Stata MP

version 16.0

Notebook generated on 26 May 2021 at 11:20:41 ET
```

Comparing "High Dose" patients in CA and FL

Input dataset from table of high dose patients (>90 daily MME) among adult outpatient opioid recipients identified using the PDMP of each state.

In [2]:

```
di "===== Proportion of high dose patients FL vs CA greater than 90 daily MME ====="
di "D1. Sum of days supply"
    csi  87295 87078   1398296  2343792
di "D2. On-therapy days"
    csi 136995 140822  1348596   2290048
di "D3. Defined observation window"
    csi 97346 86407  1388245   2344463
di "D4. Maximum daily dose"
    csi 211429 249471  1274162   2181399
```

```
===== Proportion of high dose patients FL vs CA greater than 90 daily MME =====

Definition 1


                 |   Exposed   Unexposed  |      Total
-----------------+------------------------+------------
           Cases |     87295       87078  |     174373
        Noncases |   1398296     2343792  |    3742088
-----------------+------------------------+------------
           Total |   1485591     2430870  |    3916461
                 |                        |
            Risk |  .0587611    .0358217  |   .0445231
                 |                        |
                 |      Point estimate    |    [95% Conf. Interval]
                 |------------------------+------------------------
 Risk difference |         .0229394       |    .0224949    .0233839
      Risk ratio |         1.640376       |    1.625414    1.655475
 Attr. frac. ex. |         .3903837       |    .3847723    .3959439
 Attr. frac. pop |         .1954347       |
                 +-------------------------------------------------
                               chi2(1) = 11405.78  Pr>chi2 = 0.0000

Definition 2


                 |   Exposed   Unexposed  |      Total
-----------------+------------------------+------------
           Cases |    136995      140822  |     277817
        Noncases |   1348596     2290048  |    3638644
-----------------+------------------------+------------
           Total |   1485591     2430870  |    3916461
                 |                        |
            Risk |  .0922158    .0579307  |   .0709357
                 |                        |
                 |      Point estimate    |    [95% Conf. Interval]
                 |------------------------+------------------------
 Risk difference |         .0342851       |    .0337349    .0348353
      Risk ratio |          1.59183       |    1.580486    1.603256
 Attr. frac. ex. |         .3717922       |    .3672831    .3762692
 Attr. frac. pop |         .1833353       |
                 +-------------------------------------------------
                               chi2(1) = 16446.29  Pr>chi2 = 0.0000

Definition 3


                 |   Exposed   Unexposed  |      Total
-----------------+------------------------+------------
           Cases |     97346       86407  |     183753
        Noncases |   1388245     2344463  |    3732708
-----------------+------------------------+------------
           Total |   1485591     2430870  |    3916461
                 |                        |
            Risk |  .0655268    .0355457  |   .0469181
                 |                        |
                 |      Point estimate    |    [95% Conf. Interval]
                 |------------------------+------------------------
 Risk difference |         .0299811       |    .0295201    .0304421
      Risk ratio |         1.843451       |    1.827062    1.859988
 Attr. frac. ex. |         .4575392       |    .4526731    .4623621
 Attr. frac. pop |         .2423885       |
                 +-------------------------------------------------
                               chi2(1) = 18534.92  Pr>chi2 = 0.0000

Definition 4


                 |   Exposed   Unexposed  |      Total
-----------------+------------------------+------------
           Cases |    211429      249471  |     460900
        Noncases |   1274162     2181399  |    3455561
-----------------+------------------------+------------
           Total |   1485591     2430870  |    3916461
                 |                        |
            Risk |  .1423198    .1026262  |   .1176828
                 |                        |
                 |      Point estimate    |    [95% Conf. Interval]
                 |------------------------+------------------------
 Risk difference |         .0396936       |    .0390145    .0403727
      Risk ratio |         1.386778       |    1.379279    1.394318
 Attr. frac. ex. |         .2789041       |    .2749835    .2828035
 Attr. frac. pop |         .1279419       |
                 +-------------------------------------------------
                               chi2(1) = 13991.68  Pr>chi2 = 0.0000
```

Scrape "Risk ratio" and CIs into new input dataset. Create log-transformed variables to meet normal distribution assumption of meta analytic statistics.

In [3]:

```
clear all
qui: input definition irr ll ul str31 label
1  1.640376      1.625414    1.655475     "D1. Sum of days supply"
2   1.59183     1.580486    1.603256    "D2. Accounting for overlap days"
3   1.843451    1.827062    1.859988   "D3. Defined observation window"
4  1.386778      1.379279    1.394318    "D4. Maximum daily dose"
end

gen lnirr=ln(irr)
gen lnll=ln(ll)
gen lnul=ln(ul)

qui: meta set lnirr lnll lnul, studylabel(label)
```

```
. gen lnirr=ln(irr)

. gen lnll=ln(ll)

. gen lnul=ln(ul)

. qui: meta set lnirr lnll lnul, studylabel(label)
```

Run meta analysis command using fixed effects model. Since there is no sampling variation, fixed effects is the preferred *a priori* specification.

In [4]:

```
meta summarize, fixed eform
```

```
  Effect-size label:  Effect Size
        Effect size:  lnirr
          Std. Err.:  _meta_se
        Study label:  label

Meta-analysis summary                                 Number of studies =      4
Fixed-effects model                                   Heterogeneity:
Method: Inverse-variance                                          I2 (%) =   99.91
                                                                      H2 = 1085.83

--------------------------------------------------------------------------------
                       Study |        exp(ES)    [95% Conf. Interval]  % Weight
-----------------------------+--------------------------------------------------
      D1. Sum of days supply |          1.640       1.625       1.655     15.27
D2. Accounting for overlap~s |          1.592       1.580       1.603     25.06
D3. Defined observation wi~w |          1.843       1.827       1.860     16.07
      D4. Maximum daily dose |          1.387       1.379       1.394     43.60
-----------------------------+--------------------------------------------------
                 exp(theta) |          1.542       1.536       1.547
--------------------------------------------------------------------------------
Test of theta = 0: z = 237.00                              Prob > |z| = 0.0000
Test of homogeneity: Q = chi2(3) = 3257.49                   Prob > Q = 0.0000
```

For the sake of completeness, random effects models are also run, using the Sidik-Jonkman `random(sj)` estimator because tau is expected to be large Veroniki et al., with DerSimonian–Laird `random(dl)` as well separately for comparison, but fixed effects (above) is the more technically correct model specification.

In [5]:

```
meta summarize, random(sj) eform
```

```
  Effect-size label:  Effect Size
        Effect size:  lnirr
          Std. Err.:  _meta_se
        Study label:  label

Meta-analysis summary                                 Number of studies =      4
Random-effects model                                  Heterogeneity:
Method: Sidik-Jonkman                                               tau2 =  0.0137
                                                                  I2 (%) =   99.90
                                                                      H2 =  954.41

--------------------------------------------------------------------------------
                       Study |        exp(ES)    [95% Conf. Interval]  % Weight
-----------------------------+--------------------------------------------------
      D1. Sum of days supply |          1.640       1.625       1.655     24.99
D2. Accounting for overlap~s |          1.592       1.580       1.603     25.00
D3. Defined observation wi~w |          1.843       1.827       1.860     24.99
      D4. Maximum daily dose |          1.387       1.379       1.394     25.02
-----------------------------+--------------------------------------------------
                 exp(theta) |          1.607       1.433       1.803
--------------------------------------------------------------------------------
Test of theta = 0: z = 8.11                                Prob > |z| = 0.0000
Test of homogeneity: Q = chi2(3) = 3257.49                   Prob > Q = 0.0000
```

In [6]:

```
meta summarize, random(dl) eform
```

```
  Effect-size label:  Effect Size
        Effect size:  lnirr
          Std. Err.:  _meta_se
        Study label:  label

Meta-analysis summary                                 Number of studies =      4
Random-effects model                                  Heterogeneity:
Method: DerSimonian-Laird                                           tau2 =  0.0156
                                                                  I2 (%) =   99.91
                                                                      H2 = 1085.83

--------------------------------------------------------------------------------
                       Study |        exp(ES)    [95% Conf. Interval]  % Weight
-----------------------------+--------------------------------------------------
      D1. Sum of days supply |          1.640       1.625       1.655     24.99
D2. Accounting for overlap~s |          1.592       1.580       1.603     25.00
D3. Defined observation wi~w |          1.843       1.827       1.860     24.99
      D4. Maximum daily dose |          1.387       1.379       1.394     25.01
-----------------------------+--------------------------------------------------
                 exp(theta) |          1.607       1.422       1.816
--------------------------------------------------------------------------------
Test of theta = 0: z = 7.61                                Prob > |z| = 0.0000
Test of homogeneity: Q = chi2(3) = 3257.49                   Prob > Q = 0.0000
```

Results are similar, but SJ is preferred based on simulations in Veroniki et al. The fixed effects model over emphasizes precision (e.g., confuses it for more information) in D4 due to the higher number of high dose patients. Since there is no sampling variation

Interpretation

The proportion of "high dose" patients was consitently higher in Florida across all variants. However, the magnitude of the difference varied greatly: 84.3% (95% CI: 82.7%, 86.0%) for Definition 3 (defined observation window); 64.0% (95% CI: 62.5%, 65.5%) for Definition 1 (sum of days supply); 59.2% (95% CI: 58.0%, 60.3%) for Definition 2 (accounting for overlap days); and 38.7% (95% CI: 37.9%, 39.4%) for Definition 4 (maximum daily dose). Metrics confirmed very high heterogenity between the definitions, with I2 greater than 99% and H2 of 1086, supported by tests of hetereogenity chi2 of 3257 on 3 degrees of freedom (p<0.0001), and overall effect z=237, with 1 degree of freedom and p<0.0001.

Meta Analysis of Means by Type of Opioid

In this meta analysis we examine the impact of definitional variation on acute vs. chronic pain patients, measured by opioid formulation type. We stratified the sample into three sub-groups: 1) patients receiving on only immediate-release or short-acting opioids labeled for acute pain (hereafter immediate-release; 2) patients receiving only extended-release or long-acting opioids generally labeled for chronic pain (hereafter extended-release); and 3) patients receiving both immediate-release and extended-release opioids contemporaneously within the 3 month observation period (e.g., chronic pain patients receiving opioids for breakthrough pain or during taper).

Continuing with the approach in the previous meta analysis, we calculated mean differences in daily MME between Florida and California, treating each of the 4 daily MME definitions as separate studies run on the same sample (e.g., fixed effects).

Immediate-release only

In [6]:

```
clear
input definition n_fl m_fl sd_fl n_ca m_ca sd_ca
1 1338828 34.0531498 28.4797412 2273028 30.3156249 222.6063485
2 1338828 35.0964146 30.180772 2273028 31.5819604 223.0198312
3 1338828 12.5794512 25.2892396 2273028 10.3398905 42.5422362
4 1338828 44.7478467 48.3917948 2273028 39.6430507 280.3601706
end

qui: meta esize n_fl m_fl sd_fl n_ca m_ca sd_ca, esize(mdiff)
meta summarize, fixed
```

```
     definit~n       n_fl       m_fl      sd_fl       n_ca       m_ca      sd_ca



  Effect-size label:  Mean Diff.
        Effect size:  _meta_es
          Std. Err.:  _meta_se

Meta-analysis summary                     Number of studies =      4
Fixed-effects model                       Heterogeneity:
Method: Inverse-variance                              I2 (%) =   98.63
                                                          H2 =   72.98

--------------------------------------------------------------------
            Study |     Mean Diff.    [95% Conf. Interval]  % Weight
------------------+-------------------------------------------------
          Study 1 |          3.738       3.359       4.116      3.92
          Study 2 |          3.514       3.135       3.894      3.90
          Study 3 |          2.240       2.160       2.319     89.72
          Study 4 |          5.105       4.626       5.584      2.45
------------------+-------------------------------------------------
            theta |          2.418       2.343       2.493
--------------------------------------------------------------------
Test of theta = 0: z = 63.18                     Prob > |z| = 0.0000
Test of homogeneity: Q = chi2(3) = 218.94          Prob > Q = 0.0000
```

Extended-release only

In [7]:

```
clear
input definition n_fl m_fl sd_fl n_ca m_ca sd_ca
1 26039 86.9071545 87.9504585 40038 90.2232825 100.0878302
2 26039 96.9302372 102.8249551 40038 103.7573329 134.372793
3 26039 66.8367252 81.142005 40038 72.753132 104.6161615
4 26039 143.0437107 159.4875273 40038 153.6802569 205.2125971
end

qui: meta esize n_fl m_fl sd_fl n_ca m_ca sd_ca, esize(mdiff)
meta summarize, fixed
```

```
     definit~n       n_fl       m_fl      sd_fl       n_ca       m_ca      sd_ca



  Effect-size label:  Mean Diff.
        Effect size:  _meta_es
          Std. Err.:  _meta_se

Meta-analysis summary                     Number of studies =      4
Fixed-effects model                       Heterogeneity:
Method: Inverse-variance                              I2 (%) =   86.38
                                                          H2 =    7.34

--------------------------------------------------------------------
            Study |     Mean Diff.    [95% Conf. Interval]  % Weight
------------------+-------------------------------------------------
          Study 1 |         -3.316      -4.806      -1.826     35.11
          Study 2 |         -6.827      -8.745      -4.909     21.19
          Study 3 |         -5.916      -7.415      -4.418     34.70
          Study 4 |        -10.637     -13.578      -7.695      9.01
------------------+-------------------------------------------------
            theta |         -5.622      -6.504      -4.739
--------------------------------------------------------------------
Test of theta = 0: z = -12.48                    Prob > |z| = 0.0000
Test of homogeneity: Q = chi2(3) = 22.03           Prob > Q = 0.0001
```

Both Extended-release and Immediate-release

In [8]:

```
clear
input definition n_fl m_fl sd_fl n_ca m_ca sd_ca
1 120724 82.95423 59.1676551 117804 74.1906194 64.4024217
2 120724 160.1525421 131.6299812 117804 143.9839494 151.4652358
3 120724 133.0969773 125.945819 117804 122.7372442 148.5490438
4 120724 267.949697 238.0130378 117804 250.7462218 282.0999741
end

qui: meta esize n_fl m_fl sd_fl n_ca m_ca sd_ca, esize(mdiff)
meta summarize, fixed
```

```
     definit~n       n_fl       m_fl      sd_fl       n_ca       m_ca      sd_ca



  Effect-size label:  Mean Diff.
        Effect size:  _meta_es
          Std. Err.:  _meta_se

Meta-analysis summary                     Number of studies =      4
Fixed-effects model                       Heterogeneity:
Method: Inverse-variance                              I2 (%) =   98.34
                                                          H2 =   60.27

--------------------------------------------------------------------
            Study |     Mean Diff.    [95% Conf. Interval]  % Weight
------------------+-------------------------------------------------
          Study 1 |          8.764       8.267       9.260     69.06
          Study 2 |         16.169      15.031      17.307     13.13
          Study 3 |         10.360       9.255      11.464     13.94
          Study 4 |         17.203      15.111      19.296      3.88
------------------+-------------------------------------------------
            theta |         10.286       9.873      10.698
--------------------------------------------------------------------
Test of theta = 0: z = 48.90                     Prob > |z| = 0.0000
Test of homogeneity: Q = chi2(3) = 180.81          Prob > Q = 0.0000
```

Interpretation

- ER only group had *lower* mean daily MME in Florida than California?!
- Heterogeneity by I^2 was high for all 3 definitions
- Heterogeneity was lowest for ER-only group by both I^2 and X^2
- For ER+IR group, the definitional variants would have resulted in us concluding that the average dose was 8.8 (8.3, 9.3) milligrams to 17.2 (15.1, 19.3) milligrams higher in Florida.

From: Nichole Dubinski
To: NCIPCBSC (CDC)
Subject: Chronic Pain
Date: Friday, July 23, 2021 12:11:20 PM

I'm so angry that my life has been taken from me, I can't even be nice about it anymore! This is unjust & inhuman to treat chronic pain patients like this. I was on a way higher dose then the 90MME, which is absolutely ridiculous to come up with such a thing, especially across the board for all patients needing pain meds. We are all bulit different. Different heights, weights, how the meds are absorbed etc. I have children & I'm now no longer able to do anything with them. These are years I will NEVER get back! It's destroying my marriage because my husband has to do absolutely everything, plus work full time & it's wearing on him. My whole family is falling apart due to your guidline you decided to put out, without scientific evidence! I take my meds exactly as prescribed, pass urine tests, pull counts etc. I didn't walk around drugged, I was simply living my life. I have done physical therapy, chiropractic treatment & all the procedures offered & nothing worked but my opioid medication, which you took away from me! You are torturing Americans! You are targeting pain patients & you're going after the wrong people. It's illegal street drugs! Now with all the illegal immigrants allowed to just cross the border, their is going to be a significant rise in deaths! Also the death rate has INCREASED all while you are STILL targeting reputable Dr's & pain patients! I suffer from PMDD also which is also debilitating. It causes major depression & severe pain, on top of all that is wrong with my neck & back. Taking opoiods while depressed does not make it worse. What has made my depression worse is taking my meds away from me. Sometimes I want to give up, what is the point of living when I'm not able to do a thing? What baffles me is if a person wants to take 5 oxycontin at once, knowing they could die, how does thay effect me? That is not my problem I choose to LIVE & I so desperately want my life back. Have any of you put yourself into our shoes? Imagine not being able to do a thing! I sit in a recliner daily. I also sleep in a recliner, not with my husband, where I should be!
Can you please take away the guidelines in it's entirety? They have taken many Americans lives away & punished us for not doing a thing wrong! We want to live our lives like you do daily. Please leave us pain patients & Dr's alone & let us have relationships with our Dr's that used to be so caring, instead of them ripping our meds away because they are afraid to loose our licenses. Thank you for your time with this huge matter.

Nichole Dubinski
847-420-1020

From: N
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:22:15 AM

As a chronic pain patient, I am prescribed opioids to help me function daily. Without them, I bed bound. I have tried every other option for pain control, including FIVE surgeries that left me worse.
While I completely understand the crisis in our country, there needs to be protection for patients. I follow all restrictions and protocols set for by my pain management. Submit to random drug testing and visit every three months. If a patient is complying, let their physician do their job to manage their care.
I asking for you to please let patients have their rights to care and pain relief. Leaving people in pain with no hope of help is unacceptable!

Thank you,
Nicole Erickson
nicolobolo33@gmail.com

Nothing carries more potential for change than individual acts of human kindness.~~~Jamie Winship

USING MEDICAL TECHNOLOGY TO RELIEVE PAIN AND DISRUPT THE OPIOID EPIDEMIC

LIFE EXPECTANCY in the United States increased modestly in 2018 by 0.1 years to 78.7 after falling for three years in a row, systemic opioid overdose was identified as a key driver of the decrease in previous years.[13-16]

Misuse Defined[4]
The use of prescription drugs without a prescription or in a manner other than as directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or for longer than told to take a drug; or use in any other way not directed by a doctor.

PERSPECTIVE SYNOPSIS

Millions of Americans are affected by pain and have been prescribed systemic opioids (typically oral) as part of their treatment plan by healthcare providers.[2] In the pain continuum, chronic pain can start with acute pain. Both pain types prompt an urgency of addressing patients' needs, often with systemic opioids. This is despite the limited evidence on the benefits of long-term systemic opioid therapy and evidence that long-term systemic opioid therapy is associated with increased risk for opioid misuse or addiction.[3] Here's what is known about the misuse of prescription opioids:

- An estimated 10.3 million Americans are misusing opioids with 63.6% doing so to relieve physical pain.[5]
- An estimated 25% of chronic pain patients are misusing prescription oral opioids.[6]

> ***"We cannot solve the opioid crisis, until we solve the nation's pain crisis.[1]"***
> -Admiral Brett P. Giroir, M.D.
> Assistant Secretary of Health,
> US Department of Health and Human Services

A CDC review of scientific evidence yielded many mitigation steps to reduce the risks associated with long-term systemic opioid use, including misuse, addiction and overdose.[7] In its guidelines, the CDC recommends patients with acute pain ask their doctors for treatment options that do not involve prescription opioids.[8] In addition, for chronic pain, CDC recommends nonpharmacologic therapy and nonopioid pharmacologic therapy as preferred treatments.[9] The FDA's updated opioid education Blueprint includes the use of approved/cleared medical devices for pain management as one of several nonpharmacologic treatment options healthcare providers should be knowledgeable about as part of a multidisciplinary approach to pain management.[10] Enacted into law on October 24, 2018, the federal SUPPORT for Patients and Communities Act includes provisions to raise provider and patient awareness of alternative, non-oral opioid pain treatments, including medical device-delivered therapies.[11]

As part of the comprehensive efforts in the United States to address the opioid epidemic, device-delivered therapies are being considered as an alternative or adjunct to systemic opioids in the management of acute and chronic pain. Device-delivered therapies of spinal cord stimulation, intrathecal pain pumps, and vertebral augmentation along with several other procedures have been identified by the U.S. Department of Health and Human Services in The Pain Management Best Practices Inter-Agency Task Force Report as interventional procedures that can be considered

Medtronic

MICHELSON TECHNOLOGY AT WORK

singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions.[12] Through greater awareness and use of device-delivered therapies, healthcare providers can reduce pain for many patients, potentially reducing their exposure to high dose opioid and/or long-term systemic opioid use that could lead to opioid misuse and addiction. As more patients effectively take control of their pain, these patients may no longer need to turn to misusing opioids to attempt to control their pain. This could help disrupt the opioid epidemic.

Burden of mortality is highest among adults aged 25 to 34 years; in this age group, **1 in 5 deaths in the United States is opioid related.**[23]

Medtronic Pain Therapies do not treat opioid addiction, but rather offer patients a way of managing their pain as an alternative or adjunct to systemic opioids. Medtronic has already published clinical evidence that shows reduction in the use of systemic opioids in managing and treating chronic pain with Targeted Drug Delivery (i.e. intrathecal pain pumps) and acute pain associated to vertebral compression fractures (VCF) using Balloon Kyphoplasty[17,18] as a technology for vertebral augmentation. It is important to understand that not every patient experience is the same. We continue to invest in clinical trials designed to generate new evidence to help physicians make more informed pain treatment decisions.

Medtronic supports ongoing efforts by stakeholders across the U.S. – patients, providers, payers, regulators, elected officials, patient advocacy groups, and employers – as they pursue approaches for preventing and treating prescription opioid misuse, addiction, and overdose. Medtronic is playing an important role alongside other stakeholders in helping patients take control of their pain by:

- Informing patients with acute and chronic pain of their options for device-delivered pain relief as an alternative or adjunct to systemic opioids so that patients may have an informed discussion with their doctors.
- Partnering with providers to consider non-systemic opioid pain relief in treatment plans for patients with acute and chronic pain.
- Educating payers, policymakers, and regulators to enable greater patient access to medical devices shown to alleviate pain as an alternative or adjunct to systemic opioids.

$170 BILLION

The economic impact of the opioid crisis in the United States was at least $631 billion from 2015 through 2018 and was estimated to exceed $170 billion annually in 2017 and 2018.[24]

Amongst 500 Human Resource professionals surveyed in America, **67 percent** said their organizations "are impacted by opioid use today or will be in the future," and **65 percent** reported that opioid addiction is having a financial impact on their company.[25]

SYSTEMIC OPIOIDS AND PAIN MANAGEMENT CRISES

There are two interrelated healthcare crises occurring in this area in the United States: the opioid epidemic, and the ongoing public health problem of inadequate pain management.

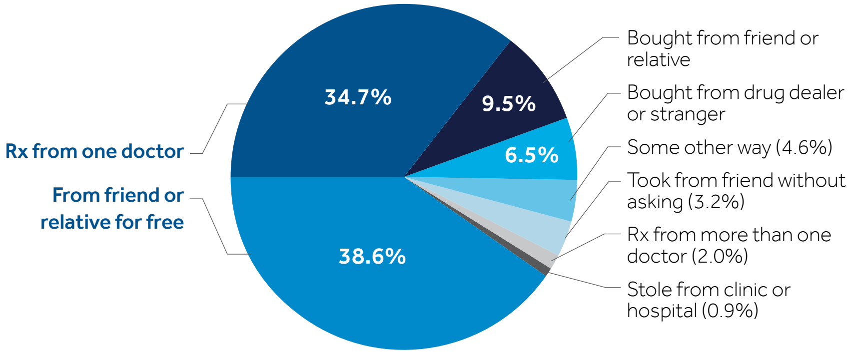
The Opioid Epidemic

The alarming opioid epidemic has had a devastating impact across the United States with 128 Americans dying every day from an opioid overdose in 2017.[19] In 2018 , opioids were involved in 46,802 overdose deaths and represented 69% of all fatal drug overdoses (67,367).[13,20,21] As a result, public officials declared the opioid epidemic "the worst drug crisis in American history."[22]

Urgency of this epidemic has drawn the attention of all American elected officials and regulators. One area that regulators were quick to look at was prescription opioid use for pain relief and how they were then sourced among people whom misused them. In 2018 , roughly 38% of people whom misused prescription pain relievers obtained them from one or more doctors.[5] In addition to recommendations on prescribing opioids for pain relief, the CDC recommends nonpharmacological therapy and non-opioid pharmacologic therapy as the preferred treatments of chronic pain.[9] If used, prescription opioids should be combined with other therapies, as appropriate.

An estimated **21% to 29%** of patients prescribed opioids for chronic pain misuse them. And, between **8% to 12%** of these patients develop an opioid use disorder.[6]

Source of Pain Relievers obtained by people who had misused prescription Pain Relievers[5]
(Year 2018, 9.9 million people age 12 or older)



Pain Management Problem
The ongoing public health problem of pain management constitutes a crisis of its own.[2] More than 100 million Americans experience chronic pain lasting greater than 3 months, costing the nation approximately $560-635 billion annually in direct medical treatment costs and lost productivity.[2] Millions more experience pain caused by a specific event (e.g. surgery, broken bones, dental work, or childbirth) that may last for 6 months.[26,27]

Although research suggests systemic opioids are effective at reducing pain and improving function in the short term, evidence on long-term systemic opioid therapy for relieving pain is limited.[3,7] Comparisons of opioids with nonopioid alternatives suggested that the benefit for pain and functioning may be similar.[31] CDC has identified long-term prescription opioid use and high daily opioid doses as risk factors that could lead to abuse or overdose.[32] An estimated 10.3 million Americans are misusing opioids with 63.6% doing so to relieve physical pain.[5] Furthermore, risks of prescription systemic opioids are high: prescription systemic opioids contributed to ~32 percent of all U.S. opioid overdose deaths in 2018.[33]

Up to **80 percent** of Americans will experience low back pain at some point in their lifetime.[30]

Patients with chronic pain have voiced their frustration with the inability to access effective pain relief and the devastating sociological impacts this has had on their lives.[34,35] These people are victims of chronic pain and the effects of the opioid epidemic on our society. Patients deserve other options for pain management through access to effective alternate and adjunct pain therapies.

An estimated **19.6 million Americans** in 2016 had high impact chronic pain (pain that limited their life or work activities on most days or every day for 6 months).[29]

INSPIRED TO PROVIDE BETTER PAIN MANAGEMENT

Medtronic has more than a 40-year history of developing innovative medical devices that have been shown to alleviate pain in different disease states.[36] Moreover, we have established expertise to demonstrate clinical outcomes and health economics of these products.

Given the current opioid epidemic and pain management crisis, our work to alleviate pain has never been more critical. That is why we leverage our capabilities and product portfolio in partnership with stakeholders — patients, providers, payers, regulators, elected officials, patient advocacy groups, and employers — to address the unmet needs of pain patients.

We are aware no single entity can solve America's opioid and pain crises alone. It is when we work in partnership that we expand patient access to non-systemic opioid pain management therapies. Therefore, we are pursuing collaboration with others in pain management to:

PAIN
affects more Americans and is costlier than diabetes, heart disease, and cancer.[28]

Broaden Therapy Awareness and Advocacy

- Increase stakeholder **awareness** of the clinical and economic evidence of device-delivered therapies along with the risks of long-term systemic opioid use to treat pain.
- Leverage social media networks, pain advocacy groups, and local treatment clinics to heighten **patient awareness** to device-delivered options that have been shown to treat pain or painful conditions. Only a physician can decide if these therapies are right for a patient.

Deliver Innovation

- Develop **novel payment models** for private and public payers that will help healthcare providers deploy evidence-based clinical workflows, guidelines, and policies for device-delivered therapies to manage pain or painful conditions.
- Explore with industry partners the **use of medical technology** to track objective patient metrics, coupled with clinical workflows, to deliver and monitor non-systemic opioid pain relief.

Advance Clinical and Economic Evidence

- Expand the body of existing **clinical and economic evidence** (independently and through partnerships with providers and payers) on the ability of Medtronic Pain Therapies — coupled with clinical workflows — to reduce or eliminate systemic opioid usage.
- Educate state and federal government officials about the need for **policies to ensure patient access** to the clinical and economic benefits of device-delivered therapies for pain or painful conditions.

MISSION-DRIVEN TECHNOLOGY TO IMPROVE OUTCOMES

With our company mission to alleviate pain, restore health, and extend life, Medtronic strives to be at the forefront of medical device innovation, challenging ourselves to develop high-quality therapies for pain or painful conditions. Our view is that medical technology should not be only for reducing pain, but also for improving quality of life. And at every stage of the process — from technology advancements to physician training — we strive to understand the patient experience through the principles of human-centered design.[37]

The Medtronic Pain Therapies portfolio includes implantable medical devices for Targeted Drug Delivery (TDD) and Spinal Cord Stimulation (SCS) for chronic pain. Our portfolio also includes products indicated for: vertebral augmentation therapies such as Balloon Kyphoplasty (BKP) for vertebral compression fractures (VCF) due to osteoporosis, cancer or benign lesion; OsteocoolTM radiofrequency ablation of painful bone tumors; and Sacroplasty for the treatment of pathological sacral fractures. These minimally invasive technologies treat these conditions, which are associated with acute pain. To date, over a million patients have received treatment from Medtronic Pain Therapies.[38] In addition to the risks of surgery, the medical devices discussed in this paper carry significant risks. Please refer to the important safety information at the end of document.

While these therapies do not treat addiction, they can help patients manage their pain. Medtronic is committed to providing clinical evidence and in studying the use of systemic opioids in managing and treating chronic pain with TDD and acute pain associated to VCF with BKP.[17,18] Through our medical education and ongoing clinical support programs, we continuously strive to educate about device therapies as an option in pain management with the goal that fewer patients will need to rely on long-term systemic opioid use.

Along with clinical evidence demonstrating pain relief, we have strong coverage and reimbursement in the United States for clinical indications recognized and covered by government and non-government payers. For example:

Two retrospective claims analyses found that **43 and 51 percent**, respectively, of chronic non-malignant pain patients eliminated systemic opioids within one year of TDD therapy.[17,47] In the second study which evaluated patients starting TDD therapy between 2012-2015, overall (regardless of discontinuation), **82% reduced** their average daily morphine milligram equivalents (MME) in the year following start of TDD therapy relative to one-year baseline MME values.[47] Among patients that eliminated systemic opioid use, the mean annual per-patient medical and pharmacy **cost savings to the payer in the first year of therapy were $11,115** relative to patients who continued, a **29% reduction**.[47]

A smaller, single-center, retrospective chart review (n=99) of patients with chronic non-malignant pain who agreed to transition from systemic opioids to TDD with the goal of eliminating systemic opioids, demonstrated that **84 percent of patients were able to eliminate systemic opioids after 12 months** when using TDD to relieve their chronic pain.[53]

- TDD and SCS are covered by Medicare under national and local coverage determinations.
- BKP has coverage from all Medicare MAC's via Local Coverage Determinations.
- Most commercial payers have published coverage determinations for all our Medtronic Pain Therapies.

Knowing how and when to use alternative and adjunctive therapies to systemic opioids is more important than ever. That is why, before committing to long-term treatment, physicians will have their patients undergo a trial for some therapies (i.e. TDD and SCS) to experience the therapy.

MEDTRONIC PAIN THERAPIES

Targeted Drug Delivery

Targeted Drug Delivery (TDD) with SynchroMed™II, also known as a pain pump or intrathecal drug delivery system (IDDS), for the treatment of chronic intractable pain, including intractable cancer pain, provides pain relief at a fraction of the oral medication dose.[39-42] An implanted, programmable pump and catheter releases prescribed amounts of pain medication directly into the intrathecal space, near pain receptors in the spine instead of the circulatory system. The CONTROL Workflow℠ in combination with SynchroMed ™II encourages systemic opioid elimination and is an alternative to long-term systemic opioids.

Intrathecal drug delivery has been shown to improve patients' ability to function, return to work, and participate in activities of daily living.[39,41,43,44] In addition to effective pain relief, TDD has been shown to reduce or eliminate use of oral pain medication and to reduce side effects compared to systemic pain medication.[17,39-42,45-47]

TDD is often viewed as a "salvage therapy" when high dose systemic opioid therapy has not worked. This is despite success of the therapy as demonstrated in randomized controlled trials, and the demonstrated cost effectiveness of the therapy.[17,40,48-52]

The implanted pump stores and dispenses medication inside the body, reducing the opportunity for diversion of the drug, for misuse by individuals who are not prescribed the opioids. Additionally, the physician programs the pump to deliver a certain amount of medication, allowing more physician control compared to systemic opioid therapy, reducing the opportunity for misuse of prescribed opioids.

Systemic opioid dose levels prior to initiation of TDD have shown significant correlation with ultimate patient success with TDD. In a retrospective study of 631 patients, those whose MME was < 50 mg/day had two times the odds of discontinuing systemic opioids following initiation of TDD (OR = 2.08, 95% confidence interval 1.42-3.02, p = 0.001).[47] Knowing that systemic dosing levels and intrathecal dose levels matter, Medtronic developed The Control Workflow℠ for TDD providing a pain relief option utilizing a low-dose protocol with the SynchroMed™ II intrathecal drug delivery system and as guidance for eliminating systemic opioids. This workflow assists physicians with patient selection and includes oral opioid weaning and treatment protocols that can be tailored to individual patients. By having an outlined workflow for physicians, we are working to simplify the therapy and expand patient access to TDD therapy.

Medtronic is currently sponsoring the Embrace TDD Post Market Clinical Study that will evaluate the use of the SynchroMed™ II intrathecal drug delivery system as an alternative to oral opioids for patients with chronic intractable non-malignant primary back pain with or without leg pain.[54] The study will follow patients who wean completely from all oral opioids and have a positive response to an intrathecal drug trial. The study will assess pain control and opioid-related side effects at six months following a route of delivery change to intrathecal preservative-free morphine sulfate.

Spinal Cord Stimulation

Medtronic's Intellis™ implantable neurostimulator for Spinal Cord Stimulation (SCS) is the smallest spinal cord stimulator implanted under the skin to deliver mild electrical pulses to the spine. SCS modifies pain messages before they reach the brain and has proven to provide long-term effective pain relief and improve quality of life.[55-57] In addition to pain relief, spinal cord stimulation is more cost-effective than conventional medical management and reoperation.[58,59] Multiple studies have provided clinical evidence to suggest some patients treated with Spinal Cord Stimulation (SCS) may be able to reduce oral opioid consumption.[60-62] Spinal cord stimulation is more effective than repeat surgery for persistent radicular pain after lumbosacral spine surgery.[63]

As a platform technology, Medtronic is providing more than just pain relief with the Intellis neurostimulator. This is the only platform that has embedded measurable activity data through Snapshot™ reporting, which tracks and shares activity, body positions and therapy usage continuously. Snapshot complements patient self-reporting with an objective look at their mobility. By reporting objective activity data, Intellis offers physicians insights into patient treatment beyond patient-reported pain scores. This may enable better treatment personalization to support improvement in function.

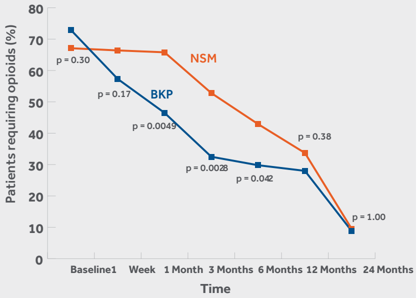
Interventional Pain Therapies

Vertebral compression fractures (VCF) are associated with a downward spiral of complications, including decreased mobility, pain, and function.[18,64-66] While vertebral augmentation (VA) is not for everyone, Balloon Kyphoplasty (BKP) and vertebroplasty (VP) are important treatment options to consider for patients with vertebral compression fractures (VCF) due to osteoporosis, cancer or benign lesion.

Early diagnosis and interventional treatment are important steps to avoiding complications associated with VCFs.[67-69] To help physicians navigate this complex condition, Medtronic is proud to support a VCF multispecialty panel of experts in recommending a clinical care pathway to guide physicians in treating the common condition of vertebral fragility fractures.[70]

"VCF Clinical Care Pathway" was recently developed by a multi-specialty panel of physicians and published in August 2018. The study – which included a systematic literature review of 83 randomized controlled trials, systematic reviews, and observational studies – aims to support greater consistency in the early diagnosis and treatment of VCFs with a goal to establish a clinical care pathway for patients with VCF to include : Key signs and symptoms of suspected VCF, Diagnostic evaluation of patients with suspected VCF, Appropriateness criteria for vertebral augmentation (VA) or nonsurgical management (NSM) Contraindications for VA and Follow-up after treatment.[70]

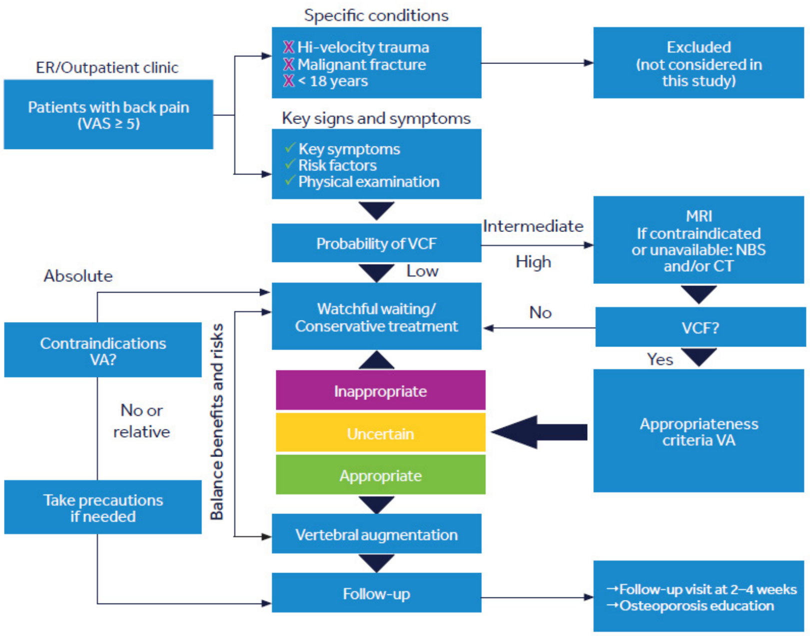
A prospective, randomized controlled trial (N = 300), **FREE** study, reported Kyphon™ BKP (n=149) demonstrated **31%** less prescription opioid use at 6 months* compared to non-surgical management (n=151) (29.8% BKP vs. 42.9% NSM, p=0.042)[18]



Kyphon™ BKP demonstrated less opioid use[18]

** Differences between groups were similar in opioid usage at 12 months (28.0% BKP vs. 33.7% NSM, p = 0.38) and 24 months (8.8% BKP vs. 9.5% NSM, p = 1.0).*

VCF Clinical Care Pathway



Kyphon™ Balloon Kyphoplasty (BKP) is a minimally invasive vertebral augmentation technology that uses orthopedic balloons to restore vertebral height and correct angular deformity due to vertebral compression fractures (VCF) from osteoporosis, cancer or benign lesion. After reduction, the balloons are deflated and removed. The resulting cavity (void) allows for a controlled deposition of Kyphon bone cement forming an internal cast and stabilizing the fracture. Risks of the procedure include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events.[18,64-66]

A prospective, randomized controlled trial (Free Study, 2011 N = 300) reported that Kyphon™ Balloon Kyphoplasty offers important clinical benefits compared to non-surgical management, including pain relief, reduced opioid use, and improved quality of life.[18]

TOGETHER TO FIND LASTING SOLUTIONS

Millions of Americans are affected by the opioid epidemic, and their best hope is partners in healthcare coming together to create lasting solutions.[2] Healthcare providers, payers, elected officials, regulators and patient advocacy groups all hold important pieces to the puzzle and must work together. It starts with novel care pathways and personalized treatment options to help these patients break their cycle of misuse or dependency. Solutions must also help the approximately 6.9 million patients who misuse opioids to alleviate pain, and these patients need effective policies and programs that will expand access to medical devices shown to relieve pain as an alternative or adjunct to systemic opioids.[71]

Partnership is the path forward in addressing the systemic opioid and pain management crises. All stakeholders must work together, pursuing effective policies and programs that will expand patient access to medical technologies shown to relieve pain as an alternative or adjunct to systemic opioids.

SynchroMed® II Drug Infusion System Brief Statement:

Review product technical manuals, including information about EMI, and the appropriate drug labeling prior to use for detailed disclosure.

Indications: US: Chronic intrathecal infusion of Infumorph® preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, Prialt® chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Drug Information: Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration, screening procedures, and under-/overdose symptoms and methods of management. Patients should be informed of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions, and signs and symptoms that require medical attention.

Contraindications: System implant is contraindicated in the presence of an infection; implant depth greater than 2.5 cm below skin; insufficient body size; and spinal anomalies. Use of the system with drugs with preservatives and drug formulations with pH ≤3. Use of CAP kit for refills or of refill kit for catheter access and use of PTM to administer opioid to opioid-naïve patients.

Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose.

An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Monitor patients appropriately after refill if a pocket fill is suspected. Failure to recognize signs and symptoms of pocket fill and seek appropriate medical intervention can result in serious injury or death. Overinfusion may lead to underdose or overdose symptoms. Strong sources of electromagnetic interference (EMI) can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. The SynchroMed II system is MR Conditional; consult the labeling for MRI information.

Precautions: Monitor patients after pump or catheter replacement for signs of underdose/overdose. Infuse preservative-free saline at minimum flow rate if therapy is discontinued for an extended period to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions.

Adverse Events: In addition to procedure-related risks, the following may occur: pocket seroma; hematoma; erosion; infection; pump inversion; post-lumbar puncture risks (spinal headache); CSF leak and rare central nervous system pressure-related problems; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; allergic response to implant materials; surgical replacement due to end of service life or component failure; loss of therapy, drug overdose, or inability to program the pump due to component failure; catheter complications resulting in tissue damage or loss of or change in therapy; potential serious adverse effects from catheter fragments in intrathecal space.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com

Infumorph® is a registered trademark of West-Ward Pharmaceutical. Prialt® is a registered trademark of TerSera Therapeutics LLC. Lioresal® is a registered trademark of Saol.

USA Rx Only

Rev 1118

Neurostimulation Systems for Pain Therapy

INDICATIONS Spinal cord stimulation (SCS) is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain.

CONTRAINDICATIONS Diathermy - Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death.

WARNINGS Sources of electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device.

PRECAUTIONS Safety and effectiveness has not been established for pediatric use, pregnancy, unborn fetus, or delivery. Avoid activities that put stress on the implanted neurostimulation system components. Recharging a rechargeable neurostimulator may result in skin irritation or redness near the implant site.

ADVERSE EVENTS May include: undesirable change in stimulation (uncomfortable, jolting or shocking); hematoma, epidural hemorrhage, paralysis, seroma, infection, erosion, device malfunction or migration, pain at implant site, loss of pain relief, and other surgical risks.

Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events.

USA Rx Only

Rev 0119

Kyphon Balloon Kyphoplasty and Sacroplasty Important Safety Information

Kyphon Xpede™ Bone Cement and Kyphon HV-R™ Bone Cement are indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism.

Osteocool Important Safety Information

The OsteoCool™ RF Ablation System is intended for the palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body and of benign bone tumors such as osteoid osteoma. It is also intended for coagulation and ablation of tissue in bone during surgical procedures, including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

Risks of the system include damage to surrounding tissue through iatrogenic injury as a consequence of electrosurgery; pulmonary embolism; nerve injury including thermal injury, puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis, and paralysis.

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UC201903424e EN, PMD021479-4.0

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MICHELSON
TECHNOLOGY
AT WORK

From: Nancy Rene
To: NCIPCBSC (CDC)
Subject: Opioid guidelines
Date: Friday, July 23, 2021 10:54:22 AM

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Let me tell you about my friend Tiffany. Tiffany was battling the pain of sickle cell disease, she had a hip replacement that was unsuccessful and walked with a severe limp. Because of opioid restrictions she was not able to get the medication that helped her through all of this. Even though sickle cell was supposedly exempted in the guidelines, doctors didn't pay attention. Tiffany died earlier this year, she was 53 years old.

It seems that no matter what advocates say, these new guidelines do not do enough to discuss the management of pain in sickle cell disease. Many adults with sickle cell don't have a regular doctor and must rely on the ER for treatment. The CDC must make it clear that these guidelines are not intended for those with sickle cell. If you fail to do this you are condemning patients to endure chronic pain with no relief in sight.

Please don't continue the mistakes of the 2016 guidelines, don't punish patients for the actions of drug companies and a few doctors, let them get the relief they deserve.

Nancy M. Rene
JVT Advocates, Los Angeles, CA

From: Nick Travers
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:56:34 PM

Hello,

My name is Nick Travers, and I would like to share my story with you, if I could borrow just a few moments of your time. Skip to the bottom paragraph if the message is too long.

My pain journey has not been very cut and dry. It started with just terrible pain in my back that wouldn't go away. Since 2017 I have been fighting like crazy to get back to some sort of life that isn't agonizing. When therapy, injections and weight loss did not help, I went under the knife. Four surgeries, three of which were fusions. Doctors didn't have answers as to why I was still in pain, so they just kept trying the same injections into my spine to no avail.

Fast forward to today, and I'm currently under the care of an amazing pain doctor that really cares about me. She knows I'm young and have a long journey ahead of me, and wants me to get better. I am currently waiting to have surgery on my hips, that were the main reason for my pain, which was misdiagnosed.

In my struggle with pain, and I mean severe pain, I have been treated like trash. I have been told I am drug seeking, I have been told that my pain doesn't make sense, and that it doesn't make sense that I have it. I've had doctors tell me that they can't help me, and send me out the door, even from the emergency room. Blood pressure 150/105, they either don't care, can't help you, or both. I've considered moving out of the country because of this, in search of help. I am thankful I am receiving help now, but it took a lot of, as they say, doctor shopping, to find my doctor. Chronic pain patients in this country are Lepers of the 21st century, sent out to die in the streets, dare anyone help us. You are the only ones that can help us, other than God.

(Think of your worst pain, then think about having that pain not go away, then think about being scolded for asking for help for that pain, then you'll have caught a small glimpse of one day in the living hell that we call our lives).

Thank you for your time.

From: nancywarncke@sbcglobal.net
To: NCIPCBSC (CDC)
Subject: Updated Draft Opioid Prescribing Guideline
Date: Friday, July 23, 2021 3:17:06 PM

Dear CDC,

I am writing regarding the Updated Draft Opioid Prescribing Guideline which the CDC National Center for Injury Prevention and Control (NCIPC) presented at their meeting of the CDC Board of Scientific Counselors this past Friday, July 16. It seems that the updated draft is very similar to the 2016 Guideline and doesn't address benefits of opioids for pain relief when used appropriately, the arbitrary MME dosing, and the exclusion of some pain conditions such as cancer and end-of-life issues.

My husband has had severe chronic pain for many years, and the 2016 Opioid Prescribing Guideline has had a significant and detrimental impact on his quality of life. As a result of spinal stenosis, severe arthritis, herniated discs, and other related back issues, he has had to undergo multiple surgeries. He has multiple fusions and metal bracing in his neck, and in June he had to undergo a four-level lower back fusion. The surgeon had to enter first from his abdomen, with a vascular surgeon carefully moving organs and nerves out of the way. The surgeon then had to go in from the back to complete the work. The surgeon told him that his facet joints were destroyed by arthritis. It was the worst case he had seen in many years. This was a very long surgery (six and one-half hours). On top of all this, he has severe shoulder pain caused by an automobile accident several years ago. (He was rear ended when stopped at a red light.)

My husband has tried all the other recommendations over the years that were supposed to help, including the implantation of a spinal stimulator. This was a nightmare. After the third surgery to reposition it, he finally had another surgery to have it removed. He has also tried acupuncture, chiropractor care, exercise, and over the counter pain relief.

Prior to the 2016 guidelines, with the help of his doctors and surgeons prescribing a combination of prescription drugs, my husband was able to function fairly well without unbearable pain. He could do light chores, go out to eat, and even go on short trips. This all changed with the CDC ruling in 2016. He is a big man – 6'8" – yet he is expected abide by the arbitrary dosing guidelines and the constant pressure to lessen his dosage. This is cruel. He has followed, and continues to follow, all the rules. He is a responsible citizen who is simply trying to live his life without unbearable pain. Please reconsider your guidelines so that people who live with severe chronic pain can work with their doctors to obtain the relief they need to live a life without suffering.

Thank you,
Nancy Warncke

From: normwetterau@aol.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 6:25:39 AM

Revised pain guidelines
I wish you would specific mention buprenoprhine in number 12 as you previously had.
I have been prescribing it for both pain and addiction for over 15 years and it is one of the most underutilized drugs. You mention other meds but I think specifically mentioning it would be helpful,you might even say low dose.I know that there is not that much research on its use in only pain in the US but it is very effective if combined with a total pain program and it has helped many of my patients who were addicted to other opioids or maybe not addicted but doing poorly.
How can we get pain doctors to consider buprenorphine

The big rage now is medical marijuana . Studies show medical marijuana has only mild effects and high dose can decrease function where as buprenorphine has good effects and pain and function. Also think of someone with chronic pain for ten years on marijuana versus buprenorphine. i see patients from pain doctors who have been given marijuana and then a need to add buprenorphine but cannot get them off the marijuana PLEASE MAKE A STRONG STATEMENT ABOUT BUPRENORPHINE

Norman Wetterau MD DFASAM
6 Clinton St
Dansville, NY 14437

From: Napoleon Wilkie
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 9:01:39 AM

One more comment, I've been a victim of this tapering of my pain medication and I now suffer from breakthrough pain from not having access to long acting pain medication and it's trying my patience.
You need to give opioid patient's more control of what they need to live a humane life.
Human being are made of inferior stuff and there are no guarantees, once damaged,
it's done and injuries inflict all manner of problems and doctors cannot reverse some injuries. Then leaves it in our hands to defend the right to have access to the proper amount of opioid to keep the wolf at bay. I've found that improper pain control leads a to psychological impact leads to impulsive decisions and some are not up to task to defend rash decisions and that leads to suicidal impulses some are victim to. To much pain and suicide is their only recourse and that's just sad and not necessary. Alot of us have reasons to live and your curbing their right to survive. Pain medication can be a sign of weakness to those who live their lives unaffected by pain. You put a man in a pain amplifier and he loses all control and his or her decisions become rash and out of control. Saving lives is more important and controlling pain is critical to a successful outcome in their delicate lives.

From: Napoleon Wilkie
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 7:35:40 AM

It's not about abuse, it's really about control.
Spinal pain cannot be controlled by any other method than prescription pain pills or narcotics. Unfortunately, some of citizens are affected by MVA, work related, and some are victims of crime.
Please have the courage to stand by those are in pain and not the statics of over dosing victims because they don't follow the instructions on the bottle. Narcan is effective way of helping this group ward off the effects long enough to call for medical assistance. It could happen to any patient that is taking narcotics to surcome to LD50 and Narcan can come to their rescue if spray it in their nose.
This is not a perfect world and my condition was overlooked by my Army doctors and I was release from active duty because of my injuries. All I can really say is I've been taking narcotics now for 20 years and I was able to hold down a job for 10 of those years and now I'm a survivor and have no thoughts of ending my life because I have a way to control the severe pain I suffer from and my marriage to narcotics is for the rest of my lifetime.
My condition is attributed to multiple MVA's and spinal cord damage. Until there's medical breakthrough, I have no choice but to protect my and other's who suffer like me, the right to use narcotics as prescribed by a physician. I've followed their advice for decades now and never had an overdose. I'm living my life without pain and it's because I'm prescribed narcotics to stop the relentless pain this body feels. Not all of are addicted, were just trying to live without severe pain.
I'm 64 years old and crippled with severe pain...

From: National Pain Council
To: NCIPCBSC (CDC)
Subject: CDC review Panel: Please Suspend Opioid Guideline immediately
Date: Friday, July 16, 2021 4:54:34 PM

It matters not “who struck John”, the CDC and its advisors from Physicians for Responsible Opioid Prescribing (PROP) are responsible for immense numbers of patients forced off their pain medicines without consent.

The Guideline was not accidental. The AMA letter of June 17 2021 and the cases finally being heard indicate serious harm is continuing daily to patients with lifelong intractable painful diseases. There are 3000 patients a day being disenfranchised** with each of those patients’ lives ruined.

https://docs.google.com/document/d/1N75hidBLJdTQxTeeLk8q_VEqIdZPlCdJK67kEs5lfiw/edit

Suicides are directly related to the “misinterpretation” excuse. CDC/PROP is responsible, no one else. They hinted, doctors jumped to. CDC IS soundING like the ten old who won’t live up to the sling shot and the dead bird.

https://thomasklinemd.medium.com/opioidcrisis-pain-related-suicides-associated-with-forced-tapers-c68c79ecf84d

Doctors are dropping like flies with Medical Boards and DEA adopting the flawed, low scientific basis (CDC) Guideline. The Guideline is being used to take careers from doctors by Medical boards and used by DEA to arrest and imprison physicians who are not drug traffickers, but doctors violating medical parameters of CDC Guideline.

This is a government inspired humanitarian crisis ten times larger than the opioid crisis itself. The new “no opioid” crisis is unique in American history as it was purposeful and had the government, who watches out for us, turning a blind opiophobic eye.

CDC, PROP - Do you have no shame?

SUSPEND CDC OPIOID GUIDELINES IMMEDIATELY

National Pain Council LLC
Raleigh, North Carolina

Jonelle Elgaway
Executive Director

Thomas F Kline MD, PhD
Director of Medical Sciences

** There are 70% (by three independent surveys) of the ten million people on constant opiate pain medicine (Volkow) BEING TAPERED or discontinued from their legacy pain medicines ALL without consent.

Divide the 7 million harmed by 5 years 4 months since publication of the unauthorized CDC Guideline =3800 a day tapered or stopped.

From: Lucky run
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:56:49 PM

To whom it may concern,

I have read the updated draft of the opioid prescribing guidelines presented at the CDC National Center for Injury Prevention and Control (NCIPC) presented at the CDC Board of Scientific Counselors on July 16, 2021. As a chronic pain patient I would like to request that the guidelines be reassessed to include the benefits of opioids for pain relief when used appropriately. The new version appears to have very few changes accommodating chronic pain patients like myself for whom these medications mean the difference between functioning, working and receiving humane treatment versus total disability without any relief from pain. The biased and skewed current and proposed guidelines have left patients with legitimate chronic pain out of the equation. Our physicians are fearful of disciplinary actions and/or losing their licenses for treating pain appropriately. This should not be the case especially when patients have exhausted and/or combined alternative and multidisciplinary approaches (e.g., acupuncture, steroid injections, cognitive behavior therapy, physical therapy, etc...) in efforts to manage pain. The current climate, in large part borne out of inadequate biased guidelines to address one problem/need has, by default, created another by deeming the needs of chronic pain patients insignificant, nonexistent. We live in fear of our doctors, who know us well and who know us to be responsible users of these medications, retiring or leaving their practices and being unable to find providers willing to continue effective and helpful regimens due to these skewed guidelines. Even picking up an opioid prescription at a pharmacy has become a trigger for negative assumptions and judgements toward individuals just trying to function and remain contributing members of society despite pain and disability. This stigma has even made it difficult to contribute these comments without feeling vulnerable which is really quite sad.
Sincerely,
ND

From: nomieivey15
To: NCIPCBSC (CDC)
Subject: Weaponized cdc guidelines
Date: Thursday, July 22, 2021 7:26:00 PM

Thank u for asking for emails from the patients and families who's lives have been devastated by these guidelines..
My husband and I have been married 27yrs, and he has had health problems since before our marriage in 1993..He is 45yrs old , physically fit, not over weight and very strong.
He has adhesive arachnoiditis, degenerative disc disease, chronic kidney disease and more.He had had the same family doctor of 23yrs who changed her behavior after we fought his insurance company that was using guidelines to force him to taper...He had been on same high dose for over 20 yrs! Why make him unstable and lose everything!! So she started not treating anything on him, using her power over his function to get him to bend..she lower fmla days without telling him..every symptom was due to his pain meds so he stopped sharing new symptoms. Every phone call , appointment, decision they made so difficult to where we avoided contacting them..she refused to treat his low testosterone unless he stopped the pain meds..he declined, we later found he had developed anemia, borderline diabetic and more!! She ended up firing him 2 weeks before his meds were due for going over his 2 days of fmla a month!! I wish I were exaggerating.
Having to find a new doctor after that trama for the whole family was so terrible..
Got him in with new nurse practitioner that works under a doctor..if course she said she could only write suboxone..we were terrified, but what choice did we have , we wanted our lives back..before this he had been working 7 days a week to complete housebound..
My family still has PTSD from that day they have him no choice but suboxone..they didn't care that his health was already In decline they did it anyway..He started jerking, passed out in front of whole clinic and our family, 911 had to be called..the er was very upset and said they never should have touched his meds! Of course after the medical staff kept yelling are getting them off the street?? What??? Talk about stigma..then er doctor came in to me , can u explain why ur husband is on this high dose???? I explained everything, the er doctor didn't even know what adhesive arachnoiditis was..they even with stigma gave him part of his dose back and said they shouldn't have done that to my husband..
All of this from guidelines? I have been forced into a roll of advocating for my husband because I'm fighting for his life. The patients must have power over function. When someone else holds that power it will always be abused..history shows us this..please we are dealing with enough with diseases and disability to add ...I begged for help advocating for my husband because it got too much for me..I lost 80lbs and a almost wanted to run away, that is how bad it got ..all due to someone else holding power over my husband function..We have had so many doctors lie right to our faces, gaslighting us..how can anyone trust like that..
There is no science behind any hard limits.
Everyone metabolizes and responds differently to meds.so we are all gonna need different doses..there are many pain patients who once they find the right med / dose they can stay at same level for decades like my husband..addiction should not be mentioned anywhere with pain patients but addicts lives fall apart when they use..pain patients lives get better enriched, the science is that.
Meanwhile every month he has 2 nurses watch him pee, and pill counts..with no promises?? How look what my husband is going through to prove he has nothing to hide..its like probation ..please help change the narrative and stigma by giving patients back power over function

From: Norah
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 6:13:24 AM

The way pain patients are being treated is so disgusting and life-threatening.

((pHone typinG))

From: Owen Wadleigh
To: NCIPCBSC (CDC); NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 6:24:02 PM

These guidelines are killing patients that have done nothing wrong other than to be stricken with crippling pain conditions. Your guidelines are forcing patients to live in constant pain which leads to depression and suicide. How you can turn your back on these people is criminal in the most basic human sense.

I have CRPS, I never heard of this condition until I had a bad accident and tore the nerves in my left arm and the pain never went away. It felt just as bad as the moment it happened. I have lived with it for 11 years nd have been told it will never be cured. Without pain meds I would rather die and if I am forced off my meds my death will be because of you.

I also had to have my right knee replaced in 2016 and when I woke up from the surgery I expected the intense pain but also expected it to subside in a few days, but it didn't. It stayed the same as the moment I woke up from surgery. It was then that I was told that CRPS can migrate and that it was now in my right leg. That depressed me so badly and caused so much pain along with my left arm that I was considering suicide. No pain meds would stop it, they would only make it barely bearable. It effected me so badly I had to move from the cold of New Hampshire to Florida, get divorced, and now just survive when before I was a productive family man with a loving family. I lost every thing to crippling pain and then was told that I had to taper down because of your guidelines. Thank God I found a doctor who understood that they were just guidelines and refused to let me die, even when other doctors were being raided and shut down for putting their patients first.

I live in fear that any day my doctor will be shut down as well, all because you have it in your brains that pain meds are bad. You should be going after the drug dealers that sell illegal drugs and leave those that are just trying to live alone. How can you sleep at night knowing that you are forcing suffering people into a living hell and causing deaths by those who can't take the pain anymore? PLEASE reconsider and let good doctors help their patients. Just after I left NH I saw that NH passed a law allowing their doctors to prescribe what their patients needed and refused to allow the government to kill their residents. If I could stand the cold I would move back, but I hope and pray that all states pass similar laws because obviously the CDC is making these “Guidelines” blindly and have never had a friend or relative in constant intense pain. Just remember that someday you too might be in our situation. Have compassion for your fellow man and please change these guidelines to allow doctors to treat patients the way they need too.

Owen Wadleigh

From: Pam Aylor
To: NCIPCBSC (CDC)
Subject: 2016 Opioid Guidelines
Date: Wednesday, July 21, 2021 4:08:13 PM

Now that you are aware of the grievous harms done to pain patients throughout this country it is time to scrap the guidelines altogether! Too many lives lost to suicide due to uncontrolled pain have happened already. We now know that the science behind MME is junk science that also must be scrapped. The people are depending on all of you to do the right thing, whether it's in honor of a loved one who died by suicide because they couldn't handle the pain anymore or, because they are still in agony of severely reduced pain medications! Opioids are a tool in our toolkit to combat our pain and they allow us to work, care for our home and others, play with our children and grandchildren, and socialize with our loved ones. Please do not dismiss us again as we desperately want to live a lowered pain life!

Sincerely,

Pamela Aylor

Sent from my iPhone

From: pbarber4408@yahoo.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:46:16 PM

Dear CDC,

I have closely followed the 2016 Opiod Prescribing Guidelines and have reviewed the proposed updates. Nothing has dramatically changed in the updates. These guidelines do not provide support for individuals like me. They do not allow my physicians much leeway in prescribing pain medication for patients like me who have had chronic pain for over a decade. Nothing is included that explains how long term pain medication may benefit a patient by improving the quality of their lives. Or how patients like me, who have had multiple surgeries, years of physical therapy, psychological help, tried alternative treatments, may benefit from pain medication. And the mme limit has affected me too.At times I needed medication for breakthrough pain or for recovery from joint replacement. My physicians felt I needed over 90 mme, but were hesitant to prescribe it because of these guidelines.

Insurance companies have used these guidelines to limit what they will approve. I realize that was not the intention of the guidelines, but that is what is occurring.

After the 2016 guidelines where approved, my physician reduced my medication to 90mme. Not because it was what was best for me, it was because of the guidelines. I realize physicians can provide an explanation as to why a patient needs over 90mme, but they already have to monitor a database, do prior authorizations for insurance, and document patients progress. They don’t need any more paperwork that takes away from seeing and treating patients.

Thank you for taking time to read this. I hope that some of my concerns can be taken into consideration when the guidelines are updated.

Thank you,

Paula Barber

Sent from my iPhone

From: Paula Berzanski
To: NCIPCBSC (CDC)
Subject: Comments on Revising CDC Guidelines for Opiate Prescribing
Date: Thursday, July 22, 2021 2:48:48 PM

Comments for CDC Possible Guideline Change:

I am writing to say don't revise the CDC Guidelines for prescribing opioids— remove them. A decision about how to treat pain should be strictly between the patient and her doctor. There should be no government interference.

I am writing as a person suffering from chronic pain for more than 25 years. I have availed myself of all possible non-pharmaceutical relief such as nerve blocks, osteopathic and chiropractic treatments, acupuncture, Cranial Sacral Therapy, physical, Epidural Non-Steroidal Anti-Inflammatory Injections and Trigger Point Injections, Massage Therapy, home exercises, Yoga and more. About 10 years ago I was referred to a pain management clinic and was prescribed opioid medication. Being on opioid pain medication afforded me the ability to work and lead a meaningful life.

In March 2018, the DEA closed my prescribing pain management clinic as an alleged "pill mill." (I never noticed or experienced anything untoward at this practice, but that's not why I'm writing.) I'm writing to bring to your attention my personal experience of trying to continue to get pain medication after this practice was shut down.

I saw two primary care (PC) doctors and tried to make an appointment with three different pain management clinics. At each of these contacts, I did not even ask about continuing on the pain prescriptions. I merely mentioned my conditions and the fact that my pain management clinic had been shut down. Both PC doctors observed I was suffering from Tachycardia brought on by too-rapid tapering of opioid medication. They both referred me to the same pain clinic. One of them suggested I try rehab, seemingly being unfamiliar with the difference between dependency and addiction.

I followed the PC's suggestions. When I called their recommended pain clinic, they were unable to see me before my prescriptions completely ran out nor in a location closer than 25 miles away, despite the existence of closer ones. I called two other pain management clinics who were unwilling to take a new patient who was on opioid medication. I did also contact the rehab center. The rehab center indicated that they would use Suboxone (another opioid) to detox me off my prescribed opioids. This would have then necessitated me subsequently detoxing off Suboxone. Additionally, the cost was going to be greater than $10K out-of-pocket.

A day prior to having their doors locked, my pain management clinic had prescribed two non-opioid medications to help with the inevitable withdrawals that were to come. One pharmacy I visited refused to fill the prescriptions stating that their headquarters wouldn't honor any prescriptions from this closed clinic due to its "legal problems."

At no point in my journey did any medical professional want to discuss my level of pain and how it could be addressed without opioid medication. The entire focus was on getting off opioids! I have accepted that I need to be on pain medication the rest of my life. My conditions are not the kind that will ever improve. Although I am now officially off all opioids, I am very sick, in a lot of pain, much less functional and devastated by the abandonment from the medical "professionals."

I would like you to know for your deliberations, that people with chronic pain are being confused with addicts on the street. Addicts are overdosing, ingesting illegally manufactured and transported substances, selling dangerous drugs and perpetuating the opioid crises. Pain patients are not. Patients with chronic pain follow lots of guidelines, pay multiple co-pays, make all trips required by the doctors and pharmacies, work with insurance companies, get prior authorizations, sign contracts, submit to urinalyses and are willing to do whatever the laws require in order to legally obtain pain medication. The two cohorts should not be confused!

The chronic pain patient is being vilified in the media, by the government and at medical institutions and pharmacies all over the country. We cannot get our pain properly treated. It is demoralizing, humiliating and inhumane. Let your task force be on notice that this is huge gap in treatment of chronic pain.

Sincerely,

Paula Berzanski

Sent from my iPad

Sent from my iPad

From: Pamela Crayne
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:58:13 PM

There is very little changes made to the guidelines from the previous 2016 guidelines and no help for those in chronic pain. Lumping illegal drugs in with prescribed medications paints a false narrative and does a great disservice to those who use their medications responsibly.

From: Pamela Curtis
To: NCIPCBSC (CDC)
Subject: Public comments for 07/16/21 meeting on the 2016 CDC Opioid Prescribing Guidelines
Date: Friday, July 16, 2021 5:01:32 PM

To whom it concerns:

My pain has been scientifically studied. I was a part of the Occipital Nerve Stimulator study of 2007 after all other pain treatment options were exhausted. I was the only person in the study to use the device at the FDA maximum of 20 milliamps. While running the device at 20, I could talk and laugh as if nothing was going on. The doctors couldn't believe it, but saw it with their own eyes. My ability to withstand that level of nerve stimulation was possible because my pain is much worse than anything the device could deliver. Yet my treatment is limited to that of someone with much less pain.

These guidelines have caused a loss of due process, loss of confidentiality, destruction of the doctor-patient relationship, stigmatization, loss of function, loss of quality of life, loss of life, and presumption of guilt of doctors, pharmacists, and patients.

All data shows that the "epidemic" is not from any increase in opioid use by the general population, but a result of overdoses from illicit fentanyl and fentalogues. 98.3% of opioid overdoses are from illicit substances. That is obviously not a prescription problem.

Medical care requires trust, and that's not possible when the DEA forces doctors to suspect all their patients of opioid misuse. So long as the DEA makes arrests based on these guidelines, they will be used as hard limits by doctors. Additionally, doctors have been given the impossible task of being responsible for their patients' actions outside of their clinics with no ability of oversight.

Ultimately we cannot arrest our way out of the problem of addiction. A regime as authoritative as the Soviet Union couldn't stop addiction. Prisons can't stop it. No amount of rules will. So long as addiction is criminalized, it requires addicts to hide, lie, and cheat their way through life. Take the punitive damages away, and it allows addicts to be honest about their condition without fear of reprisal. We could then easily separate addicts from genuine pain patients and treat each appropriately.

I thank you for your time & consideration.

Sincerely,
Pamela Curtis
End Pain Stigma (nonprofit)

PS I have no conflicts of interest and take no salary from my nonprofit. Our nonprofit takes no industry money.

From: Patricia Ellen Daly
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline re: Pain Management
Date: Friday, July 23, 2021 4:48:58 PM

With all the advances that have been made in Integrative Pain Management over the past 5 years, how could you possibly even consider adopting the same guidelines you adopted 5 years ago?

Stringent restrictions on Opioid prescribing must be eased. Opioids when prescribed skilfully, are a necessary option for the treatment of acute and chronic pain.

And why have you not recommended the use of "alternative" therapies (e.g. massage, acupuncture, medical marijuana) whose efficacy is being established daily by clinical trials, How long will we have to wait for these efficacious non-pharmacological therapies to be adopted by mainstream health care insurance companies?

To where can low and moderate income Americans turn for pain relief?

Does President Biden, who has agonized for many years about pain in his children and in himself, know that you are failing
to keep up with so many countries by remaining stuck in such outdated guidelines re: Opioid prescription and non-pharmacological palliative care? I will send him a copy of this email to you.

Yours in exasperation

Pat Daly, Ph.D.,

From: Phyllis Dunbar
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:42:13 PM

I'm in need of some one, to understand that if a person is truly trying to get help in understanding the need of some that truly suffers from chronic pain where do you turn?

From: Phyllis Dunbar
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:44:59 PM

I'm looking for anyone to understand a chronic pain patients need.

From: Peebs60 PEEBS60
To: NCIPCBSC (CDC)
Subject: Re:IMPOSED 90 MME
Date: Thursday, July 22, 2021 12:04:22 PM

Dear board;
Please hear my cry.
I do not have much cry left because I am exhausted due to the battle I have been on since 2016 CDC opioid "guidelines " . Because of this I decided to go ahead with the most barbaric of them all surgery. I had an ALIF & PLIF 11.5 hour surgery to correct my twisting and bending spine since all of a sudden my pain med were taken from me. I was on 120 mg of oxycodone which was making my life tolerable. Then I was lied to and told it was believed that my own body would produce it's own pain relief by my my taking nothing. I was taken down to 40 mg.
So I went to Barnes Jewish Hospital and the head of orthopedic surgery and adult spinal deformity said he could hopefully change my life enough where I never had to see pain mgt.again. I was in.
It was a hideous 12 months .He unfortunately had to strip my abdominal muscles and took out the back rib to reinforce the rod from breaking. Now my entire left flank is left screaming, and since I was previously fused C4-7, now the vertebrae between T4-1 are bending and and causing a listhesis. I can't sit in 3 years or use my arms. I am only allowed 5 percocet a day and I have literally been tortured with every ungodly painful and unhelpful injection under the sun.
I am not going to get better by one injection. Or all the PT or dry needling hasn't made much of an impact on my life. If I can't be afforded the only thing to aid in my quality of life then honestly there is no reason to fight or live. If that is your objective or PROP'S goal (buprenorphine made me sick and dizzy) then you deserve everything God has in store for what your heart had done to me and others.
I now distrust government, doctors and hospitals and what America stands for. I am a 61 year old Christian woman and an independent, individual thinker. I am angry, fed up and outraged that my country could and has done this to me/ us.
God can not Bless America when you don't honor him.
Sincerely, honestly
Polly Gentry
224-730-1422

From: peebs60
To: NCIPCBSC (CDC)
Subject: Re: CDC OPIOID GUIDELINES & 90 MME outrageous recommendations
Date: Thursday, July 22, 2021 9:14:09 PM

Dear board,
Scientists alone know that between height, weight, and liver metabolism and DNA specification of which medication works the best for chronic pain, that 90 mme has no Scientific value. Also, if you read about pain and all the research elizabeth Kubler Ross did with hospice and pain and how pain controlled made for a quality of life only by small frequent dosage of heroin cocktail to keep the pain at bay. She also found that some were found to be in remission and had no problems with tapering off. As was my situation.
I have frequently been on high doses of oxycodone and fentanyl and been titrated down . I never once thought I needed to take more.
Also Dr Kolodny is a psychiatrist and addiction specialist. He also has mislead the opioid crisis of our country on medical care. The problem was the loopholes the pain clinics that afforded businesses to open clinics with bad doctors and then you had your problems. Remember Florida? All the people traveling there and camping out in the parking lots? That was mayhem and chaos. That drug lords opened " pain clinics " and falsified everything. They had 1 bad dr.who was paid off writing prescriptions right and left!
Also, Kolodny doth protest too much. Investigate him later. I/ We are suffering so badly. The moral fiber of this country has been gravely damaged.
You can restore some sort of trust even though many doctors won't abide again by your ruling if you do have compassion again. They are now too afraid and have to go by their corporate business bosses not their individual doctor opinions anymore.
So much damage has been done even if you do turn this around it going to take a lot to get compassion back into medical care.
Sincerely,
Don't be afraid to get to the truth. It may not always be the most popular but it will always be in right standing with the results of the path of your life and what God Blesses.
Polly Gentry

Sent from my Galaxy

From: Peggy Gillis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:52:01 PM

The pain is hard to describe! The words don't come easy to write..
But I will try.
Once my doctor of 18 years told me I wouldn't be affected by this Opiod crisis...
It worked for me, giving me some quality of life!
To be able to control the pain that is horrible at times.
I ran an office of 26 agents, did all the bookkeeping, files, banking, trust accounts, payroll, etc.
Taking these allowed me to function!
And not one of my employees knew, or saw me unable to function!!
I drove hundreds of miles a week, not impaired!
I was honest, aware, alert n able to be out of severe pain!!
Now I've been weaned down to hardly anything! My doctor so afraid to loose his license!!
Who are any of you to judge me, my life!
Angry, frustrated!!
I do see now the ones who go black market, illegally to get help!
That's not me!! But I feel that's what you all are pushing these people to do!
I'm not ever doing this, no matter what I need. But I'm hurting!!!!
Day to day I live, suffer, my family suffers.
My husband of over 40 years stands by me everyday! Has to help me do things that others take for granted.
I lived a peaceful life, a life without a lot of pain everyday. Now I'm suffering, not being able to function, being able to enjoy life!
If you asked my kids, husband, brother, sisters, inlaws, friends you would hear what I've dealt with for years, what I'm dealing with now.. And hasn't affected me taking higher doses that helped me!
These people that abuse these are not going to stop, there are drug dealers out there, they want some kind of highs! For whatever reason!
I see a doctor regular, I take them as prescribed.
I've been a damn guinea pig before starting the onions and after, now..
The problems with the medicines have caused so much problems and I will not take anymore.
Was just in the ER with severe side effect from a neuro doctor's script given to me!
I'm angry, that someone can play God with my life like this!!
I've done no wrong! Broke no laws! Have been honest...
Now I'm to suffer for others crimes! My family to suffer.
My life to be cut short!
Yes, pain can n will kill a person.. I would never wish this upon my worst enemy, though I don't have any!
Please allow the doctors to control who needs these, who is at risk! I'm surely Not one of these!!!
Want affidavits from 30 people, I could provide them easily! My record is unblemished and accurate.
It's not the honest, reliable, chronic pain sufferers that have to suffer from those who seek the highs, seek the numbing from everyday life.. the alcoholics that die from drinking I know many who have since my teen years every year. Very easy to get, legal..
I don't drink, never have. Never have done street drugs either!
And would never overdose for any reason!

Please stop this insanity, give us back the lives we are losing keeping this from us!!!
Sincerely,
Peggy Gillis
1901 U Ave
LaGrande, Ore. 97850

Sent from Yahoo Mail on Android

From: Geo. NoName
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 10:45:41 AM

I have migraine headaches . I would have a terrible time getting along without pain meds. Years past Doctors started this problem by taking kick backs from pharmacy companies. They were paid off to push pain meds without caring about the results. Common sense rule needs to be followed when prescriptions are written by Doctors. It's insane to, close the door on pain meds when so many people need these drugs. Sincerely Palmer Baldwin, Gresham, Or.

From: P Hillman
To: NCIPCBSC (CDC); Lindley, Tonia (CDC/DDNID/NCIPC/OD)
Subject: BSC Meeting Public comment July 16, 2021
Date: Thursday, July 22, 2021 10:59:27 PM

I'm a patient living with severe chronic illness. I advocate for pain patients to have reasonable access to pain medication and I have no conflicts of interest. It's clear to me that the goal of the guideline as stated by Debora Dowell:

(The) "overall goal is safe and effective pain care to maximize the benefits and minimize the risks of opioids in pain management in general." Also to, "maximize benefits and minimize risk of guidelines itself."

is simply lip service. The actions of the authors speak louder than their words at this meeting. The authors are intelligent enough to use words like "patient centered" yet produced guidelines which are anything but patient-centered. There is no mention of the impact of undertreated pain or the benefits that opioids can provide. If "safe effective pain treatment" is the goal, they have failed massively. You cannot ignore that there will ALWAYS be a subsection of patients who have failed all else and will require opioids, many at levels higher than 90 MME, to be able to do activities of daily living and have some quality of life. You simply cannot have a guideline with arbitrary MME limits and expect the Guideline to be patient-centered. It is virtually impossible due to pharmacogenetics, which make MME indisputably inaccurate dosing guides that these authors refuse to accept, and the propensity for policy makers and lawmakers to imbed the Guidelines into law and hard edits. Anyone who does not see that the use of MME is a fatal flaw in the guidelines is living in fantasy land and has no interest in patients having an accurate dosage that will reduce harm.

It would be one thing if pain patients were the majority of the people dying by overdose but that has never been the case and these others know it. This is a crisis proven to be mostly made up of non-medical drug users.

According to Dr. Walenski, 594,000 overdose deaths out of 841,000 between 1999 and now DID NOT involve Rx opioids. 72% of ODs in 2019 alone DID NOT involve Rx opioids yet the authors continue to pursue a guideline that is solely focused on Rx drugs with the fantasy that following this guideline will make a difference in the number of OD deaths. This result could only happen if prescribed drugs are responsible for the OD deaths. CDC's own data dispels that myth with no reasonable contradiction possible. This guideline was so poorly written that, by the authors own admission, it has been widely misapplied to the detriment of pain patients. But, it's not only pain patients that have been abandoned and left to suffer without their life-saving medication. Those with SUD in any form have been largely ignored because of the political obsession with Rx opioids and the money and power that can be gained by that false narrative. This narrative has literally killed thousands and harmed millions.

I applaud the OWG's efforts to instill ethics, evidence based treatment, and logic into the Guideline in an effort to protect patients from further harm by CDC's Guidelines but unfortunately, it's clear that the authors of the Guidelines and even some in the OWG have no intention of making the

Guideline patient-centered. Instead they prefer to continue to implement the same harmful policy that is killing people. It is unconscionable to continue something that has killed thousands and tortured millions. History will not view these actions favorably. Which side of history do you want to be on?

Most of the opioids litigation is done now. Drop the false narrative and stop drug prohibition before you kill us all...or is that the goal?

Roger Chou and Deborah Dowell should not be allowed to author the Guidelines. Dr. Chou has clear conflicts of interest with his ties to the authorship of the original Guideline, his ties to PROP, his history of making anti-opioid biased statements/policy, his financial gain for biased opioid reviews, his connection with AHRQ, and his connection with the BSC. Dr. Dowell was an original CDC Guideline author, appears to have ties to PROP, clearly has an anti-opioid bias, is unable to acknowledge inappropriate scientific dosing principles such as MME, and appears unable to accept major scientific principles that are crucial to patient safety and the understanding opioid metabolism and uptake. Such immense COIs should not be tolerated and put patients in grave danger.

UDT should only be used under certain circumstances. It is extremely expensive and often not covered by insurance. It is subject to false positives and negatives and can lead to patient abandonment and mistreatment. Even patients who have SUD deserve to have their pain treated. UDTs violates 4th amendment rights and should only be used in certain circumstances as determined by the physician. We know from CDC's data that pain patients are almost never involved in overdose deaths so why stigmatize them and drain their financial resources unnecessarily? Such tests are likely to damage the patient/provider relationship.

In conclusion, save a life. Repeal and DO NOT replace the fatally flawed CDC Opioid Guidelines.

Sincerely,
Peggy Hillman

Sent from Mail for Windows 10

From: Pam Howard
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:01:27 PM

To Whom It May Concern,
I am a chronic/intractable pain patient. Besides Degenerative Disk disease, Arthritis in my back, Spinal Stenosis, Disk protrusions & scoliosis, I also have Complex Regional Pain Syndrome. I was on 10mg Norco, 1 every 6hrs. My pain clinic shut down with no notice in May. I'm glad it's not because any drs or providers did anything weird or illegal with meds, but unfortunately 7 of providers fraudulently billed medi-cal. My pcp has left me in horrific pain all because she is scared due to your guidelines. Since your guidelines, meds are being ripped away from pain patients. Pain patients are blowing their livers out due to taking 6000 or mg of tylenol daily because they are so desperate for some pain management. Some are going to the streets, but most are killing themselves. Why are you ok with this? My CRPS is also called the suicide disease. Theres nothing above it on the McGill pain scale. During my 2yrs at the pain clinic, the dr said we could go to percocet. I declined because, even though it would control my pain better, the Norco worked still. It would bring it down from a 10 to about a 7. Your still hurting, but there was a difference. That's what pain management is about. Its trying to control the pain as much as we can. Knowing you'll never be completely pain free. Every morning I take a quick shower, it's like someone is shooting me with a nail gun. 24/7 the bone pain is like a sledgehammer being pounded on my bones. The nerve pain aka electrical shocks is relentless also. As is the muscle pain which doesn't include the muscle spasms. The skin sensitivity is like sandpaper being rubbed on you. Why would anyone tell us to just suck it up & live with it. Well, pain patients aren't living with it. Those who's needs were tapered so significantly or had all meds taken away, are killing themselves!! Yet drs are handing out Gabapentin & Suboxone like candy and those 2 meds are highly abused! Those of us stable on our meds, passing all our tests should be left alone and not targeted. You guys because of your illegal and messed up guidelines have scared the hell out of drs who do want to help us. You've allowed the DEA to interfere with our drs. There are hundreds of pain drs, pcp & addiction specialists who have told you guys that your causing & allowing catastrophic consequences to us pain patients. Opiate meds do help us chronic/intractable pain patients! Please listen to us! We are not addicted. We take our meds as directed. All it takes is a simple surgery or maybe you sprained an ankle & guess what?? Your life has now changed forever. If you could feel CRPS for just 1hr, you would know why we need our meds. CRPS is just one of many debilitating pain disorders out there. Stop blaming us for what addicts do. Prescriptions have fallen down yet opiate deaths are skyrocketing! Its because of heroin & illicit fentanyl!! That is not us. We just want a little bit of quality of life back. People are dying because of you & your misapplied guidance. They are blowing their brains out because of you & your unscientific guidance. We are unnecessarily suffering due to drs & Law Enforcement taking your guidelines as actual law. Your new updated guidelines also look the same. No facts, just you listening to anti opiate zealots. You have the blood of pain patients on your hands! Please listen to us and do the right thing.
Thank you, P. Howard

From: Pashondra James
To: NCIPCBSC (CDC)
Subject: CDC 2016
Date: Friday, July 23, 2021 4:26:23 PM

The CDC GUIDELINES FROM 2016 HAS HARMED SO MANY PEOPLE INCLUDING MYSELF. I WAS ABLE TO FUNCTION FOR SO MANY YEARS WITH MANAGED PAIN CARE. ONCE THE GUIDELINES CAME OUT I WAS AUTOMATICALLY CUT OFF BY MY PAIN DOCTOR CITING THE GUIDELINES AS REASON WHY!! IM NOT NOW NOR HAVE I EVER BEEN A CRIMINAL AND HATE BEING MADE TO FEEL LIKE ONE BC I HAVE RARE ILLNESS THAT CAUSES CHRONIC CONSTANT WIDESPREAD PAIN. ITS TIME TO LET DOCTORS BE DOCTORS AGAIN AND LET LEGIT CHRONIC PAIN PATIENTS GET RELIEF!!!

Sent from my iPhone

From: Pollen Lethe
To: NCIPCBSC (CDC)
Subject: My lack of opioids leaves me bed ridden and at high risk of heart attack and stroke
Date: Sunday, July 18, 2021 11:14:28 AM

My pain spikes so hard blood vessels pop in my legs because I am denied appropriate doses of a medication I used to take at higher doses fine. I know for a fact that if I was allowed to have a higher dose of opioids I could function, because I did, for years. Since the prejudice propaganda you released has been used against me I can't get out of bed and sometimes I have to wear diapers and shit and piss while stuck in bed because of it. I have no quality of life because you decided in your infinite wisdom to deny people care before you properly studied the problem. Opioids will be used with or without your permission and by denying us safe and regulated opioids you are denying our right to live. You force people to take illegal drugs to not have a heart attack from unmanaged chronic pain. I can never properly express to you how much you ruined my life. I have attempted to take my life multiple times since my opioid dose has been lowered. I recently had to make a deal with myself that I will use any option to manage my pain regardless of legality because it's that or end my life. If I'm going to die because of opioid stigma then I'm going to do so fighting for dignity and quality of life, by any means necessary. Shame on your office for what you have done to pain patients. You have condemned us to a life of suffering and irreparable disability. The fact that I can take illegal drugs and function but I can't take my prescription and function says it all.

From: Patrick McCoy
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:04:39 PM

I’m deeply concerned on restrictions being placed on opiate patients. You’re placing opiate patients in extreme danger with restrictions. Without my current opiate therapy you’re taking away my functional ability. I live alone, I fix my meals, do my laundry, maintain a home and care for 2 dogs. I’m a chronic pain patient, fused from L-1 thru S-1. I currently need my fusion extended up 3 more levels. I take my medication appropriately, see my doctor once every 2 months and do my urine test once every 4 months. Do not allow pain patients to suffer anymore than what we’re currently suffering. Any restrictions placed on pain patients could lead to more patients to take their own lives. Don’t hold responsible pain patients accountable for the actions the abuser. We’re human and we’re fighting a battle of pain in our own bodies, restrictions on opiates will cause more to lose the battle. Your actions will take a heavy toll on patients suffering from chronic pain. My medication makes my life possible, without it life would be impossible.

Sent from my iPhone

From: Paula Middleton
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:24:02 PM

Hello

I just read your new proposal for opioid use for those who have chronic pain or other pain issues.

The non drug route is often cost prohibited because patients can't afford the co-pay for physical therapy or other therapies. It would be great if patients could combine different therapies to control their pain. But it doesn't work that way in the real life of people with chronic pain.
I am a chronic pain patient and have tried all of the different devices that can be inserted in the body to control nerve pain, fibromyalsia, degenerative bone issues, myopathy in both legs, numb feet and other issues.
The only thing that consistently works is opioid treatment. With this therapy I am able to have a better life. Without drug therapy I often had thoughts of ending my life because the constant pain was to much.
You guys have to remember that those of use that have real constant pain need to have drug therapy to be able just walk and function.
Try this and let me know how it feels to have that constant deep pain that will not allow you to go out or just do simple things like visit with friends and family.

For guys put a clamp on your balls for an hour and tell me how it felt. You can't get ride of the pain because it is always there.
For women clamp a sensitive area.
Imagine that pain all over every day and it never stops. Opioid therapy is the only thing that allows me to live my life.

For doctors to treat persons with chronic pain and have no clue what it feels like to have constant pain should not treat persons with chronic pain.

I would recommend that doctors that do pain management take mindfulness classes. Many of those doctors,PM's and staff people treat persons that have real chronic pain like addicts or criminals. There has to be compassion in this area of medical issues. If I had cancer or end of life I would be treated better. Hospital emergency doctors are just as clueless about chronic pain.

Please don't punish those in real pain and in control of there pain meds. For a bunch of people who fake pain or those who sale opioids and people get addicted or die.

Rethink some of the recommendations and think about those of use on fixed income or those who work but still can't afford those co-pays for other non drug therapy.

Thankyou

From: Peter Pischke
To: NCIPCBSC (CDC)
Subject: Public Comment for July 16th, 2021
Date: Friday, July 16, 2021 3:27:37 PM

My name is Peter Pischke, These are my full comments for the NCIPC BSC meeting held on July 16th, 2021. I spoke during the session's public comments, here are my full comments, please use these to fill out what I shared.
- Peter Pischke

Hello,

My name is Peter Pischke. I am an independent health & disability reporter primarily working with the New York Daily News.

Thank you for allowing public input & not playing games.

Your "click the invisible unmute button" trick during the meeting in February was cowardly and manipulative. I am glad this session's public comments is working as it should. I only hope the words of the honest & good reach the hearts and minds of those here.

From this meeting & document released yesterday, we know the CDC learned few lessons on the moral abomination & scientific perfidy of the 2016 CDC guidelines.

It is evident to anyone paying attention that your workgroup is divided between a small faction that understands rightly that the guidelines have led to millions of deaths, suffering, inequity & bigotry against disabled Americans.

Standing against them are the NCIPC members' leadership prefers. This group ignores the harm caused by the guidelines. Instead, they are concerned to protect the prohibition it created or, & reprehensibly, feel it does not go far enough.

This is outrageous and morally bankrupt. Every stat, study & meta-analysis shows that the addiction rates are up, overdose deaths are up, access to medication is at an all-time low since the Civil War, and little is gained for that cost.

We recently lost Erin Gilmer, a disabled human rights lawyer.

I know this is an inflammatory statement, but I share it because it is the truth.

That death is at least partially on the hands of the CDC & NCIPC's. Not only them.

To all those oh so benevolent activists hoping to strip patients of access to opioids, I pray that you or your family never needs pain treatment when someone comes down with cancer, must go to hospice, or requires major surgery. Pray that you never have to live with the consequences of the world that you have created.

Lastly, I implore those scientists with the actual influence & authority to write the guidelines, the same that created this deadly menace in the first place. Especially Dr. Roger Chou, who admitted in a previous meeting that even he, the very creator of the guidelines, got attacked by his hospital system, and state medical board for overprescribing, citing Chou's own work as justification.

This is wrong, insane & evil. In your heart of hearts, you know it is true.

I implore you & remind you of your moral duty to restore patients' rights & access to adequate pain treatment.

If not, then the condemnation will come on you as a dark smudge against your name in history as future generations recognize the barbarity the NCIPC & the CDC enabled. Listing what you have done as another of the great human rights tragedies of the 20th & 21rst centuries.

From: Pat Scanlan
To: NCIPCBSC (CDC)
Subject: help chronic pain patients
Date: Sunday, July 18, 2021 8:21:52 AM

Stop punishing chronic pain patients for illegal use of narcotics. My son has chronic pancreatitis, he needs pain medication in order to function. In order to work and to be a productive member of society. He is under a doctor's care and never would misuse his medication.

--
Patricia

From: Pat Scanlan
To: NCIPCBSC (CDC)
Subject: Chronic pain patients
Date: Tuesday, July 20, 2021 1:47:43 AM

Chronic pain patients do not use drugs to get high. They use them so that they can function in their daily lives.

From: Pam Trotter
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:46:51 PM

The updated guidelines you presented are MORE DANGEROUS than those you shoved out in 2016. I did not think it would be possible for access to pain medication to get any more difficult but these proposed guidelines will certainly leave many more chronic and acute pain patients left out in the cold.

The decision to prescribe opioid medication needs to be made with the doctor and the patient. Not the CDC, DOJ or FBI.

This agency needs to steer clear of limiting or making any recommendations on MME. By doing so you are advancing the misguided agenda of PROP. Is the CDC getting paid by the manufacturer of suboxene like the members of PROP?

The only reason I have been able to maintain an executive level career for the past 16 years is because I have been prescribed both long-acting and short-acting opioids for my chronic pain. Without this medication I wound be on disability and in horrific pain. Is that what you are looking to advance …. More people on disability…. More people left without their dignity?..

Your regulations had some severe unintended affects. At least I hope they were unintended. A partial list is below;

1. Post-op, patients are left to lay in horrendous pain. Hospitals are AFRAID to prescribe post-op opioid medication. Instead they are offering the laughable IV Tylenol.
2. Untreated acute and chronic pain is causing increased suicide rates. Life just isn't worth living for people in daily unbearable pain. If you think practicing yoga or meditation is going to miraculously cure chronic or acute pain you need to question your intelligence.
3. DEA and DOJ are arresting and prosecuting the wrong people. Going after doctors who are doing their job is ridiculous. These government agencies have OUTRIGHT FAILED to stop the heroin and illicit fentanyl crisis. To make themselves feel better about this inability they break HIPPA regulations and access patient's PDMP. Then they start to harass doctors and pharmacists.

Your government agency had an OBLIGATION to include chronic pain patients in the development of any revised Guidelines. You OBVIOUSLY DID NOT.

I sincerely hope you do not publish these guidelines as presented. It would be another travesty of justice against the most weak in the United States.

Pam Trotter
10665 Cherry Hills Dr
Cherry Valley, CA. 92223

Sent from my iPad

From: paula@vin.com
To: NCIPCBSC (CDC)
Subject: CDC pain guidelines
Date: Thursday, July 22, 2021 1:17:39 PM

CDC,

I am a chronic pain sufferer who was well controlled and lived a largely normal life, including working full time prior to 2016. I am concerned about the new guidelines proposed for 2021.

All of the serious problems identified by numerous researchers, clinicians, pain management experts, patient advocates, and patients over the past 5 years are still present in the new Updated Draft Guidelines released on July 16.

These include:

- A biased focus on risks and harms of opioids with *no discussion* of the benefits of opioids for pain relief when used appropriately
- Arbitrary use of MME dose limits with no basis in science
- And the exclusion of certain pain conditions (Cancer, Sickle Cell Disease, Palliative Care and End-of-Life Care) as if they are more worthy of pain control — pain is pain!

Since the introduction of the CDC Guideline in 2016, there has been overwhelming and widespread evidence of serious adverse consequences to thousands of pain patients including forced tapering, documented suicides, and sudden loss of access to medication, triggering withdrawal.

Despite claims to make a concerted effort to include the views of a wide variety of pain management experts, pain advocates, and pain patients in the development of the Updated Draft CDC Guideline, the authors have produced a new version with very few changes.

Current best practice in pain management is widely recognized to be a multimodal, multidisciplinary, integrated model of care that includes a combination of therapeutic options. However, there is no mention of therapeutic options in the new Guideline. The CDC’s endorsement of an integrated model of pain care including both pharmacological and non-pharmacological therapeutic options could help to break down barriers to access for many of these therapeutic options.

We hope that in drafting the final Guideline, the CDC takes these views into consideration.

Thank you,

Paula Ibsen

From: Preston Ward
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:49:56 PM

To whom it may concern:

The 2016 Opioid Prescribing Guidelines are an unmitigated disaster and need to be scrapped entirely. But by far the most important part to excise is the "suggested" maximum prescribable amounts. Although these are nothing more than guesses, somehow they've become law. Any physician who exceeds them will be arrested for "over-prescribing opioids". How is that possible when doses are patient-dependent?

Even though my board-certified pain specialist didn't want to taper me down to 360mg MME four years ago, he was forced to. As a result, there are some days when my pain is still so bad that I will just start spontaneously screaming from the pain. This really bothers my caregiver to hear me screaming and causes her psychological distress. I will sometimes also start screaming in my sleep and wake myself up, too. What is the point of torturing me like this? I have tried literally everything possible. I spent four full years trying non-narcotic options before finally having to be sent to Pain Management. I know you don't like to hear this and that they go against who pays you, but the simple fact is: OPIOIDS SAVE LIVES.

My pain specialist cannot raise my dose because of the "suggested" limit of 360mg MME. I'm SUPPOSED to be in Palliative Care. The (relatively) new maximum prescribable amount for board-certified specialists made my pain so bad that I became bedbound for ~20 hours a day, and has remained this way for four years. I was perfectly fine before on a much higher dose. So to say that the Guidelines have destroyed my life is no exaggeration at all.

I received referrals to Palliative Care from no less than four different physicians. But each one that I called said that I had to be terminal. That's funny, because I thought that's what Hospice is for. Now, both Hospice and Palliative Care require you to be terminal. And what's even weirder is that two of my physicians (unrelated) have told me that the pain is killing me. So even though two of my physicians have told me the pain is literally killing me, and even though Palliative Care has a (now relatively) new requirement that one be terminal to get into Palliative Care, apparently there is an exception if what's killing you is the pain that's the result of the 2016 Opioid Prescribing Guidelines. So I have to ask: Is the purpose of the 2016 Opioid Prescribing Guidelines to kill people?

Another thing that needs to be changed about the Guidelines is that we need full transparency of anyone having anything to do with the creation and editing of the Guidelines with all financial entanglements reported.

Respectfully submitted,
Preston Ward

From: Patricia Williams
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:49:41 PM

I see no “ updated” in these updated guidelines; they seem to be the old “ one size fits all” guidelines almost verbatim. Thank heavens I am not currently in need of pain relief myself because over the past years I have noticed what the new hysteria/prohibition has done to patients and doctors. My husband has recurring bladder neck blockage which requires repeated surgeries..we are up to number 13. For years, he received a small amount of Percocets or Oxycodone for 3 or 4 days until the catheter came out with no problem, then suddenly his surgeon told us that surgery didn’t “ rate” any prescription pain relief…while most over the counter are also counter-indicated due to bleeding risk. Since we know this surgeon well, he finally relented and told us that he personally agreed with us and resented his medical judgement and discretion being usurped by bureaucrats, cops and politicians…but his hands were tied. I recently watched a close friend deal with her mother’s protracted death from cancer and saw that, in spite of the supposed exception for both cancer and palliative care, my friend’s mom was vastly UNDERMEDICATED even while in hospice care and she suffered horribly. I personally am postponing needed surgeries out of fear of pain and I was actually considering going abroad for surgery when Covid restrictions put everything on hold.

Sent from my iPhone

From: Pain Advocacy Coalition
To: NCIPCBSC (CDC)
Cc: PainAdvocacyCoalition@protonmail.com; huntingharleygirl@gmail.com; duane.pool@g.austincc.edu; Lauren Deluca
Subject: Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids
Date: Friday, July 23, 2021 10:48:38 AM

Rescind the 2016 Center for Disease Control (CDC) Opioid Prescribing Guidelines as Failed Public Health Policy

Transparency

Where is the admission, accountability transparency regarding the purposefully, knowingly manipulated and concealed CDC data utilized as a foundation for instituting highly flawed public health policy, ultimately leading to "clinical misapplication" of recommendations further harming patients being used as arbitrary regulations to support prosecution and incarceration of physicians, institute state laws for arbitrary dosage thresholds, permitting third party administrator refusal to cover prescriptions or pharmacists to fill prescriptions, fueling stigma and denial of care to patients experiencing acute, chronic or intractable pain?

https://link.springer.com/content/pdf/10.1007/s40122-021-00254-z.pdf

Credibility

Because the CDC purposefully skewed data, and have not taken steps to amend said data, the CDC does not have a leg to stand on to institute any public health policy whatsoever, regarding prescribing opioids.

The 2016 CDC Opioid Prescribing Guidelines should be rescinded for that reason alone.

Manipulating the Healthcare Landscape

Considering that the CDC data was fundamentally skewed to drive a false narrative, pander to special interests with an agenda to profiteer by implementing and declaring a "faux crisis" in order to institute opioid prohibition, and no attempts were made by the CDC to remedy skewed data to date, yet academia, federal agencies, legislators, public health officials, non-profits, pharmaceutical, technology, device companies, and the media continue to quote or utilize incorrect information, further driving the harms to patients, immediate action should be taken to rescind the 2016 CDC Opioid Prescribing Guidelines.

Lack of Oversight

CDC actions are responsible for one of the biggest wealth transfers in history, funded by US taxpayers to the tune of billions, a "crisis" was required in order to rationalize litigation to raid pharmaceutical companies, fund state coffers, academia and NPO's when in fact, the overdose deaths are in reality, clearly attributed to illicit drugs, not legally prescribed pain medications.

Agenda

The 2016 CDC Opioid Prescribing Guidelines have literally unleashed a "Pandora's Box" as it relates to patient care, as the ultimate goal is to shift from individualized care, to population health, self management, CBT, multi-modal, interventional medicine void of opioids as a long term treatment option, as a healthcare cost cutting measure.

Stakeholders with Ambitions
Data is the new gold, and algorithms will drive patient care, and patient context will matter not, in the age of artificial intelligence.
Patients who fall outside the median, who require individualized care, tough luck!

Big Data, and other stakeholders with deep pockets and a lot invested is counting on the CDC to continue to uphold their false narrative, as the age of artificial intelligence, algorithms and patient surveillance is upon us, and it is highly lucrative.

For this reason, patient's voices are being systematically silenced and censored.

Justification
To justify this shift, the CDC Guidelines were instituted to enable studies on patients who were being forcefully tapered, without "informed patient consent," because patients would not voluntarily consent to tapering, these studies were necessary to justify both population health cost cutting measures and opioid prohibition.

Patients are now commodities, not human beings in need of compassionate healthcare but merely a dot plotted on a algorithm graph.

CDC actions have culminated in an effort to dilute patient-physician autonomy and has culminated in physicians leaving the field of pain management, patients being abandoned by primary care, patients suffering from decreased mobility/ quality of life, pain from forced non-consensual tapers, under-diagnosed pain and under-treated pain, subsequent medical complications, accelerated mortality, preventable deaths, to include both suicide and now, having no access to medical care, patients are forced to turn to the streets to self-medicate, risking overdose from a unsafe illicit drug supply.

Denial of medical care does not an addict make.

Ongoing Corruption
Yet, the negligence in federal oversight continues, further harming patients.

Example: Roger Chou declared a conflict of interest (as it turns out with AGRQ charged with conducting clinical studies) during the July 16th, 2021 public meeting, yet the BSC/ CDC failed to comment or bring further transparency regarding this conflict of interest?

This is just one of many examples of well documented failure to disclose, collusion and profiteering.

The level of corruption including conflicts of interests, profiteering and downright exploitation of vulnerable patients by multiple shareholders who seem only concerned with their bottom line, new avenues of revenue, or protecting existing avenues of revenue and certainly not the suffering of living beings with painful diseases, physical trauma, or end of life pain is ethically and morally deplorable however but it is highly profitable.

The entire process has been corrupted.
From beginning to end.
Not to mention potentially illegal.
This is just the tip of the iceberg as this issue relates to ongoing corruption.

The focus needs to return to caring for patients- by directly returning autonomy to physicians and patients, to make their own informed clinical decisions, within context of the patient's individualized needs.

Congressional Oversight
This is why many patient advocates are calling for the 2016 CDC Opioid Prescribing Guidelines to be rescinded and for a Congressional Hearing to be initiated to bring transparency and oversight to this issue, and other issues including the continuous revolving door of public health officials, allocation of tax dollars and hidden funding to NPO's and Foundations, including the CDC Foundation, as the CDC actions or lack there of, and other shareholders, don't just border on unethical but, potentially illegal.

Implications
So ultimately, the CDC and other federal agencies have taken power of attorney over US citizens by instituting draconian public health policy as a method to profiteer from human suffering and death as patients are precluded from utilizing opioids as a tool to manage pain and the corpses of addicts continue to pile up on the street, we can conclude that the 2016 CDC Opioid Prescribing Guidelines are an inescapable public health policy failure.

Failed Public Health Policy
By denying access to pain medication that give patients functional mobility and quality of life, the fall out and ramifications of infringing on patient rights include denying informed healthcare choices and informed consent, privacy, coercion into treatment modalities that are invasive and ineffective, contributing to suicides and financial disasters, increasing stressors upon caregivers and families, increasing discrimination and stigma, leaving patients as a medical liability to physicians, and further leaving patients with no viable, accessible avenue for recourse when harmed.

There is only one action to take, based on these conclusions.

Viable Option
Because of the above conclusions, the only viable options left to patients now is to call for a immediate "Congressional Hearing" as lives are in jeopardy, and further demand that the 2016 Center for Disease Control (CDC) Opioid Prescribing Guidelines as "Failed Public Health Policy" to be immediately rescinded.

Thank you for considering this feedback.

Pain Advocacy Coalition
July 23rd, 2021

From: Patient Advocate
To: NCIPCBSC (CDC)
Subject: Updated CDC Guideline for Prescribing Opioids
Date: Friday, July 16, 2021 2:15:35 PM

Hello, I have been listening to the BSC and OWG meeting taking place. I participated in the CDC Event, Stakeholder Conversations in september.

I am a well known, respected patient advocate. I'm also a 30 year, rare disease, chronic pain patient. I suffer from a hereditary, genetic pain disorder and rare, complex multiple spine conditions. I am disabled and receive Social Security Disabilty since 2007.

Here are my thoughts on the Guidelines and revisions:

The attempt to decrease the od problem has been a complete, shameful failure! Nothing is being done about the od's from the illicit, illegal drug use epidemic.

To little to late. The damage caused to patients and physicians cannot be undone. Responsible, legitimate patients have committed suicide because they were abandoned and had no hope. Their quality of life and function was taken away without any legitimate reason.

There is now a serious shortage of pain management physicians and any Dr. willing to treat a patient's pain, especially offering continued care. It's not worth being a target of the DEA and risking their livihood.

PDMP's, Narxcare, Urine tests, are a violation of our right to treatment and privacy. They are only used to deny treatment. This is discrimination, and results can be interrpredted differently or incorrectly.

Politicians, Medicare/Medicaid, pharmacies, hospitals and benefit providers have churned out a ridiculous number of restrictive policies and laws based on the Guidelines in every state, not based on medical or scientific facts. Revising the Guidelines will not change that now.

The damage and loss of life is unforgivable. We are at the point of no return. Shame!

Thank you.

From: Peggy F.
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:17:38 PM

You need to make opiods more accessible to patients with chronic long term pain. It is nearly impossible for a patient to get anything stronger than a Tylenol 3. I have had to beg my doctor to give me stronger meds and he is so scared of reprisal from you he is scared to help me. Even though I am a responsible patient. I still have pain that puts the tylenol 3 to shame. And dont say its between me and my doc cause thats just not true. You have put so many regulations on them im sure its hard for them to do their best to help me.
Please reconsider your actions for all of us responsible drug users.

Sent from Yahoo Mail on Android

July 16, 2021

Testimony before the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids

My name is Adriane Fugh-Berman and I am a physician and professor at Georgetown University Medical Center, where I direct PharmedOut, a research and education project that promotes rational prescribing. I am also on the executive committee of PROP and I serve as a paid expert witness in state and local government litigation against the opioid industry.

The 2016 CDC guideline is an evidence-based tool that has been crucial to decreasing inappropriate and dangerous prescribing of opioids for chronic pain. The 2022 guideline will be just as important. Although the US has made progress in decreasing opioid prescriptions, we continue to prescribe more opioids than any other country, and this has contributed to the estimated 93,000 overdose deaths that occurred in 2020.[1] You may hear from others that these deaths are due to fentanyl-laced heroin, not prescription drugs, but most heroin users started with prescription opioids.[2] Overexposing any population to highly addictive opioids results in many preventable harms.

It is unfortunate that the Opioid Workgroup (OWG) comments attempt to undermine the CDC guideline and perpetuate myths disseminated by opioid manufacturers. Complaining that the CDC guideline "focused heavily on the risks or potential harms of opioids, while less attention was focused on the potential benefits of opioids, or the risk of not taking opioids" is certainly an industry-friendly view.[3] Focusing on elusive benefits was what brought us the opioid use epidemic in the first place.

The OWG's recommendations assume that opioids are effective for chronic pain (although best evidence does not support this)[4] and seeks to gut language saying that non-opioid options are

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[1] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

[2] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013 Sep 1;132(1-2):95-100. doi: 10.1016/j.drugalcdep.2013.01.007. Epub 2013 Feb 12.

[3] Pg. 2: "Many workgroup members felt that the guideline focused heavily on the risks or potential harms of opioids, while less attention was focused on the potential benefits of opioids, or the risk of not taking opioids or undertreating pain"; Pg 7 "Many workgroup members noted that the supporting text was not balanced, and a full discussion of risks and benefits are needed – that address risk/benefits of prescribing opioids and of not prescribing or limiting opioids. For example, the discussion about older adults focuses on risks of opioids, but there is no discussion about risks of untreated or undertreated pain in this population (e.g., potential worsening of blood pressure, mood, cognition).

[4] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. doi: http://dx.doi.org/10.15585/mmwr.rr6501e1; Department of Veterans Affairs [Internet]. VA/DoD clinical practice guideline for opioid therapy for chronic pain. 2017 [cited 2021 July 16]. Available from: https://www.healthquality.va.gov/guidelines/Pain/cot/; Chou R, Turner JA, Devine EB, Hansen RN, Sullivan SD, Blazina I, Dana T, Bougatsos C, Deyo RA. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health Pathways to Prevention Workshop. Ann Intern Med. 2015;162(4):276-86; Kroenke K, Krebs EE, Bair MJ. Pharmacotherapy of chronic pain: a synthesis of recommendations from systematic reviews. Gen Hosp Psychiatry. 2009;31(3):206-19.

"preferred"[5] — even though nonopioid treatments are often as or more effective than opioids and are safer.[6]

Several statements in the OWG are just wrong, including "continuing opioids and not tapering opioids avoids risks of poor analgesia, worsening functioning, and suffering…"[7] In fact, chronic opioid use results in both tolerance and hyperalgesia, and chronic opioid use is associated with depression and decreased functioning.[8]

The OWG comments minimize the benefits of non-opioid treatments and casts them as too difficult to obtain.[9] In line with industry, the group opposes recommended limits on dose or duration. Although no risks of opioids are acknowledged, the OWG is concerned about the putative "risks of tapering" [10] — even PDMPs have "harms." [11] The proven role of buprenorphine in medication-assisted therapy for addiction is termed "emerging" rather than "established."[10]

The "tension" cited between "public health benefits versus patient benefits"[12] is a bizarre construct. Public health benefits ARE patient benefits. The OWG observations substitutes sentiment for evidence and flies in the face of both science and medicine. Prescribers were grateful for the 2016 CDC guideline, which can be credited with decreasing opioid

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[5] Pg. 3: Some workgroup members felt the language in this recommendation is somewhat too strong, given problems with some of the cited evidence. Words like "are preferred" might be softened to "may be preferred" or "may be effective". Although the harms of opioids are very well-defined, the benefits (especially long-term) are not well understood and difficult to study.

[6] Krebs EE, Gravely A, Nugent S, Jensen AC, DeRonne B, Goldsmith ES, Kroenke K, Bair MJ, Noorbalocchi S. Effect of opioid vs nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: the SPACE randomized clinical trial. JAMA. 2018;319(9):872-82; Moore PA, Ziegler KM, Lipman RD, Aminoshariae A, Carrasco-Labra A, Mariotti A. Benefits and harms associated with analgesic medications used in the management of acute dental pain: an overview of systematic reviews. *JADA*. 2018;149:256,265. e3; Moore RA, Wiffen PJ, Derry S, Maguire T, Roy YM, Tyrrell L. Non-prescription (OTC) oral analgesics for acute pain-an overview of Cochrane reviews. *Cochrane Database Syst Rev*. 2015;11:CD010794.

[7] Pg. 4-5: "Also, not fully acknowledged is that continuing opioids and not tapering opioids avoids risks of poor analgesia, worsening functioning, and suffering, and potentially illicit opioid use.

[8] Lembke A, Humphreys K, Newmark J. Weighing the Risks and Benefits of Chronic Opioid Therapy. Am Fam Physician. 2016 Jun 15;93(12):982-90.

[9] Pg. 9: "When describing benefits and harms, it is important to recognize real-world patients' lack of access to many nonopioid pain management strategies."

[10] Pg. 5: "However, there were some specific issues that were noted as concerning by some members, these included: never going back up in dosage during opioid tapering; lack of inclusion of observational studies showing potential dangers of tapering; minimal discussion about risk of tapering; role of patient-centeredness approach; representing the role of buprenorphine as established rather than emerging; an explicit discussion of goals of tapers is needed, particularly related to public health versus individual patient outcomes; there seems to be an underlying assumption that the goal is to get to zero MME, but perhaps it should be to get to a safer dose or better symptoms or function; a section on iatrogenic harms of tapering may be warranted."

[11] Pg. 7: Some workgroup members expressed caution regarding potential harms of the PDMP, particularly when algorithms are used to create risk scores that lack evidence without qualifications.

[12] Pg. 2: "Many workgroup members noted how the guideline has a constant tension between public health benefits versus patient benefits... Workgroup members felt it is important to directly address this tension between risks and benefits to public health versus individual patients, and to contextualize how individual providers should use this guideline in caring for their patients versus considering potential public health consequences."

overprescription in the U.S. We hope and expect the new guideline to continue to uphold the highest standards.

From: Rose Bigham
To: NCIPCBSC (CDC)
Subject: Public Comment for 7/16/2021 BSC/NCIPC Opioid Workgroup report on draft updated CDC Guideline for Prescribing Opioids
Date: Friday, July 23, 2021 3:02:21 PM
Attachments: image001.png

Attn: BSC/NCIPC:

There were many excellent and compelling public comments made during the 7/16/2021 meeting. I hope they are considered with the full seriousness and attention they deserve. I would like to reiterate a few issues important to me, a disabled person with a chronic/progressive condition causing intractable pain, who has taken prescribed opioids above 90 MME for more than 15 years without problems.

1. **Undue bias in the original 2016 CDC Opioid Prescribing guidelines:** The original guidelines were inappropriately influenced by multiple members of PROP. The PROP organization is made up of anti-opioid zealots, overwhelmingly NOT pain specialists, most of whom have personally profited on the 'prescription opioid epidemic' they themselves helped to create and evangelize. The lack of transparency and oversight was egregious back then, and the patient outcomes and harms have been immeasurable. I say that because no one has bothered to measure them. The only thing measured has been the rate/dosage of opioid prescriptions written REGARDLESS of illness, patient history, prognosis, and pain levels. It is the most harmful and brand-damaging effort in the history of the CDC. That the allegedly 'recused' lead author is anywhere near the possible revision of these guidelines is criminally inappropriate. He is not a pain specialist. The only research into pain management he has done is in anti-opioid efforts. It is beyond troubling that the CDC would re-engage this lead author who is largely responsible - along with the multiple PROP members who authored or were in the CEG - for the immense patient and provider harms which resulted from the original guidelines. Please ensure that no anti-opioid zealots are involved in the guideline revisions; especially those who personally profited by testifying in opioid lawsuits. This should be a minimum bar set by the CDC.
2. **Updated data on the true cause of the overdose crisis:** Your own published data reveals what many of us have known all along: prescription opioids play a minor role, at best, in the ongoing overdose crisis. Prescription opioids were never the main cause of the overdose crisis, and that is widely acknowledged. Illicitly-manufactured fentanyl and its use in combination with other substances are responsible for nearly ALL fatal drug overdoses. The original CDC effort to limit prescription opioids? Was misguided at best; maliciously targeted disabled people in pain and their providers at worst. And those guidelines and the resulting policies contributed to MUCH HIGHER fatality rates among those suffering from substance use disorders as well as those who innocently took a single illicit pill, only to never wake up again. Not to mention - the 'opioid epidemic'? You mis-branded the problem from the start. The American public was sold a story: blame the doctors, blame pharma - and they bought it. The resulting laws, policies, regulations and legal prosecutions which resulted from the broad and continuing ‘mis-implementation’ of the CDC Opioid Prescribing Guidelines will take

YEARS to correct. Please ensure that the NEW guidelines accurately reflect the data that the CDC and others have now reported widely: it has always been primarily about illicit fentanyl, heroin, methamphetamines, alcohol, and others long before RX opioids ever become a factor. Please correct these inaccurate and harmful assumptions going forward.

3. **Ongoing patient and provider harms**: In addition to the harms already caused by the 2016 CDC Opioid Prescribing Guidelines, the future looks bleak for people in pain and the providers who care for them. Many providers have completely stopped treating patients with chronic pain due to concerns about aggressive oversight and persecution by the DEA. Many pain specialists have retired rather than continuing to navigate the problematic and evolving legal and regulatory landscape. How many medical students do we anticipate going in to pain medicine given this current environment? How many pain specialists - treating chronic and intractable pain - do we currently have in every state, and nationwide? The AMA has already communicated - multiple times - how dire the situation is for patient and providers alike. In addition to correcting the messaging in the Guidelines which were based on inaccurate data by anti-opioid zealots, the CDC must make a strong statement about resuming appropriate pain care for people in chronic pain and every other kind of pain, and that providers who treat them must be protected from inappropriate persecution. We are not only losing people with substance use disorders to illicit and deadly street drugs; we are losing disabled people in agony who cannot tolerate their suffering any longer. And millions more struggle with activities of daily living they used to manage effectively with long-term opioids, but are now .. Limited. Inactive. Stuck at home. This problem has become so very much worse since the 2016 guidelines were released, but because no one is tracking patient outcomes or measures - other than rate of prescriptions written - then CDC and other federal agencies have no idea how horrific the impact has been to the American public. Specifically: access to pain care is a human right. Lack of access to effective pain care is a DISABILITY RIGHTS ISSUE. You owe the American public some effort to correct the impact of the 2016 Guidelines. Quickly and clearly.
4. **MME limits**: Get rid of them. The moment that CDC determined that there was an acceptable MME number, the battle was lost. Anyone who was above that number was doomed. I was among them, for a while. Just as there is no 'safe' MME dosage, neither is there one 'unsafe' MME dosage. It is the kiss of death for individualized healthcare, and the beginning of incentives and rewards for limiting opioid prescriptions to people in pain, regardless of whether they were appropriate or not. There have been plenty of studies and research illustrating that the use of MMEs was NEVER a good idea. Kill the MME targets, once and for all. And then remove all of the incentives and measures which followed their implementation.
5. **Urgency**: Things are incredibly bad out there. Tens of millions of people suffer from high-impact pain. Many people in pain have lost all hope of ever having their pain managed again. Many patients have been abandoned from care; yet another measure that no one is tracking. (Sidebar: Has anyone checked the PDMPs nationwide for patients who used to receive long-term opioids but no longer do? Are they still alive? Are they doing better without opioids, or worse? Because they are not in the PDMP

they are not on anyone’s radar. Check into it.) No one expects to be pain-free; they just want to be able to have some functionality, SOME of the time. We don’t know how many chronic pain patients we have lost to suicide because no one in any federal agencies is tracking it. We will continue to lose people - people who did not ask to be disabled, and most of whom have never misused a prescribed medication in their lives - due to opioid-phobia. And in the meantime, various states, insurance companies, medical groups, and policy makers are continuing to create new guidelines based on the 2016 guideline even now, furthering the harms. I understand that it takes time to create new guidelines, and we will be waiting until 2022. But in the meantime? Make a strong statement. Admit - more clearly and publicly - that there were errors in the earlier data, and that the agency is taking another look. Direct efforts towards the true cause of the overdose crisis: illicitly made fentanyl and analogues, and poly-pharma drug toxicity. Assure medical providers everywhere that the pendulum is swinging back, and that appropriate and individualized pain care will not be punished. Focus the efforts on effective, accessible, affordable treatment for those with substance use disorders and NOT on punishing providers treating people with pain and their patients who have pain.

The CDC should never have attempted to limit the prescribing of ANY medication. Would you limit prescribing of NSAIDs? Blood thinners? Tylenol? Insulin? All of these are deadly, sometimes when used at directed. Even more so if mistakes are made or intentionally misused. But the CDC doesn't touch them, because it is not your purview. It's the FDA's.

CDC needs to dig itself out of this horrible mess, and the sooner you come clean about the mistakes and the bias which got CDC to focus on prescribed opioids in the first place, the sooner that American medicine can resume safe, effective, humane care. Until then? The horrific atrocities will continue. We cannot wait until 2022 for a clear message.

Respectfully,

- Rose Bigham, Co-Chair, Washington Patients in Intractable Pain

WashPIP
Washington Patients In
Intractable Pain™

Rosalie Consiglio
January 16, 2018

On Dec 5th 2017, at Howard County General Hospital, I underwent spine surgery to remove the laminae and discs from L2 to L4, to place rods and screws, and to apply bone graft for fusion. During recovery, I was not given many of my regular medications, although I requested them several times. Before the surgery I had sent a list of all medications I was taking to the orthopedic nurse in the surgery center, (Mary Jane Scuto?) Many of my medications can have dangerous adverse effects if stopped abruptly. Also, for the 3 days I was there, my pain was not adequately nor correctly managed according to my pain management physicians instructions, hospital policy, and CDC standard guidelines for the treatment of chronic pain.

I am a 53 y/o chronic pain patient with DDD (degenerative disc disease) in all levels of my spine. The severity of the DDD ranges from moderate in my cervical spine, for which I underwent surgery in 2015, to moderate/mild in the thoracic levels, and more severe in my lumbar spine, where I suffer from spondylolisthesis (slipped vertebrae) of L5, for which I underwent surgery in 2008. The 2008 surgery consisted of removing the laminae from L4 to S1, repairing the discs, the placement of rods and screws, and bone graft for fusion. The cervical spine surgery I am not as clear of the details, but it involved removal of a bone spur, widening of a foramina, the placement of a metal plate and fusion of levels C5-7. The surgery on Dec 5th was similar to the 2008 one, except on levels L2-L4, also with rods and screws, and fusion. All 3 surgeries were performed with the purpose of preserving function, for the lumbar surgeries - to remain able to walk, and for the cervical - right arm weakness/numbness. There was no expectation nor was there any intent that any surgery would reduce pain or "cure" me of my chronic pain. I suffer from severe, intractable, 24/7 nerve pain, which is, in itself, an incurable disease. My chronic pain disease was in part caused by my original pain not being adequately diagnosed or treated at Howard County General when I first began having symptoms in August of 2004. After numerous ER visits, I was given a lumbar puncture without first doing an MRI, and got a spinal fluid leak. Then after several more ER visits, specialist visits, and MRIs, with still no diagnosis, in May of 2005 I checked myself into the psych ward telling them I wanted to commit suicide if they could not help me. The psychiatrist referred me to pain management and I was finally able to lead a normal life, and worked for 8 more years. I have cauda equina syndrome, with nerve damage of the bladder and bowel. I believe I may have had cauda equina since 2004 since I began having the symptoms then, but was never actually diagnosed with it until 2013. My pain may have been caused by the spondylolisthesis and delayed treatment of cauda equina syndrome beginning ~2004, and delayed treatment of anterolisthesis causing severe cervical spine pain since 2004. My pain is well documented to affect my heart rate and blood pressure, therefore it is necessary to treat the pain for life-saving reasons, not just for comfort. I was told by a rheumatologist and cardiologist that if I did not keep my pain under control I would die of a stroke or heart attack. This is why I was so adamant about having my pain under control post-op.

Prior to the December 5th sugery, I had been taking MSER, Morphine Sulfate extended release - generic for MS Contin - 15mg-3X/day since 2007 for pain and gabapentin - 800mg-3X/day specifically for nerve pain. I also take Amrix - 15mg-1X/day for muscle spasms, Nucynta 50mg 1-3 per day for breakthrough pain, and also a few other non-pain medicines. See attached medication sheet for other medicines and also vitamins, supplements, and herbal remedies. Before my surgery, in the prep room, a nurse went over all my medications that I was currently prescribed, but in the computer they were incorrect. She changed them in the computer as I went over the list with her.

In the late afternoon of December 5th, as the anesthesia began wearing off, my pain began slowly creeping up on me. I gazed up at the IV, and was horrified to see that no pain medication had been set up for me post-op. I rang the bell for the nurse and advised her I was in pain, and that I was a chronic pain patient, and that I needed my afternoon morphine-ER pill, my gabapentin, and a short acting pain medicine. It was then that I found out that all of the medications that the nurse had put in the computer in the surgery prep area that morning had not been saved, and reverted back to medications and dosages from God knows how long ago, probably 10 years ago when I was on 2/3 the dose of morphine and no gabapentin. I was told that there was no doctor on the floor and they would have to page the on-call doctor. They brought me 10mg of percocet and some tylenol, which was all that had been prescribed, every 6 hours. 10 MG OF PERCOSET!!!???? Seriously???? That is like taking an aspirin to me. For spine surgery? Were they insane???

For the next few hours, that seemed like days, my pain became steadily worse. Not only the incision pain in my back, which was mild in comparison, but horrific abdominal pains, tonic-clonic jerks/twitches, and the burning skin pain, like my body is on fire all over, that comes with withdrawals. My husband became very concerned and explained to the nurse that I was going through withdrawals, that it was going to get ugly, and that I could die of a stroke or heart attack according to my last pain specialist who tried to take me off opioids 12 years ago. (He was just trying to re-evaluate my pain level to switch from fentanyl to a safer long-acting medicine in pill form, and after that horrible detox, that almost took my life, he told me never to detox again.) The nurse came in and gave me a canned response they give to patients who are in pain and waiting for their next dose, in a condescending tone, that just made me angry. Meanwhile, my husband was out at the nursing station, frantic, trying to tell them this was a life or death situation.

Finally, later in the evening, after what seemed like an eternity, they hooked me up to an IV dilaudid with a button I could press every 5 minutes. I pressed it as much as I could, but ended up passing out from the pain, exhausted, only to wake up a few hours later in withdrawals and pain again. That night was a nightmarish rollercoaster ride through hell, with ups of passing out for a few hours, to the lows of being in withdrawals. The next day, when the doctor came in, they finally agreed to change my medication in the computer to my correct ones and the correct doses. So they started giving me the gabapentin. The doctor was hesitant to give me the morphine pills because I was on the IV dilaudid. I tried to explain to him that the morphine was my long-acting medicine, and I needed it to stop the withdrawals, and the IV was a short-acting, like my breakthrough pain medicine. I had been texting with my pain doctor, who told me "You should also get your Long acting morphine, too. You need BOTH!!" I don't know if the doctor called her, or he just believed the texts, but I finally got one morphine pill some time early afternoon. But then when the shift changed, I asked for my afternoon dose, and the nurse said that the computer said only 2 per day, not 3, which was what the computer had said before the changes. I think the problem was that none of the medication changes they made in the computer would stick at shift change. So at shift change, it would revert to my old 10 years ago doses. When my surgeon came in, I told him what was going on, and he said he would get a pain management specialist.

Late afternoon on the second day, they finally brought in a pain specialist. She said that she would raise my MS-Contin to 3 per day, and increase the pain pump from every 6 minutes to 2 minutes. But then after the she left, the nurses said they wouldn't be able to change it until the next dosing schedule, which was in the evening!! So I missed my afternoon dose. When it was time for the evening dose, I must have pressed the button every 2 minutes on the dilaudid and passed out again, so they skipped it! When I woke up, they would not give it to me and said I had to wait for the next dose. I tried to explain to them that I had to get the long-acting medicine in me so that I could stop relying on the pump, and that hey must wake me up to give it to me if necessary.

The problem with my pain control was that they were not dosing me every eight hours and I had several time periods in the beginning of my pain control where I had to go 12 or 15 hours without a dose. When you are in a post-op situation you should not be going longer than eight hours, you should actually, if anything, be less than eight hours if you miss a dose to catch up. I had to fight for every single dose of pain meds, even when it was longer then 8 hours since I had the last dose. Every time I asked for my medicine, I got a canned response that I could tell that a nurse had been told to memorize. They said they didn't want to over-drug me because they were worried about respiratory depression. Well then why did they not once hook up my CPAP?? The CPAP was never even unpacked the entire time I was there!

Also, they were not giving me my food or anything to drink; I could not get my own food and water myself, as I was too weak, and in too much pain to move or get up. I was starting to get malnourished, weak, some symptoms of dehydration, and my condition was deteriorating by the minute. My pain was getting worse; it was totally out of control, and I started getting a lot of weird symptoms that made me think I was having serious complications of untreated pain, such as TIA, seizures, contractures, ascites. The second night, the nurse took my blood sugar in the middle of the night and it was so low that she made me drink orange juice. I remember her yelling at me to drink and sticking the straw in my mouth. But they still made no effort to bring the tray close to me so I could reach my dinner or water. Orange juice is a temporary fix, not a solution, I also needed food!

I began to see that this was similar to what happened to me with the 2008 surgery all over again, in a different hospital. Back then, my pain was also not adequately managed, I was only on IV morphine, but they were giving me very high doses, and it still didn't work. But I did not know that the reason why I was in so much pain was because the IV was a short-acting medicine, and as a chronic pain patient I needed my long acting medicine as well. I had the same symptoms: too much pain to sit up and eat, not drinking, but it went on for a week in the hospital, and I was dying. My immune system broke down; I got infections, a high fever, and DIC. Because of the DIC, they had to take the IV out. (Looking back, it probably was not DIC, it was probably just a very bad flare-up of my cryoglobulinemia, because I had the hepC back then.) As soon as they took me off the IV and gave me oral morphine-ER, I got better within a day. At the time I was certain that it was because someone was stealing and diluting the IV morphine bags, some addict lurking in the hospital, and there is no way to steal the morphine ER pills! But now I realize that IV just doesn't work for me, it is a short acting medication. They sent me home on 3 pills of the 15mg morphine-ER every 8 hours, and to wean down to my regular dose of 1 pill every 8 hours on a tapering schedule over a couple weeks.

Anyway, back to this 2017 surgery, where I could not even get one of my morphine pills. I woke up on Dec 7th, and I realized that I had to leave that torture facility AMA before they killed me!! Hospitals obviously have NO CLUE how to treat post-op pain for chronic pain patients. I signed myself out because I was not getting proper care. I believe that had I stayed there, my condition would have worsened, and I could have died. When I got home I took three morphine to catch up, because that was what my pain doctor had prescribed in 2008, and I had been texting my pain doctor. I also took 100 mg of Nucynta (tapentadol). Within an hour I was sitting up in the recliner with my appetite back, and I was eating, and getting up to use the bathroom on my own. I could not function at all without my pain properly managed, not even enough to sit up to eat or drink. Once my pain was under control, I was finally able to heal!

I now have a neurosis of hospitals, similar to PTSD. I never will stay or be admitted to one again. I will be getting all of my surgeries and procedures outpatient from now on. I know better how to care for myself at home. I felt that I was tortured for three days, and treated like a drug addict.   The dose that worked was 3 morphine every 8 hours, and within 3 weeks I had weaned down to my normal dose. I believe that its possible that a chronic pain patient may always need to double or triple their baseline long-acting medicine during post-op or other acute pain episodes, but its also possible that it was just necessary for me because being inadequately treated for so long following surgery created an enormous pain flare cycle that had to be broken before any recovery could take place.

I think the main point that I am trying to make is that pain kills! Doctors and nurses have to realize that when people are in pain, and not recovering well, they may be dying from under-treated pain. The pain must be adequately treated first before any healing can happen. It wasn't just me, I heard another patient screaming in pain down the hall as well. He sounded like an old man. How can anyone listen to someone screaming in pain and not have the compassion to help them? It is inhumane. Also, when a chronic pain patient is in the hospital recovering post-op, they MUST be given all of their medicines, and in the same or greater dosages they were taking before they came to the hospital, then on top of that, they should be given what a normal person without tolerance takes for post-op or greater. One article recommended giving chronic pain patients ketamine for post-op, a medicine used for anesthesia! Above all, no patient should EVER be made to go through withdrawals while recovering post-op. Because of the opioid epidemic, I can understand why doctors do not want to write prescriptions to patients who are LEAVING the hospital; I never asked for that; my pain doctor handles that. But no doctor should be stingy with medicines that a patient requests for pain WHILE IN the hospital. Treating the pain of a patient inside the walls of the hospital has nothing to do with the opioid epidemic. Doctors and nurses in hospitals need to be trained to treat chronic pain patients appropriately and manage their pain.

Quotes from Articles and Studies

Sudden, Unexpected Death in Chronic Pain Patients

https://www.practicalpainmanagement.com/sudden-unexpected-death-chronic-pain-patients

CDC Guideline for Prescribing Opioids for Chronic Pain

https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
"When opioids are reduced or discontinued, a taper slow enough to minimize symptoms and signs of opioid withdrawal (e.g., drug craving,

anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection) should be used. A decrease of 10% of the original dose per week is a reasonable starting point;"
"Ultrarapid detoxification under anesthesia is associated with substantial risks, including death, and should not be used (*200*)."
From the Table:
"Effects of decreasing or tapering opioid doses versus continuation of opioid therapy-
Pain and function-Abrupt cessation of morphine was associated with increased pain and decreased function compared with continuation of morphine."
"Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain: Outcomes related to abuse - No evidence"

Postoperative pain management for patients who are long-term users of opioids
https://www.ncbi.nlm.nih.gov/pubmed/21348214

Treat the Pain... Save a Heart

Good pain control can prevent angina, hyperlipidemia, and tachycardia
https://www.practicalpainmanagement.com/pain/other/co-morbidities/treat-pain-save-heart

From: Rosalie Consiglio
To: NCIPCBSC (CDC)
Subject: Inpatient Post-op Chronic Pain Petients
Date: Thursday, July 15, 2021 5:28:07 PM
Attachments: letter pain med surgery.odt

The attached letter I wrote to Howard County General Hospital about my treatment post-op for spine surgery in Dec 2018. I had to leave the hospital AMA on the 3rd day because they were not adequately treating my pain.

I could not register in time to make a comment, but I was told I could submit a comment or question to this email.

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Rosalie Consiglio
410-294-8080

Comparison of 2016 CDC Opioid Prescribing Guideline for Chronic Pain
and
2021 Updated Draft CDC Guideline for Prescribing Opioids
(Note: 2016 Guideline in black, 2021 in red; Both 2016 and 2021 versions have 12 recommendations.)

Determining When to Initiate or Continue Opioids for Chronic Pain

1) Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.

Determining Whether or Not to Initiate Opioids for Pain

Recommendation #1: Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient. (Recommendation Category: A; Evidence Type: 3)
When a patient has severe pain from an acute injury, or surgery, THEY NEED OPIOIDS!!!! Chronic pain syndrome is the RESULT of UNDER-TREATING pain in the acute phase. There is never any danger from treating a patient in pain AT the hospital. First off, for acute pain from an injury or surgery, these should always be immediate release meds, unless the patient is a chronic pain patient already on ER pain meds. But for a regular patient, we must be very careful here, because one of the ways people get addicted to opioids is when their doctor prescribes too much pain meds for an injury or surgery BY PRESCRIPTION, not AT the hospital. If possible, its best to monitor the patient to see what is the lowest dose they need to treat their pain, and only give them enough for one or two days, and have them call back if they need more. If the cause of the injury goes away, they should get better, not worse. If they come back and got worse, then something else is going on, and you mis-diagnosed the cause of their pain.

2) Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

Recommendation #2: Nonopioid therapies are preferred for subacute and chronic pain. (preferred by whom? because the most important person here is the patient, who must live each day in pain, suffering, not being able to live a normal life.) Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. (who decides this? If they help with the pain, but patient is getting worse, because they have a disease with no cure, and would have gotten worse anyway, then the pain meds should not be discontinued. This should be up to the patient first, then the doctor, never the CDC guidelines. It must be re-enforced that these are only guidelines!! These Guidelines are for primary care, orthopedists, neurologists, rheumatologists etc. NOT for chronic pain doctors or pain management specialists treating chronic pain patients. Pain Specialists are expected to know way more about chronic pain and the treatment of it, and SHOULD NOT NEED GUIDELINES!!!) If opioids are used, they should be combined with other therapies as appropriate. (Recommendation Category: A, Evidence Type: 3) I agree with this. Mixing two meds, for example, opioids and gabapentin or opioids and a muscle relaxer, make it stronger to allow for a lower dose of the opioids.

3) Before starting and periodically during opioid therapy, clinicians should discuss with patients known

risks and realistic benefits of opioid 1 therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection and Dosage

Recommendation #3: When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. (Recommendation Category: A and Evidence Type: 3) It depends. If the patient has 24 hour pain, and the prognosis is a disease that is progressive and incurable, they may as well go on the ER. The ER has the advantage of releasing only a small amount of medicine at a time, so that the patient doesn't feel the side effects of feeling "high." This allows for the patient to drive, work, and live a normal life. When I was first had chronic pain, I worked for NASA as a flight controller for the Hubble Space Telescope, and I was able to work 9 more years on ER pain treatment. Immediate release meds release all at once, causing the side effects of feeling stoned, but also do not control the pain as well.so that the patient will be on a rollercoaster of feeling pain for 2 hours, then stoned and no pain for 1 hour, then normal, no pain for 1 hour, then pain again for 2 hours. This goes on day after day, and makes pain patients want to commit suicide.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4) When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

Recommendation #4: When opioids are started for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day. (Recommendation Category: A and Evidence Type: 3) It is difficult to put limits on how much pain meds. Some people may have a higher tolerance, or just have worse pain. If there is any question that the patient may be in danger, then maybe have them observed inpatient for a day while on the new dose to evaluate effectiveness and to be sure it is not too much. Also, combining opioids with gabapentin, muscle relaxer, or others may help increase effectiveness.

5) When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

Recommendation #5: For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation Category: A and Evidence Type: 4) It is way MORE HARMFUL to a chronic pain patient to have their pain meds reduced or tapered, than any harm/risks of staying on it. The last time I tried it was 2007, because I was on fentanyl and xanax, and I didn't trust the fentanyl with all the deaths. My HR and BP sky-rocketed to dangerous levels. I was told to never try to detox or switch my meds at home. The biggest problem is not the patients, its the system. Why are these patients in so much pain to begin with? Most of them are mis-diagnosed, or they need

surgery but don't have insurance. One patient I knew, it was her teeth! She could not afford to have the dental work done that she needed. If we had universal health care, we would not have so many chronic pain patients. Doctors often treat only the **symptoms** of disease, not the **causes.** And pain happens to be a symptom of so many.
6) Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of
immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

Opioid Duration and Follow-Up Recommendation #6: When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed. (Recommendation Category: A and Evidence Type: 4)

7) Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Recommendation #7: Clinicians should continue opioid therapy for subacute or chronic pain only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. (Recommendation Category: A, Evidence Type: 4) They need to be more worried about the risks of un-treated or undre-treated pain. Heart attack or stroke from high BP and HR, also depression and suicide from living with pain, the stress of not getting enough pain meds.

Assessing Risk and Addressing Harms of Opioid Use 8) Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

Assessing Risk and Addressing Harms of Opioid Use Recommendation Statement #8: Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present. (Recommendation Category: A, Evidence Type: 4 same answers as before. the risks of un-treated or undre-treated pain is worse.

9) Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

Recommendation #9: Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should reviewPDMP data when starting opioid therapy for acute or chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. (Recommendation Category: A, Evidence Type: 4)

10) When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

Recommendation #10: When prescribing opioids for chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11) Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

Recommendation #11: Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants. (Recommendation Category: A, Evidence Type: 3) It depends on what is considered CNS depressant. Benzos, yes, but muscle relaxers and nerve pain meds actually work well with opioids, and increase the effectiveness.

12) Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

Recommendation #12: Clinicians should offer or arrange treatment with medication for patients with opioid use disorder. (Recommendation Category: A, Evidence Type: 2)

From: Rosalie Consiglio
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 3:21:23 AM
Attachments: NCIPC_MyRecomCDC.pdf

Attached are my comments on the draft 2021 recommendations.

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Rosalie Consiglio
410-294-8080

From: rosemariemgendron@gmail.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:46:20 PM

I have had CRPS II for 14 years, have two spinal cord stimulators, 11 operations, and still require opioid medication, monthly visits to Beth Israel Pain Clinic (at least 3 hrs. by car with my husband) to maintain a half decent life. Without my medications, my pain level would be unbearable. Unfortunately, there is no cure, no simple procedure to stop CRPS. I recently tried a pain patch that would have cost over $1,000 a month. It doesn’t matter because it didn’t work but if by a miracle it did, I would have paid over $12,000 annually to be pain free. As a senior citizen, that’s not easy but Medicare doesn’t cover the cost (what else is new). People need meds to function - it’s not easy but it’s the way it is. Making it harder for chronic pain sufferers is not acceptable. Believe me, we will do what it takes to cope and attempt to live without constant care from others. Don’t penalize those of us who can’t function without meds.

Sent from my iPhone

From: Rhonny Glaser
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:36:44 PM

Hello

I think it is a very sad thing that so many in pain have been made to suffer.
When used properly, pain meds (opiates), have many benefits to those suffering and give them some ability to live life and function. The FDAs policies have made most doctors "fear" prescribing opiates, even when they are aware of a patients suffering. This is not right. I do not feel that the FDA should override doctors. It is not their place. If they want to truly save lives, go after cigarettes. That would be an honest and just intervention. Pain med interference is not.

Rhonda Glaser
USAF Veteran
Sacramento, CA

From: Rick Hillman
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:25:31 PM

I am a chronic pain patient who has been adversely affected by the guidelines. These guidelines have led to increased days in pain without adequate levels of relief due to the chronic back and leg pain I have been experiencing. Your MME basis of prescribing seems archaic when a persons pain levels are considered as a secondary thought in the process. I've endured days and nights with less than enough relief. Pain levels increase for me with any activity and only remain constant when I remain bound to my recliner. Your rule that allows for cancer and end of life care to not follow these guidelines remains without reason. Pain is Pain no matter what disease, cause or stage of life one finds themselves in. These guidelines do nothing to help pain patients and if nothing else, make pain patients consider many other means of relief including illicit drugs or even suicide. No pain patient goes out looking for illegal drugs but after these guidelines came into effect, you've driven many to consider it, All in the name of halting a few bad actors. Too many patients suffer needlessly because of these misdirected guidelines. Government has no place in the exam room with me and my physician and has even less business telling me when my pain is relieved based on an arbitrary scale or guideline. I've endured too many days of excruciating pain with access to too few medications due to bureaucrats in between me and my doctor.

Richard Hillman
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Rick Hillman

From: Ralph Hodges
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:39:40 PM

Once again your have proved to be nothing but a bureaucratic government creation that needs to be dismantled. In 2016 you turned millions of peoples lives into nightmares and did harm during the pandemic with misinformation.
This step will not help anyone suffering from chronic pain conditions and will send more patients to buying street drugs.
Thank you for nothing!
Ralph Hodges

From: Dobygale Rita
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:07:58 PM

I was severely affected by the 2016 guidelines. I am a cervical spine cord injury patient. I was prescribed 80mg of oxycontin twice a day to help with intractable pain caused by this injury. I was cut off in a day, the day I was to pickup my script. I went into immediate withdraw, sickened, unable to function as a normal human due to the sickness. After a small battle with United Health care I was put on Metadone untill taper. I am still in a withdraw symptom state due to the 13 years that I took the opiate. I didnt get any help during this time...all my phone calls to my representatives were answered with excuses that this country is in an opiate epidemic. Its a shame this wasnt handled better. Thank you for listening.

Rita Kimbel

From: Rebecca Lambert
To: NCIPCBSC (CDC)
Subject: Opiates and chronic pain
Date: Wednesday, July 21, 2021 12:38:02 PM

To whom this may concern,

Please bare with me as there is a lot to say.

I am a chronic pain patient who suffers from chronic necrotizing pancreatitis, with pseudocyst. I am also a recovering addict alcoholic of 10 years, who suffers from an anxiety disorder and PTSD due to trauma as a child and the murder of my son at age 18.
My pancreatitis was caused, I believe, by the Moderns vaccine, as I got sick almost immediately after receiving the 2nd shot.

I would like to tell you how difficult it has been to receive the care that I need.
I live in a small town, hours away from any hospital, so in an emergency with my pancreas, I have to drive 3.5 hours to Las Vegas, which is where the specialists are.
There is a small urgent care clinic in town, but they would not even help me to stop the pain, in order for me to get through the drive to get to hospital. I've been told by the providers there that "they would never risk losing their license and would never prescribe opiates". They have even mentioned being afraid of being flagged by the DEA. THESE PROVIDERS LIVE IN FEAR OF PAIN PATIENTS!
I have suffered days, and hours of excruciating pain, that I literally did not, should not have had to go through.
As well, I am apparently every pharmacists worst nightmare! A pain patient with an anxiety disorder.
I was allowed to take Xanax for my anxiety and PTSD prior to becoming a pain patient. Now I have to chose pain, or peace. I can't have both, EVEN THOUGH I have been told by my doctor that I can take the Xanax just make sure I take it 2 hours after any pain meds. But no, I can't get a pharmacist to fill my prescription.

Let me explain.
I became addicted to a LEGAL, sold at smoke shops and Corner stores everywhere. It's called Kratom, and the DEA won't regulate it even though it is as addicting as any opiate, because it works on the same receptors. "Addicts" everywhere are taking it to get the help they need, and can't get, from their doctor. My reason is because I have arthritis in my spine and bulging disks, have already had 1 fusion, and don't want to do it again. At the time I started taking it, I was told it was natural, non addictive, and legal. Little did I know those were lies. But again even with proof that people have died taking Kratom the DEA doesn't schedule it and allows it to be sold to anyone.

I was talked into taking Suboxone by my doctor to avoid the withdrawals from Kratom, and was on Suboxone for 2 years, not able to stop because it made me SO MUCH MORE SICK, than the thing I was taking.
I finally was able to get off Suboxone, but it still shows on my records. Suboxone=addict right?
Wrong. People take Suboxone for a lot of reasons, and addiction isn't only why. But if you take it, you are definitely flagged as an addict, and if you should develop a chronic pain disease, you will have a VERY hard time receiving care. Pharmacists are the new doctors in

Nevada, they will come between a patient and a doctor or dentist in a heart beat. I need to have 4 teeth pulled, and need an anti anxiety medicine before they can do it called Haldol. The pharmacist refuses to fill the prescription for 2 pills, because of the fact that I used to take Suboxone. Used to! She also says I was doctor shopping be ause I have 4 opiate prescriptions filled by 4 different doctors. She accused me of doctor shopping even when I brought her my medical records showing that the prescriptions were written because I was hospitalized 4 times for over a week each and had different doctors each time, BUT THEY WERE FROM THE SAME HOSPITAL. She said she can't risk losing her license. Again, she is afraid to do her job. I have resorted to using mail order products to fill my own teeth, until I can find a surgeon to remove them, which is going to cost 3 times what it would have cost to have the medication and have them pulled. It's 2 pills. Instead of her discussing drug interactions with me she just refuses to have them filled.
Then there are the lies that pharmacists will tell you in order to avoid filling your prescriptions:
We don't carry that medication, or Your doctor doesn't want us to fill it (even after the doctor wrote it).
They will come up with any reason instead of just talking to the patient. Or, they just simply not fill it and wait for you to come try to pick it up.

Finally, I have never taken a pain medication, or anxiety medication that was not prescribed to me, nor have I taken it more than was prescribed. I even let my husband dole them out to me. The fact is, I have no desire to take more than prescribed. If the medication stops my pain, that is what I need it for. I do not get high, or feel high after taking pain medications I simply have lack of pain.

There are a lot of jokes about pill seeking patients, and any one of them would also apply to a pain relief seeking patient.
A pain relief seeking patient will:
Become emotional when told they cannot get pain medication, even and especially when they are in pain all of the time.
A pain relief seeking patient will ask for a specific pain medication. Because they are chronically in pain, they know what works and what doesn't. Doctors who confuse them with drug seekers will outright deny the medication a pain relief patient is asking for, as kind of a "gotcha" moment. They will give you medication that isn't as strong on purpose.
Pain seeking patients ARE drug seeking patients!!! Because we have to be!
The sad part is that pain patients can no longer be honest with their doctors, because if they are, they won't get treated, especially if you have any history of mental illness, or abuse in your past. So ex addicts are NOT telling their doctors everything. It's sad, because I used to share everything with my doctor's, but now that I have chronic pancreatitis, I just can't, because I can't risk it.

I don't ever want to have to go back to Kratom. I don't, but I cannot swear to myself that if my doctor quits prescribing me opiates (which he has already told me he will do at some point) , and I am in interactive pain that can't be controlled, and I can't drive to the hospital for 3.5 hours, that I won't break down and buy it. I e been working to get the stuff OFF of the counter, and I'm scared I could be driven back to it by pain. But at least the DEA, won't pull the corner store's license if I do.

This is all backwards! Doctors are using the CDC guidelines for acute pain management, telling patients it the law when it's NOT. EVEN pain management specialists use the CDC guidelines as excuse to pull chronic pain patients off of the meds that help them function each day. I repeat, I do NOT get a "high" off of my pain meds! Maybe the first few times I took them, but certainly not anymore. They help keep pain at bay along with diet and taking care of myself.

I wouldn't wish this kind of pain on my worst enemy, especially knowing that they will have to jump through hoops and suffer in silence a LOT of the time. They will be pushed to tears by doctors, dentists, pharmacists, and even family members who don't understand what it's like living in pain every day 24 hours, no relief, for MONTHS at a time.

The CDC needs to re write those recommendations. The therapeudic dose needs to be set higher for chronic pain patients at the very least.

Thank you for reading this and taking what I am saying into consideration.

Rebecca Lambert

From:	Richard Lawhern
To:	NCIPCBSC (CDC); Lindley, Tonia (CDC/DDNID/NCIPC/OD)
Cc:	Volkow, Nora (NIH/NIDA) [E]; AMA Opioid Task Force; CDC Info (CDC cdcinquiry.onmicrosoft.com); HHS Assistant Secretary for Planning & Eval
Subject:	Comments for the Record - July 16, 2021 Meeting of the NCIPC Board of Scientific Counselors
Date:	Sunday, July 18, 2021 3:15:35 PM
Attachments:	Comments to the July 16 NCIPC BSC Meeting.docx Comments on AHRQ Review for Acute Pain - September 2020.docx AHRQ Methodological Errors - Final - Jan 2021.docx

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For Tonia Lindley and administrative staff, National Center for Injury Prevention and Control, Board of Scientific Counselors

Please forward to Acting Director Captain Christopher Jones, to all members of the Board, and to all members of the Opioid Work Group, now dis-banded under sunset regulations.

CC and BCC copies to ~500 US and medical professionals, knowledgeable pain patients and caregivers.

Dear Tonia, et al,

This letter submits three documents for review and incorporation into minutes of your July 16th virtual meeting, which I attended by Zoom session. I was unable to speak in the public session due to the large numbers of patients and advocates registered. Thus, I am submitting extended comments as invited in your previous correspondence.

Three documents are hereby offered:

Attachment 1 is my commentary on the meeting. At 5600 words and 18 references, this will not be a trivial read.

Attachment 2 is my first-round comments on a draft of Comparative Outcomes Review 240, published in December 2020, by the Agency for Healthcare Research and Quality. This appears to have been a major input to the ongoing revision and expansion of the 2016 CDC Guidelines.

Attachment 3 is my second-round comments offered to the Director of AHRQ following publication of COR 240. Taken in combination, Atch 2 and 3 substantively call into question the scientific and ethical integrity of multiple AHRQ reports in which Dr Roger Chou has been the principal author The issues involved include unacknowledged bias, technical and methodological errors, cherry-picking of data and over-generalization of findings, and failures of public transparency in AHRQ internal review processes.

I am available by phone for discussion of these documents 0900-1600 Eastern Time Weekdays, at 703.216-0724.

If historical performance is any guide, publication of the transcribed minutes of the meeting may occur not earlier than 60 days hence. However, every day that CDC delays retraction and repudiation of its opioid prescribing guidelines, is a day in which physicians will continue to leave pain medicine practice and patients will continue to die from your inaction. Thus, I strongly suggest that the Acting Director should make a personal commitment to a publication date. Please issue a statement concerning who will read these comments, how their accuracy will be assessed, and how pertinent comments will be integrated into regulatory policy for prescription opioid analgesics and physicians who employ them in treating acute and chronic pain.

By way of prefacing your review and inclusion of these comments in the public record, I offer the initial introduction from Atch 1, below:

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Introduction:

In accordance with published announcements of the US CDC National Center for Injury Prevention and Control, this paper is submitted for inclusion in the minutes of the July 16, 2021 public meeting of the Board of Scientific Counselors. This meeting was focused on findings and concerns of an appointed advisory "Opioid Work Group (OWG)," pertaining to a revised and expanded draft of the 2016 CDC Guidelines on prescription of opioid analgesics to adults with chronic non-cancer pain.

Issues of CDC Charter: I note in beginning these comments, that US CDC has no legislative charter or authority for issuing guidelines on prescribing or dosing for any number of non-opioid medications used to treat infectious diseases, depression, diabetes, hypertension or other health problems that the agency actively tracks and on which it periodically reports. Interjection of the Agency into opioid guidelines in 2016 was grossly inappropriate in a mission that is normally addressed by FDA. Highly negative and destructive results of this unjustified adventure in mission creep reinforce the need for CDC to be removed from all further participation in the regulation of medical practice standards for other than infectious disease.

A Fundamental Issue of Medical Science: The central measure of merit for the 2016 opioid "guidelines" -- and for the draft rewrite -- was an intended reduction in the availability of medically prescribed opioid analgesics, employing threshold values of Morphine Milligram Equivalent Daily Dose (MMED) as criteria. In this context, an exchange between Wilson Compton of the Board of Scientific Advisors and Capt Debra Houry was exceptionally revealing.

Compton asked how outcomes of the 7-8 June 2021 FDA Workshop on "Morphine Milligram Equivalents" might affect the CDC's understanding of the uses of MMED. Captain Houry's comments seemed calculated to avoid substance and to indulge in meaningless generalities. She spoke in terms of needing more "nuance" in applying MME as a criterion.

The reality of the FDA workshop is vastly different from that suggested by Captain Houry. Although public comments on the Workshop remain open until August 9th, major conclusions are already clear from comments available in the Federal Register. We now know from multiple sources that MMED is junk science -- scientifically invalid and deeply harmful as a criterion for limiting opioid dose or duration. This reality is (in somewhat less stark terms) confirmed in a June 2020 letter from the CEO of the American Medical Association to the Director of CDC.

The following references are drawn from my own May 2020 lFDA Workshop comments, filed in the Federal Register.

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Jeffrey A. Singer, MD, "If Lawmakers Really Want to 'Follow the Science', They Will Repeal Codified Opioid Guidelines". Cato At Liberty, May 24, 2021. https://www.cato.org/blog/lawmakers-really-want-follow-science-they-will-repeal-codified-opioid-guidelines

Josh Bloom, PhD, "Comments to the FDA – Opioid Dosing Based on Milligram Morphine Equivalents is Unscientific", American Council on Science and Health, May 24, 2021, https://www.acsh.org/news/2021/05/24/comments-fda-opioid-dosing-based-milligram-morphine-equivalents-unscientific-15561

Sally Satel, MD, "The Truth About Painkillers" National Affairs, Nr 47, Spring 2021. https://nationalaffairs.com/publications/detail/the-truth-about-painkillers

Additional published references address the pivotal role of individual genetically mediated variations in opioid metabolism. Taken in combination, these references effectively invalidate any and all efforts to generalize standardized criteria for opioid dose across general patient populations or specific disease entities. This literature brings new urgency to the observation of the 2019 HHS Task Force on Best Practices in Pain Management, that there is no one-size-fits-all pain patient or therapy plan.

Tom Lynch, Amy Price, "The Effect of Cytochrome P450 Metabolism on Drug Response" Am Fam Physician. 2007 Aug 1;76(3):391-396. https://www.aafp.org/afp/2007/0801/p391.html

Donna J. Belle and Harleen Singh, "Genetic Factors in Drug Metabolism", Am Fam Physician. 2008 Jun 1;77(11):1553-1560 https://www.aafp.org/afp/2008/0601/p1553.html

Andrea M. Trescot, MD, and Semyon Faynboym, MD "A Review of the Role of Genetic Testing in Pain Medicine", Pain Physician 2014:17 ISSN 1533-3159

Bhushan A Kapoor, Prateek Lala, Julie L.V. Shaw, "Pharmacogenics and Chronic Pain Management" Clinical Biochemistry, 2014. http://dx.doi.org/10.2016/j.clinbiochem.2014.05.065

A Central Recommendation: Given the abject failures of MMED as a measure of merit or a viable standard of practice in administering prescription opioid therapies, I must assert that the 2016 CDC Guidelines are consequently flawed beyond any possibility of repair. The only scientifically and ethically sound action now open to the CDC is outright public repudiation and withdrawal of its 2016 guidelines –

without replacement.

No amount of marginal tinkering will help. The CDC royally messed up on basic science and its present revision writers group continues to do so. As evident from almost all of the public comments submitted in the July 16th meeting of the BSC, CDC must now repair the fully predictable damage that they did to millions of patients and thousands of medical practitioners. Repudiation and withdrawal of the guidelines are the only adequate mechanism for making this correction.

A Legal Dimension: As one element of guideline withdrawal, CDC should act upon a recommendation by the CEO of the American Medical Association in a June 2020 letter to the Director of CDC. The AMA recommended that all State laws placing hard limits on prescription opioid dose or duration should be repealed. I believe that CDC must now go further to recommend that US Department of Justice and State Attorneys General conduct a judicial review for at least the last 10 years, of actions to sanction, suspend or revoke licenses, or imprison physicians for fictitious “over-prescribing” based on MME thresholds. Judgments involving MME as a criterion, must be vacated with a monetary award of damages to physicians whose practices and lives have been ruined by this bogus pseudoscience.

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Richard A "Red" Lawhern PhD
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Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

Comments to the July 16, 2021 Meeting of

The US CDC National Center for Injury Prevention and Control

Board of Scientific Counselors

Richard A Lawhern PhD

Author Note: My name is Richard Lawhern PhD. I am a non-physician volunteer advocate for chronic pain patients. I have 25 years' experience as a medical literature analyst and forum moderator for peer to peer patient and family support groups in social media, with tens of thousands of patient communications. I have published over 125 papers and articles in medically oriented journals and mass media, some of them co-authored with medical professionals. I sit on two editorial boards as an invited patient advocate. No other organization has reviewed or approved these comments. I likewise have no financial or professional conflicts of interest.

Introduction:

In accordance with published announcements of the US CDC National Center for Injury Prevention and Control, this paper is submitted for inclusion in the minutes of the July 16, 2021 public meeting of the Board of Scientific Counselors. This meeting was focused on findings and concerns of an appointed advisory "Opioid Work Group (OWG)," pertaining to a revised and expanded draft of the 2016 CDC Guidelines on prescription of opioid analgesics to adults with chronic non-cancer pain.

Issues of CDC Charter: I note in beginning these comments, that US CDC has no legislative charter or authority for issuing guidelines on prescribing or dosing for any number of non-opioid medications used to treat infectious diseases, depression, diabetes, hypertension or other health problems that the agency actively tracks and on which it periodically reports. Interjection of the Agency into opioid guidelines in 2016 was grossly inappropriate in a mission that is normally addressed by FDA. Highly negative and destructive results of this unjustified adventure in mission creep reinforce the need for CDC to be removed from all further participation in the regulation of medical practice standards for other than infectious disease.

A Fundamental Issue of Medical Science: The central measure of merit for the 2016 opioid "guidelines" -- and for the draft rewrite -- was an intended reduction of the availability of medically prescribed opioid analgesics, employing threshold values of Morphine Milligram Equivalent Daily Dose (MMED) as criteria. In this context, an exchange between Wilson Compton of the Board of Scientific Advisors and Capt Debra Houry was exceptionally revealing.

Compton asked how outcomes of the 7-8 June 2021 FDA Workshop on “Morphine Milligram Equivalents” might affect the CDC’s understanding of the uses of MMED. Captain Houry’s comments seemed calculated to avoid substance and to indulge in meaningless generalities. She spoke in terms of needing more “nuance” in applying MME as a criterion.

The reality of the FDA workshop is vastly different from that suggested by Captain Houry. Although public comments on the Workshop remain open until August 9th, major conclusions are already clear from comments available in the Federal Register. We now know from multiple sources that MMED is junk science -- scientifically invalid and deeply harmful as a criterion for limiting opioid dose or duration. This reality is i(in somewhat less stark terms) confirmed in a June 2020 letter from the CEO of the American Medical Association to the Director of CDC.

The following references are drawn from my own May 2020 Workshop comments, filed in the Federal Register.

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Jeffrey A. Singer, MD, “If Lawmakers Really Want to ‘Follow the Science’, They Will Repeal Codified Opioid Guidelines”. Cato At Liberty, May 24, 2021. https://www.cato.org/blog/lawmakers-really-want-follow-science-they-will-repeal-codified-opioid-guidelines

Josh Bloom, PhD, “Comments to the FDA – Opioid Dosing Based on Milligram Morphine Equivalents is Unscientific”, American Council on Science and Health, May 24, 2021, https://www.acsh.org/news/2021/05/24/comments-fda-opioid-dosing-based-milligram-morphine-equivalents-unscientific-15561

Sally Satel, MD, “The Truth About Painkillers” National Affairs, Nr 47, Spring 2021. https://nationalaffairs.com/publications/detail/the-truth-about-painkillers

Additional published references address the pivotal role of individual genetically mediated variations in opioid metabolism. Taken in combination, these references effectively invalidate any and all efforts to generalize standardized criteria for opioid dose across general patient populations or specific disease entities. This literature brings new urgency to the observation of the 2019 HHS Task Force on Best Practices in Pain Management, that there is no one-size-fits-all pain patient or therapy plan.

Tom Lynch, Amy Price, “The Effect of Cytochrome P450 Metabolism on Drug Response” Am Fam Physician. 2007 Aug 1;76(3):391-396. https://www.aafp.org/afp/2007/0801/p391.html

Donna J. Belle and Harleen Singh, “Genetic Factors in Drug Metabolism”, Am Fam Physician. 2008 Jun 1;77(11):1553-1560
https://www.aafp.org/afp/2008/0601/p1553.html

Andrea M. Trescot, MD, and Semyon Faynboym, MD "A Review of the Role of Genetic Testing in Pain Medicine”, Pain Physician 2014:17 ISSN 1533-3159

Bhushan A Kapoor, Prateek Lala, Julie L.V. Shaw, “Pharmacogenics and Chronic Pain Management” Clinical Biochemistry, 2014.
http://dx.doi.org/10.2016/j.clinbiochem.2014.05.065

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A Central Recommendation: Given the abject failures of MMED as a measure of merit or a viable standard of practice in administering prescription opioid therapies, I must assert that the 2016 CDC Guidelines are consequently flawed beyond any possibility of repair. The only scientifically and ethically sound action now open to the CDC is outright public repudiation and withdrawal of its 2016 guidelines – without replacement.

No amount of marginal tinkering will help. The CDC royally messed up on basic science and its present revision writers group continues to do so. As evident from almost all of the public comments submitted in the July 16th meeting of the BSC, CDC must now repair the fully predictable damage that they did to millions of patients and thousands of medical practitioners. Repudiation and withdrawal of the guidelines are the only adequate mechanism for making this correction.

A Legal Dimension: As one element of guideline withdrawal, CDC should act upon a recommendation by the CEO of the American Medical Association in a June 2020 letter to the Director of CDC. The AMA recommended that all State laws placing hard limits on prescription opioid dose or duration should be repealed. I believe that CDC must now go further to recommend that US Department of Justice and State Attorneys General conduct a judicial review for at least the last 10 years, of actions to sanction, suspend or revoke licenses, or imprison physicians for fictitious “over-prescribing” based on MME thresholds. Judgments involving MME as a criterion, must be vacated with a monetary award of damages to physicians whose practices and lives have been ruined by this bogus pseudoscience.

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Specific Recommendations of the CDC Writers Group and the BSC Opioid Work Group

A presentation by the Acting Director of CDC/NCIPC described the process now being employed in revision and expansion of the 2016 Guidelines. A further presentation by Dr Chinzano Cunningham, OWC Chair, tellingly summarizes a wide variety of concerns expressed by members of this advisory group. In my view, the presentation offers a few baby steps toward correction of the CDC's fundamental errors in 2016. But in another sense, it represents a missed opportunity and a failure of process.

As acknowledged by Dr Cunningham during the July 16th meeting, the OWG was not charged by the BSC with developing a "consensus position" on the validity or implications of its findings and concerns. Indeed, the OWG report reflects many instances where no consensus was reached and/or multiple contributors voiced contradicting positions during OWG deliberations. OWG members also voiced concern that the revised draft is "unbalanced" between concerns for public health versus issues of individual patient health.

Anyone familiar with the process of development for consensus medical practice standards must immediately recognize a fundamental failure in this process.

If OWG reviewers could not reach consensus on validity of the basic premises of the proposed Guideline revision, then the public can only conclude that the medical community is in deep disarray and confusion over what "treatment guidelines" should actually look like. Given this state of confusion, any balanced reading of medical ethics must recognize the potential for deep harms to patients, attending inappropriate or scientifically unsupported practices. In fact, those deep harms have been widely recognized and discussed in popular and medical literature over the past five years.

In the company of multiple commentators in the July 16th meeting, I assert that such harms derive not from "misapplications" of the 2016 guidelines, but rather from the content and intended outcomes of that fatally flawed document.

References:

Jacob Sullum, "The Intensifying Conflict Between Opioid Control and Pain Control"
Practical Pain Management, Vol 18 Issue #2, April 12, 2019.
https://www.practicalpainmanagement.com/resources/practice-management/intensifying-conflict-between-opioid-control-pain-control

Chad Kollas, MD, "PROP's Disproportionate Influence on U.S. Opioid Policy: The Harms of Intended Consequences *Palimed – A Hospice and Palliative Medicine Blog.* June 2021.
https://www.pallimed.org/2021/05/props-disproportionate-influence-on-us.html#disqus_thread

Remaining comments of the author are organized around the 12 recommendations of the revised draft guidelines, plus the introduction and conclusion sections.

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Recommendation #1: “Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient.” [Category A]

My Comments: the assertion that non-opioid therapies are “preferred” in acute pain is unsupported and outright false. The state of methodological rigor in the medical trials literature for alternatives to opioid therapy is abysmal. It is acknowledged as such in the AHRQ Comparative Outcomes Review on Treatments for Acute Pain, mentioned as a source in the NCIPC Acting Director’s overview briefing. Specifically, protocols for “usual therapy” in this literature are only loosely defined, rendering evaluation of outcomes for opioid versus non-opioid therapies very imprecise.

A careful reading of the AHRQ report on non-pharmaceutical / non-invasive therapy trials reveals that none of these trials have evaluated opioids versus alternative non-pharmacological therapies on an either/or basis. The investigator were forced to “assume” that such therapies were applied as adjuncts to “usual treatments” that were rarely documented in trials protocols.

However, the 2016 guidelines and the draft rewrite of those guidelines both attempt to address the so-called “opioid crisis” by falsely asserting that non-opioid therapies are “preferable”. In the revised guideline draft, the CDC writers group is essentially proposing **not** to “augment” opioid therapy with non-opioid measures, but rather to replace opioids with a broad class of so-called “alternative” therapies that are highly experimental, display very weak medical evidence and have almost entirely marginal and temporary impact on pain and quality of life. This implicit substitution of experimental therapies for opioid pain relievers known to be effective in millions of patients is profoundly unethical and irresponsible.

As an additional observation, I must also suggest that assignment of any “Category A” recommendations in the draft revised guideline will turn the entire document into a *mandated practice standard* -- **NOT** a “guideline” to be tailored to each individual patient. CDC has no legislative authority to issue any such practice standards for non-infectious disease. And such mandates fundamentally violate central recommendations of the 2018-2019 HHS Inter Agency Task Force on Best Practices in Pain Management.

The following abstract summarizes my input to the Agency for Healthcare Research and Quality in extended comments on their outcomes assessment for opioid versus non-opioid prescription medications for acute pain (Comparative Outcomes Review 240). This information was filed with AHRQ in the Fall of 2020:

ABSTRACT:

> In its year-long effort to assess the trials literature pertinent to treatments for acute pain, the Agency for Healthcare Research and Quality has labored mightily to produce a mouse. The resulting report is clearly biased by an anti-opioid agenda, drawing conclusions that are largely unsupported by the 115 trials they extracted from an identified literature of over 20,000 reports. Missing is any evidence of participation by patients or their advocates. Also missing is acknowledgment of the abysmal state of rigor and depth in the trials literature. The report demonstrates no credible basis for its top-level claims that Tylenol and NSAIDs are superior to opioids in the treatment of acute pain in medical disorders such as kidney stones.
>
> This report should be withdrawn for a major reconsideration in light of findings of both the American Medical Association Opioid Task Force, and the HHS Interagency Task Force on Best Practices in Pain Management.

I also filed the following overall observations in my comments to AHRQ:

> Use of the terms “are probably” or “might be” to describe outcomes of trials suggests to me a systemic anti-opioid bias throughout the report and its appendices. When reported details of the referenced trials are examined with care, we find no protocols, methods, or analysis to establish either probability or possibility of the claimed outcomes, from the original sources.
>
> What we find instead are assessments of “medical evidence weak” or “no evidence”, describing the majority of 151 randomized controlled trials summarized in the report (from more than 20,000 candidate trials initially flagged from medical literature database search, of which 1871 were subjected to full text review).
>
> It must be assumed that such terms were introduced as opinions by the AHRQ report writers, or peer reviewers, or both. Given that the draft report fails to identify names and affiliations of the writers, it becomes practically impossible to research their professional publications for known biases and predispositions. Likewise important is that there is no evidence of participation in this review process by any patient advocate or representative.
>
> A major shortcoming of this report is its failure to adequately acknowledge confounds in the medical literature and in the analysis of the AHRQ writing team, which significantly compromise any ability to generalize results meaningfully in prescription guidelines or policy.
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> Specifically, there is no mention of the terms “genetic” or “genomic” anywhere in this report. Yet we now know from other sources that there is high variability in individual responses to prescription opioid medications, due to polymorphism in the expression of six liver enzymes which mediate opioid (and 90% of other medications) metabolism. This medical reality is plausibly a major underlying

> reason why no currently available patient profiling instrument has demonstrated reliable prediction accuracy for risk of dependence, tolerance, addiction or mortality in medical patients managed on opioid therapy. Lack of such instruments is acknowledged in the report, but no explanation for the reasons associated therewith is offered.
>
> The practical impact of natural patient metabolic variability is that it is literally impossible to generalize conclusions concerning opioid safety or effectiveness, based on any fixed dose or duration criteria. As acknowledged by both the May 2019 report of the HHS Interagency Task Force on Pain Management, and the American Medical Association in its June 2020 comments to a CDC Call for Stakeholder Comment in the Federal Register, there can be no one-size-fits-all patient or therapy plan. Trying to generalize a single standard of pain care – even for a single disorder – is a fool's errand and very likely to remain so for the foreseeable future.
>
> A clear implication from HHS and AMA findings current as of September 2020 is that fundamental premises and assumptions embedded in the AHRQ systematic review concerning risks or harms must be withdrawn and reconsidered from the ground up. AMA is now on public record challenging the US CDC to undertake nothing short of an across-the-board repudiation and withdrawal of all legislated hard limits on prescription opioid daily dose or duration. This challenge in effect renders much of the AHRQ outcomes review moot.
>
> Also of concern is the process by which this draft report has been issued. AHRQ has circulated it only to their internally managed email distribution lists, with a review period of 30 days. In an outcomes review of this magnitude, a more appropriate venue would be the US Federal Register, for a period of at least 60 days. However, the draft – if it is issued at all – will require major revision and refocus along lines suggested herein, before any public review is announced.

For purposes of the minutes of the July 16th meeting of the BSC, I have attached the full text of two rounds of my comments as submitted to the Director of AHRQ.

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Recommendation #2: Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. [identified as "Category A"]

My Comments: Buried deeply in the June 2018 AHRQ Systematic Outcomes Review for Non-Pharmacological / Non-Invasive Therapies, is an acknowledgment that should be taken to heart by CDC. There are presently no validated patient profiling instruments that accurately predict which patients are "at risk" or under what conditions they are at risk for iatrogenic opioid dependence, addiction, or overdose mortality. The only "risk assessments" we presently have are grounded upon patient narratives and the experience of the attending medical doctor, augmented by urine and blood testing for non-prescribed substances. Urine testing (as partly acknowledged in the Acting Director's presentation) is notoriously subject to false positives and inaccurate physician interpretations.

Reference: Richard A Lawhern PhD and Steven E Nadeau, MD, "Behind the AHRQ Report - Understanding the limitations of "non-pharmacological, non-invasive" therapies for chronic pain." *Practical Pain Management,* Vol 18, Issue #7, October 3, 2018.

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Recommendation #3: When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

My Comments: For numerous medical conditions and individual patients, long-acting opioids are an essential element of therapy for avoidance of sleep disturbance due to under-medication. Likewise in chronic pain, once an initial therapy plan is put in place, there is a tendency among busy clinicians to avoid re-examination of medication profiles simply because of the paperwork involved.

Reference: Jennifer P Schneider MD, PhD, "Editorial: Why are ER Opioids Out of Favor?" *Practical Pain Management,* Volume 20 Issue #3, June 18, 2020

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Recommendation #4: When opioids are started for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day.

My Comments: As acknowledged in July 16th discussions between the Board of Scientific Counselors and Opioid Work Group members, the 50/90 MME thresholds quoted in this recommendation have no support in either data or science. It is entirely plausible that these specific numbers are an arbitrary artifact of the dose range conventions used widely in published papers on hospital admissions. Such thresholds have no plausible or validated relationship to patient risks of harm, other than a weak association of higher dose levels with protracted prescribing and elevated rates of mortality. However, ignored in this association is that higher prescribing doses tend to be consequences of more severe pain and more complex underlying medical conditions in which mortality may derive from the medical condition rather than the use of opioids in managing pain.

Published CDC data reveal that there is no relationship between rates of opioid prescribing versus rates of opioid-related overdose mortality on a US State-by-State basis. Age cohort demographics of prescription directly contradict any medical model for cause and effect between prescribing and overdose mortality. Seniors over age 62 are prescribed opioids three to six times more often than youth under age 19. Yet overdose related mortality in youth is three to six times higher than in seniors over age 62 Mortality in seniors has remained relatively stable at the lowest levels in any age group, while skyrocketing in youth during the past 20 years.

References:

Richard A. Lawhern, PhD, "Tracking Down the 'Research' Behind The CDC's Opioid Prescribing Guidelines", National Pain Report, August 10, 2016. http://nationalpainreport.com/tracking-down-the-research-behind-the-cdcs-opioid-prescribing-guidelines-8831122.html

Richard A Lawhern PhD, "Stop Persecuting Doctors for Legitimately Prescribing Opioids For Chronic Pain", STAT First Opinion, June 28, 2019, https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/

Jeffrey A Singer MD, Jacob Z Sullum, Michael E Schatman PhD, "Today's nonmedical opioid users are not yesterday's patients; implications of data indicating stable rates of nonmedical use and pain reliever use disorder" *Journal of Pain Research,*V12:617-620, https://www.researchgate.net/publication/330922982_Today's_nonmedical_opioid_users_are_not_yesterday's_patients_implications_of_data_indicating_stable_rates_of_nonmedical_use_and_pain_reliever_use_disorder

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Recommendation #5: For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

My Comments: Multiple patient comments were received in this meeting, describing the damage done by forced tapering of opioid medications among "legacy" patients who have long used them under medical supervision. Arguably, the so-called "guideline" issued by CDC in 2016 has single-handedly destroyed the practice of pain medicine and the lives of millions of patients, by encouraging US DEA, Department of Justice, State Medical Boards and Attorney Generals to conduct a witch hunt against ANY doctor who prescribes opioids. However, there is simply no evidence whatever that forced or coerced tapers help any patient in any way, or reduces "risks" of iatrogenic opioid addiction or mortality.

As only one example among many, a letter addressed to the Governor of Oregon by several prominent leaders in pain medicine illustrates the extreme hazards generated by mandated programs of prescription opioid reduction.

Reference: Sean Mackey, MD, PhD, Dan Carr, MD, Richard Steig, MD, Lynn Webster MD, Chad Kollas, MD, Bob Twillman, PhD, FACLP, "RE Health Evidence Review Commission – Chronic Pain Task Force Revised Proposal" , December 4, 2018 ,

https://dontpunishpainrally.com/wp-content/Flyer-Files/CPP%20News%20Source/Letter%20to%20Oregon%20Governor%20Kate%20Brown.PDF

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Recommendation #6: When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed.

My Comments: Clinicians are trained in med school to limit all medication dosing to quantities needed for the expected duration of acute pain; they do not need an additional guideline to inform such conservative practices. However, I know of no published trials that validate either one to three days or seven days as generalizeable limits on dose duration for all acute pain. Duration of severe acute pain can vary significantly between medical complaints and treatment procedures. A three day opioid prescription might be adequate in some patients who present at an ER with fingers mashed in a car door closing. But such a limited prescription would certainly not be recommended for the immediate post-operative period of a radical mastectomy.

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Recommendation #7: Clinicians should continue opioid therapy for subacute or chronic pain only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.

My Comment: For all of the reasons mentioned previously, this recommendation is highly misdirected. In typical medical practice, opioids are continued when full healing is not obtained or when pain has failed to improve sufficiently to justify reducing dosage. Transition between acute and chronic pain may in some patients be a consequence of under-medication. And as previously noted, there are no proven quantitative or predictive measures of "risk" for opioid dependence, addiction, or mortality. Thus judgment of the appropriateness of continuing opioid treatment must rest with the physician and patient working in collaboration.

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Recommendation #8: Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME), or concurrent benzodiazepine use, are present.

My Comments: While a history of opioid abuse may influence treatments jointly chosen by physicians and their patients, there are no substantive data establishing a strong relationship between medical prescribing and opioid overdose. Co-prescribing Naloxone to patients with a history of opioid abuse suffers from the disability that Naloxone is typically administered by first responders after the subject is already entering or has already entered respiratory arrest.

This issue is also overshadowed by the reality that literally millions of legacy chronic pain patients are known to benefit from opioid doses over 90 MMED. Likewise, the supposed "risks" of co-prescribing opioids and benzodiazepines have been vastly over-hyped and misrepresented in medical literature.

In a landmark demographic analysis of the State of North Carolina for a year, Nabarun

Dasgupta PhD and his colleagues estimated "number needed to treat" associated with hospital admissions or mortality in patients exposed to both opioids and benzodiazepines. The number of patients in whom co-prescription appeared to be associated with confirmed mortalities was about one in 1200. Other published work from multiple investigators reveals that risk of overdose mortality in medical patients co-prescribed opioids and benzodiazepines is on the order of 0.25% to 0.50% per year – comparable to mortality in post-stroke patients treated with anti-fibrillation drugs. It is entirely plausible that benefits of co-prescription in improved patient sleep and reduced anxiety outweigh presumed risks of respiratory suppression.

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Recommendation #9: Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for acute, subacute, or chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

My Comments: There is no consistent evidence that current uses of PDMP data have led to reductions of patient overdose or addiction risks. However there is some evidence that PDMP reports may be associated with increased mortality. And there is wide-spread concern for the suppressing effect of "high prescriber" letters generated to physicians by PDMP managers. These databases are designed primarily as law enforcement aids. They are subject to significant errors and misinterpretations. And in an era of hugely failed electronic records automation, mandatory PDMP reporting adds further burdensome paperwork to the management of chronic pain patients.

References:

"Patients, Privacy, and PDMPs: Exploring the Impact of Prescription Drug Monitoring Programs", CATO Institute, October 3, 2019, https://www.cato.org/events/patients-privacy-and-pdmps

Florence Chaveroff, PhD, "Effect of Prescription Drug Monitoring Programs on Fatal, Nonfatal Drug Overdoses " *Clinical Pain Advisor,* May 7, 2018, https://www.clinicalpainadvisor.com/home/topics/opioid-addiction/effect-of-prescription-drug-monitoring-programs-on-fatal-nonfatal-drug-overdoses/?hmEmail=K94ZAed5ZOY-7wDLgBL2flaxi6PNtbcobBw7PB6lV5tDLaRTPPCuQA2?utm_source=twitter&publishDate=False&timestamp=636610296731105361

Jeffrey A Singer, MD, "More Evidence That Prescription Drug Monitoring Programs Might Increase Overdose Deaths" *Cato at Liberty,* February 14, 2021.

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Recommendation #10: When prescribing opioids for subacute or chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

My Comments: As elsewhere noted in these remarks, current training of physicians in the interpretation of drug testing is highly problematic. From social media postings, we learn that patients are routinely discharged without recourse on the basis of a single “anomalous” test result. Such results may include indications of marijuana use, even in states where Medical Marijuana is legal.

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Recommendation #11: Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants.

My Comments: As elsewhere noted, there are presently no validated, field-tested patient profiling instruments with proven predictive accuracy for identifying patients at increased risk for prescription opioid misuse, dependency, addiction or mortality. Lacking such instruments, clinicians and general practitioners may find themselves at the mercy of the very few patients who misrepresent themselves in hopes of obtaining drugs for resale. Alternately, they may become victims of the ongoing draconian “war on drugs” conducted by US DEA, DoJ, State drug enforcement agencies, Attorneys General, and State Medical Boards. As the HHS Inter Agency Task Force on Pain Management informed us, there is on one-size-fits-all patient or therapy plan. Yet regulatory and law enforcement agencies have forced thousands of physicians out of pain management practice, based in substantial part on the misdirected and arbitrary rationale of the 2016 CDC Guidelines.

To the extent that we may infer the rationale of the present writers of the draft revision and expansion of the Guidelines, it would appear that they have learned nothing from five years of horrendous patient and practitioner lived experience.

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Recommendation #12: Clinicians should offer or arrange treatment with medication for patients with opioid use disorder.

My Comments: Other commentators from among the medical professional community have pointed out that pain treatment in the US is provided by a large body of medical practitioners who have neither training, experience, nor licensure as addiction specialists. Likewise, the number of specialists in pain management is inadequate to provide needed services in oversight for patients prescribed over 50MMED – and that community is shrinking due to the unjustified draconian persecution of DEA and State drug control authorities.

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Introduction and Conclusion Sections: OWG Observations

- Discussion regarding disparities and equity comes too late
- Need more explicit statement about being a clinical guideline, not a payer or governmental policy
- Authorship issues—few unnamed reviewers, unclear how public input was factored into the Guideline, many references had a lead author who authored the Guideline
- Must acknowledge real-world lack of access to non-opioid pain management

My Comments: The third concern voiced by the Opioid Work Group is highly problematic for the current draft update to the 2016 Guidelines. The unnamed principal author of several outcome reviews tasked by CDC on the Agency for Healthcare Research and Quality was Dr Roger Chou of the Oregon Health and Science University. Dr Chou was funded to lead research teams on behalf of AHRQ, to generate these reviews. And it is reasonable to infer that his influence over their content has been major.

However, Dr Chou also serves on the Board of Scientific Counselors of the National Center for Injury Prevention and Control. This arrangement puts him in the position of being able to lobby for the acceptance of his own work as public policy – a fundamental professional and financial conflict of interest. Dr Chou recused himself from participation in the July 16th meeting during roll call – but should have done so years ago.

Particularly troubling in Dr Chou's professional history is a close association and co-authorship of papers with individuals who are now or have been affiliated with an anti-opioid advocacy group named "Physicians for Responsible Opioid Prescription (PROP)". I must suggest strongly that this association may account for much of the “lack of balance” noted in both the 2016 CDC guidelines and the present attempt to rewrite this fatally flawed document.

Reference: ibid Chad Kollas MD https://www.pallimed.org/2021/05/props-disproportionate-influence-on-us.html#disqus_thread

Related fundamental issues pertain to the details of the AHRQ reports for which Dr Chou was principal author. I am particularly concerned with AHRQ Comparative Effectiveness Review 240 (Treatments for Acute Pain), for which I submitted comments on September 13, 2020 during draft review, and again with endorsement by 25 medical professionals, in January 2021 after publication.

This group characterized content of CER 240 in the following terms:

> **ABSTRACT:**
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> In its year-long effort to assess the trials literature pertinent to treatments for acute pain, the Agency for Healthcare Research and Quality has labored mightily to produce a mouse. The resulting report is clearly biased by an anti-opioid agenda, drawing conclusions that are largely unsupported by the 115 trials they extracted from an identified literature of over 20,000 reports. Missing is any evidence of participation by patients or their advocates. Also missing is acknowledgment of the abysmal state of rigor and depth in the trials literature. The report demonstrates no credible basis for its top-level claims that Tylenol and NSAIDs are superior to opioids in the treatment of acute pain in medical disorders such as kidney stones.
>
> This report should be withdrawn for a major reconsideration in light of findings of both the American Medical Association Opioid Task Force, and the HHS Interagency Task Force on Best Practices in Pain Management.

We requested that the Director (later Acting Director) of AHRQ convene a Red Team Review of the subject analysis, by an independent team of medical professionals and patient advocates. From the non-responsive return correspondence we received, it became apparent that the Director instead forwarded our comments to the original analysis team – in essence, putting the foxes in charge of the institutional hen house.

AHRQ routinely publishes comment reviews after issuance of their final reports. And they did so for CER 240. My comments were summarized in their after-action review, as well as receiving about 20 independent endorsements by others. However, none of the AHRQ “peer reviewers” responded on substance or merit to any of my original comments. And tellingly, their after-action review fails to provide even one published reference to refute the concerns we attempted to raise.

Thus I must advocate strongly to the NCIPC BSC and to CDC senior management, that AHRQ outcomes reviews should be disqualified from use in formulating public policy for treatment of pain. Grounds for this position are a major failure of public transparency and clear misrepresentation of the state and implications of the available medical trials literature. The Agency appears to have attempted to create an appearance of public transparency, but has clearly chosen not to address the substance of these issues.

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The Agency for Healthcare Research and Quality Labors Mightily To Produce a Mouse

By

Richard A. Lawhern, PhD.

September, 2020

On August 31, 2020, the US Agency for Healthcare Research and Quality (AHRQ) announced availability of a draft systematic outcomes review on **“Treatments for Acute Pain".** The report is intended to support revision and expansion of the 2016 CDC guidelines for prescription of opioids to adults with chronic non-cancer pain, by inclusion of new guidelines for acute (short term) pain treatment. In this intention, the draft report hugely fails.

I have downloaded, reviewed and commented on this draft via the AHRQ in-house gateway: https://effectivehealthcare.ahrq.gov/products/treatments-acute-pain/draft-review

ABSTRACT:

In its year-long effort to assess the trials literature pertinent to treatments for acute pain, the Agency for Healthcare Research and Quality has labored mightily to produce a mouse. The resulting report is clearly biased by an anti-opioid agenda, drawing conclusions that are largely unsupported by the 115 trials they extracted from an identified literature of over 20,000 reports. Missing is any evidence of participation by patients or their advocates. Also missing is acknowledgment of the abysmal state of rigor and depth in the trials literature. The report demonstrates no credible basis for its top-level claims that Tylenol and NSAIDs are superior to opioids in the treatment of acute pain in medical disorders such as kidney stones.

This report should be withdrawn for a major reconsideration in light of findings of both the American Medical Association Opioid Task Force, and the HHS Interagency Task Force on Best Practices in Pain Management.

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MY COMMENTS AS SUBMITTED

Section 1. Comments on the Evidence Summary of the draft report

Main Points (Bullet Points quoted from the Report)

· • Opioids are probably less effective than nonsteroidal anti-inflammatory drugs (NSAIDs) for several acute pain conditions (postoperative pain, surgical dental pain, and kidney stones) and might be similarly effective to NSAIDs for low back pain.

My response:

One of the more subtle reporting biases found in this report is that opioids are rarely a treatment of first choice in low back pain not associated with surgery. It is thus to be expected that NSAIDs will be a default first treatment in mild to moderate low back pain. The inclusion of single-dose trials in the data review introduces a bia against opioids, in that no opportunity is offered for appropriate dose titration to reach effective levels of medication.

· • Opioids might be and NSAIDs are probably more effective than acetaminophen for surgical dental pain, but opioids are probably less effective than acetaminophen for kidney stone pain.

My Response:

Again, the anti-opioid bias is evident in any connection between this “main point” and single-dose trials. Having myself been treated on multiple occasions for kidney stones -- with both acetaminophen and low-dose prescription opioids -- I can attest that acetaminophen is far less effective or immediate in moderating pain in some patients. More fundamentally, this assessment is widely reflected in patient reports from social media.

· • An opioid might be more effective than Gabapentin for acute neuropathic pain.

My Response:

This is one of the few areas of the report in which “might” is appropriately used. During 24 years of online support group moderation as a non-physician subject matter expert in chronic neuropathic face pain, I have observed that Gabapentin is widely used off-label in management of such pain. Some patients respond positively to titrated/divided doses over 1200 mg/day; others receive no pain relief from this medication; some are initially relieved only to have pain recur within weeks or months for no explained reason. A few display allergic reactions to the med. “Brain fog” (cognitive disorganization) and word finding difficulty are common side effects in many.

For significant numbers of patients, opioids offer improved outcomes for both effectiveness and fewer side effects.

· • Opioids are probably associated with increased risk of short-term adverse events versus non-opioid pharmacologic therapy for acute pain, including any adverse event, study withdrawal due to adverse events, nausea, dizziness, and somnolence, but serious adverse events are uncommon in randomized trials.

My Response:

Although serious short term adverse events may be uncommon in randomized trials, withdrawal by patients placed on placebo is common due to uncontrolled breakthrough pain. Moreover, many adverse events associated with non-opioid pharmacologic therapy are not observed in hospital settings, but instead occur later in re-admissions for liver toxicity, cardiac irregularities, ulcers or colitis reactions. Failure to acknowledge this obvious confound compromises the integrity of the observation.

· • Being prescribed an opioid for acute low back pain or postoperative pain might be associated with increased likelihood of use of opioids at long-term follow-up versus not being prescribed.

My Response:

This assertion is almost certainly an example of the post hoc ergo propter hoc fallacy. Prevailing medical practice looks upon prescription opioids as an option for relatively severe pain that is unresponsive to other interventions. Initial high severity and protracted duration of pain are associated with later emergence of chronic pain syndromes. Since opioids are used in more severe or intractable pain, we would expect continuing use during long-term follow-up compared to cases where pain is less severe and opioids are not initially tried.

Large-cohort studies (not referenced by the AHRQ report) of post surgical pain are also available that demonstrate rates of long-term prescription (>90 days continuous renewals) in opioid-naïve post-surgical patients on the order of 1% or less. Within this 1%, some proportion reflects not exposure to opioids in any habituating sense, but rather the failure of a surgical procedure to fully address the original cause of pain. This distinction is not acknowledged in the AHRQ report as a confound, and it should be.

· • Heat therapy is probably effective for acute low back pain, spinal manipulation might be effective for acute back pain with radiculopathy, massage might be effective for postoperative pain, and a cervical collar or exercise might be effective for acute neck pain with radiculopathy.

My Response:

Radiculopathy pain is associated with nerve pinch or lesions. Spinal manipulation in such cases must be administered with profound caution to avoid further damaging nerves that may already be compressed or damaged. Studies which mix patient populations with and without radiculopathy introduce potential confounds that should be acknowledged and assessed before drawing any general conclusions on effectiveness or treatment risks.

· • Research is very limited on the comparative effectiveness of therapies for sickle cell pain, acute neuropathic pain, neck pain, and management of postoperative pain following discharge.

My Response:

These research limitations are no less applicable for other categories of pain addressed by the AHRQ report and have in fact been highlighted in a Cochrane Review of the 2016 CDC Guidelines on prescription of opioids to adults with chronic non-cancer pain. In fact, the current AHRQ review unintentionally offers significant support for an assessment that the current state of medical trials literature lacks methodological rigor to such a degree that generalizations drawn by AHRQ writers are clearly inappropriate and should be withdrawn outright.

TECHNICAL EXPERT PANEL

Quoting from the report:

"In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts."

My Response:

If these important defining elements of the study do not represent the views of individual technical and content experts, then whom DO they represent? And precisely how were they arrived at? In areas of research where conclusions may be controversial, it is customary to entertain a "minority report". However, the AHRQ report instead opts for an effort to create the illusion of collegial unanimity.

Treatments for Acute Pain Systematic Review [Structured Abstract]

My Response:

Remarks on the Key Points apply equally to the structured abstract.

Section 2. Comments on the Introduction section of the draft report.

"Opioids, traditionally considered the most potent analgesics, are frequently used for acute pain. Therefore, acute pain management must be considered within the context of the current opioid crisis. Opioid prescribing quadrupled from 1999 to 2010; concurrently, the number of opioid analgesics deaths and opioid use disorder cases similarly rose sharply. 17 In 2017, an estimated 47,600 Americans died from opioid overdose (approximately 17,000 from prescription opioids 18).”

My Response:

As offered in the AHRQ report, this phrasing is another example of the post hoc ergo propter hoc fallacy. It is now known from multiple published sources that there is no cause-and-effect relationship between rates of opioid prescribing by doctors to their patients, versus rates of opioid overdose-related mortality. Seniors over age 62 have the highest rates of opioid prescription for pain and the lowest rates of overdose mortality – for the most part stable for the past 17 years. Youth under age 19 have the lowest rates of prescription but demonstrate mortality rates three to six times higher than seniors. This demographic inversion cannot be explained by any medical model that posits prescribing as a substantial cause of either opioid addiction or overdose deaths.

It is also known that there is no correlation between prescribing rates versus mortality on a US State-by-State basis. Data published in the CDC Wonder database for 2017 inform us that the trend line for opioid mortality versus prescribing rates is for lower mortality in US States where prescribing is highest. Multiple demographic studies and published reports of US CDC itself also confirm that the major driving factors in the current “opioid crisis” are illegal fentanyl, heroin, and Methamphetamine -- not prescription drugs. When a prescription opioid is found in postmortem drug toxicity screens, it is almost always found in association with multiple illegal substances and alcohol. At least one published estimate of the proportion of overdose deaths attributable to a single prescribed opioid alone is on the order of 2.5%.

As confirmed by the AMA in its recent comments to CDC, to represent the US opioid crisis in prescription-centric terms is a profound and fallacious mischaracterization.

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“The 2016 Centers for Disease Control and Prevention (CDC) guideline focused on chronic pain, but included one recommendation to limit opioids for acute pain in most cases to 3 to 7 days. This recommendation was based on evidence indicating an association between use of opioids for acute pain and long-term use. 35”

My Response:

This earlier recommendation has likewise been challenged by the AMA in its recent comments concerning needed revisions to the 2016 guidelines.

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“In the last several years, over 25 states have passed laws restricting prescribing of opioids for pain; nearly half of the states with limits specify that they apply to acute pain.20,36 Although data indicate some effects of policies in reducing opioid prescribing, studies on clinical outcomes are lacking."

My Response:

June 2020 AMA comments to the CDC likewise challenge CDC to actively advocate for repeal of these laws.

As a final observation on this section of the AHRQ draft report, I note that the introduction is remarkable not only for what it says, but for what it doesn't. The report ignores well established contradictions to its own politically pre-determined messages.

Notably, neither the authoritative work of Dr Nora Volkow and the National Institute on Drug Abuse nor the published commentaries of the American Medical Association are discussed.

Specifically, Dr Volkow and a co-author state in the New England Medical Journal:

"Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids — even among those with pre-existing vulnerabilities...Older medical texts and several versions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) either overemphasized the role of tolerance and physical dependence in the definition of addiction or equated these processes (DSM-III and DSM-IV). However, more recent studies have shown that the molecular mechanisms underlying addiction are distinct from those responsible for tolerance and physical dependence, in that they evolve much more slowly, last much longer, and disrupt multiple brain processes."

Nora D Volkow, MD and Thomas A McLellan, Ph.D., "Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies" . *NEMJ* 2016; 374:1253-1263 March 31, 2016]. http://www.nejm.org/doi/full/10.1056/NEJMra1507771

Section 3. Comments on the Methods section of the draft report.

Author's Note: With eight key questions, it should immediately have become apparent that many would go unanswered when review of published trials narrowed down the eligible trials set to 151 out of 20,000. However, the review team appears not to have made an effort to refine their focus.

Section 4. .Comments on the Results section of the draft report.

Author's Notes:

Among the 115 trials that survived AHRQ quality review, the assessed strength of medical evidence (SOE) was “low” in 52, “low to moderate” in 3, “moderate” in 15, and “insufficient” in 29. This level of evidence does not engender confidence in generalizations from such results.

The report section on Applicability is worth repeating and parsing (bold emphasis by the author):

Applicability

“A number of issues could impact the applicability of our findings. Most randomized trials were conducted in emergency department or postoperative care unit settings, which might reduce applicability to outpatient management of acute pain. Further, **trials of pharmacologic therapy frequently evaluated a single dose and some trials of nonpharmacologic therapy evaluated a single treatment session, potentially limiting the applicability of findings to a multidose course of treatment.** Trials excluded important patient subgroups, such as persons with a history of substance use disorder, prior opioid use, and psychological or medical comorbidities, or did not report information regarding these factors. In addition, trials were not designed to evaluate how benefits or harms varied in subgroups defined by these factors or others, such as age, sex, and race/ethnicity. **Another limitation to applicability is that most trials—particularly trials of pharmacologic therapy—were designed to assess short-term (<1 week, and often <1 day) effects on pain, with few trials evaluating effects on non-pain outcomes or at longer term followup.** Finally, the applicability of findings for one pain condition addressed in this review to another pain condition in this review, or to acute pain conditions not addressed in this review, is uncertain. For example, opioids were associated with decreased pain versus acetaminophen for dental pain, but increased pain versus acetaminophen for kidney stone pain. The applicability of findings from one acute pain condition to others may vary depending on the type and nature of the pain. For example, evidence on pharmacologic therapy for low back pain may have high applicability to neck pain, another musculoskeletal condition in the spine, but less applicable to sickle cell pain, neuropathic pain, or abdominal pain.”

My Response:

Potential limitations on applicability summarized above seem to fly directly in the face of stated “Key Findings” earlier addressed. It may not be going too far to suggest that these limitations should prompt outright withdrawal of this AHRQ report, in light of the profound weaknesses revealed in medical trials literature.

The many confounds revealed here contradict the top level key findings of the report with respect to comparative effectiveness of opioid analgesics versus NSAIDS or other non-opioid treatments. We simply cannot say from such weak evidence whether non-opioid therapies “probably” or “may” be superior to opioids. Such statements in the report are highly irresponsible and ill-supported.

* * *

Research Gaps

"It is important for future studies on opioids to evaluate longer-term outcomes, including long-term use and potentially associated harms (e.g., opioid use disorder, overdose, impaired social and emotional cognition, and workforce nonparticipation). Well-designed clinical registries that prospectively enroll patients with acute pain prescribed and not prescribed opioids could complement randomized trials evaluating long-term outcomes."

My Response:

Wording of this text reflects an uncritical anti-opioid bias and assumption of harms that is unsupported by medical literature. It also ignores a reality of randomized controlled trials involving a placebo arm. As we are informed by a Cochrane Review, the relative paucity of long-term trials on opioid effectiveness is for the most part a research artifact: many pain patients placed on placebos drop out of conventional randomized trials. To obtain a more balanced trial, it may be necessary to instead perform "enriched enrollment" trials.

See

Baraa O. Tayeb, Ana E. Barreiro, Ylsabyth S Bradshaw, Kenneth K H Chui, Daniel B Carr, "Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain: Adequate or Inadequate?" *Pain Medicine*, Volume 17, Issue 11, 1 November 2016, Pages 2036–2046.
https://academic.oup.com/painmedicine/article/17/11/2036/2447887

5. Comments on the Discussion section of the draft report

None Offered

6. Comments on the References section of the draft report.

In the report section on Opioid Therapy, the AHRQ team missed or perhaps deliberately ignored a landmark study which contradicts their conclusions concerning the centrality of medical opioids in our public health crisis:

Eric C. Sun, Beth D. Darnall, Laurence C. Baker, Sean Mackey, "Incidence of and Risk Factors for Chronic Opioid Use Among Opioid-Naive Patients in the Postoperative Period", JAMA Internal Medicine 2016;176(9):1286-1293.

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2532789

In another of the references, AHRQ writers chose to emphasize the appearance of a dose-dependent relationship between initial opioid use in acute pain and long-term use in chronic pain. They ignored the absolute numbers of patients in which such a relationship was inferred. Likewise, they jumped to conclusions on cause and effect that were unsupported by the data offered.

See

Gabriel A Brat, Denis Agniel, Andrew Beam, Brian Yorkgitis, Mark Bicket, Mark Homer, Kathe P Fox, Daniel B Knecht, Cheryl N McMahill-Walraven, Nathan Palmer, Isaac Kohane, "Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study"*, BMJ* 2018;360:j5790 *http://www.bmj.com/content/360/bmj.j5790.long*

Although the draft report of the HHS Task Force on Pain Management is referenced, its central conclusion that there is no one-size-fits-all pain patient or treatment plan is conveniently ignored.

Also of concern is the inclusion of six references in which Dr Roger Chou is a co-author. Dr Chou has been centrally involved in multiple AHRQ systematic outcome reviews on treatment of pain, as well as being a principal author of the 2016 CDC Guidelines. He has a record of publications co-authored with key figures and founders of the organization "PROP - Physicians for Responsible Opioid Prescribing." PROP and its members have a long history of anti-opioid advocacy and financial self-interest.

If Dr Chou has been a contributor to the current AHRQ report, then I must strongly demand that he recuse himself from any further review of this document, on grounds of professional conflict of interest. His first instinct must be to defend his own body of work, regardless of the consequences to patients or colleagues.

7. Comments on the Abbreviations and Acronyms section of the draft report

None offered

8. Comments on the Appendixes of the draft report.

None Offered

9. General comments on the draft report.

I write and speak as a technically trained non-physician patient advocate for people with chronic pain, with 24 years experience in this field. I have published over 100 papers, articles, public addresses and conference proceedings in a mix of mainstream medical journals and mass media. I sit as an invited participant on two editorial boards, neither of which has reviewed or approved the remarks below.

Overall Observations by the Author:

Use of the terms “are probably” or “might be” to describe outcomes of trials suggests to me a systemic anti-opioid bias throughout the report and its appendices. When reported details of the referenced trials are examined with care, we find no protocols, methods, or analysis to establish either probability or possibility of the claimed outcomes, from the original sources.

What we find instead are assessments of “medical evidence weak” or “no evidence”, describing the majority of 151 randomized controlled trials summarized in the report (from more than 20,000 candidate trials initially flagged from medical literature database search, of which 1871 were subjected to full text review).

It must be assumed that such terms were introduced as opinions by the AHRQ report writers, or peer reviewers, or both. Given that the draft report fails to identify names and affiliations of the writers, it becomes practically impossible to research their professional publications for known biases and predispositions. Likewise important is that there is no evidence of participation in this review process by any patient advocate or representative.

A major shortcoming of this report is its failure to adequately acknowledge confounds in the medical literature and in the analysis of the AHRQ writing team, which significantly compromise any ability to generalize results meaningfully in prescription guidelines or policy.

Specifically, there is no mention of the terms “genetic” or “genomic” anywhere in this report. Yet we now know from other sources that there is high variability in individual responses to prescription opioid medications, due to polymorphism in the expression of six liver enzymes which mediate opioid (and 90% of other medications) metabolism. This medical reality is plausibly a major underlying reason why no currently available patient profiling instrument has demonstrated reliable prediction accuracy for risk of dependence, tolerance, addiction or mortality in medical patients managed on opioid therapy. Lack of such instruments is acknowledged in the report, but no explanation for the reasons associated therewith is offered.

The practical impact of natural patient metabolic variability is that it is literally impossible to generalize conclusions concerning opioid safety or effectiveness, based on any fixed dose or duration criteria. As acknowledged by both the May 2019 report of the HHS Interagency Task Force on Pain Management, and the American Medical Association in its June 2020 comments to a CDC Call for Stakeholder Comment in the Federal Register, there can be no one-size-fits-all patient or therapy plan. Trying to generalize a single standard of pain care – even for a single disorder – is a fool’s errand and very likely to remain so for the foreseeable future.

A clear implication from HHS and AMA findings current as of September 2020 is that fundamental premises and assumptions embedded in the AHRQ systematic review concerning risks or harms must be withdrawn and reconsidered from the ground up. AMA is now on public record challenging the US CDC to undertake nothing short of an across-the-board repudiation and withdrawal of all legislated hard limits on prescription opioid daily dose or duration. This challenge in effect renders much of the AHRQ outcomes review moot.

Also of concern is the process by which this draft report has been issued. AHRQ has circulated it only to their internally managed email distribution lists, with a review period of 30 days. In an outcomes review of this magnitude, a more appropriate venue would be the US Federal Register, for a period of at least 60 days. However, the draft – if it is issued at all – will require major revision and refocus along lines suggested herein, before any public review is announced.

Section 10. Does this report describe both the problem and the evidence in a way that you could understand?

Although the report describes a problem and reviews evidence, its conclusions are biased and substantially divorced from the many confounds revealed in the trials that it purports to review and synthesize.

11. Did you find this report unnecessarily difficult to read?

No comments offered

12. Could you find and understand the results and conclusions?

No comments offered

Methodological Errors in “Treatments for Acute Pain – A Systematic Review” (AHRQ)

Richard A Lawhern PhD

January 2021

Abstract:

This paper expands on comments by the author, offered to a September 2020 circulated draft of Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review 240, titled “Treatments for Acute Pain: A Systematic Review” **[Ref 1, 2].** Author’s original comments to the draft were transmitted online to AHRQ and by email to the Director and senior staff of the Agency. This updated communication presents an evidentiary basis for a mandatory and substantial revision of Comparative Effectiveness Review 240 by AHRQ, followed by a window for public comments, before its republication. There is no other recourse to mitigate stigmatizing depictions of patients in pain who require opioid analgesia, as well as misleading and false interpretations of available opioid trials incorporated into the recently published review.

Analysis of Medical Evidence

From the AHRQ Report Structured Abstract: “Meta-analyses were conducted on pharmacologic therapy for dental pain and kidney stone pain, and likelihood of repeat or rescue medication use and adverse events….”

“Results: One hundred eighty-three RCTs on the comparative effectiveness of therapies for acute pain were included. Opioid therapy was probably less effective than nonsteroidal anti-inflammatory drugs (NSAIDs) for surgical dental pain and kidney stones, and might be similarly effective as NSAIDs for low back pain.”

Author’s comments:

Study Design [Ref 3, 4]

In meta-analyses, mean changes from baseline to post-treatment on pain measures are pooled for the opioid and comparator, from which pooled opioid–comparator group differences are derived.

Randomized controlled trials (RCTs) and meta-analyses measure central tendency, with a core assumption and necessary pre-condition being normal distribution (e.g., the "bell-shaped curve") in treatment/comparator/placebo response.

Analgesic response in chronic pain patients shows bimodal distribution with pain reduction either substantial or near-absent/absent. Bimodal distribution in opioid response appears within 2-4 weeks of randomization and treatment initiation**. [Ref 3]** A clinical population with bimodal distribution in treatment response violates the core assumption of normal distribution in RCTs and meta-analyses.

Meta-analyses and systematic reviews, when appropriately used, are powerful tools for understanding efficacy and safety in many areas of medicine. However, few understand that they are not useful in analgesic response. With meta-analyses and systematic reviews, the authors decide what is "evidence." Roger Chou MD was a lead author of the 2016 CDC Guideline and its derivative systematic review – a document considered by many patients and medical professionals to be the exemplar of conclusions based on evidence selected and defined with prejudicial intent.

The conclusions of the December 2020 AHRQ review are not helpful to clinicians treating pain patients. This Review should be disqualified from incorporation in ongoing efforts by the CDC to expand and revise its 2016 guidelines for prescription of opioids to adults with chronic non-cancer pain.

Opioid Selection [Ref 6-8]

Excluding (1) trials in acute renal colic pain with parenteral delivery of opioid and nonopioid, and (2) trials comparing opioid agonists to multimodal (e.g., tapentadol) or partial agonist (e.g., buprenorphine) opioids, 47 trials reported in this review compared opioids to NSAIDs or acetaminophen, with codeine or tramadol as the selected opioid:

All oral opioid vs NSAIDs or acetaminophen comparisons: 38 of 47 trials (80.8%)

Acute post-operative pain: 5 of 11 trials (45.5%)

Acute low back, musculoskeletal, and dental pain: 33 of 36 trials (91.6%)

Thus, in trials comparing opioids to NSAIDs or acetaminophen (excluding parenteral delivery), the selected opioid was codeine or tramadol in 80.8% of trials overall, and in 91.6% of acute low back, musculoskeletal, and dental pain trials. There are several implications in this selection:

- Codeine and tramadol are both weak opioid analgesics. Both require hepatic enzymatic conversion to an active analgesic metabolite. A significant proportion of the patient population possesses a genetic variation of cytochrome 2D6 that causes polymorphism. Consequently, these individuals poorly convert codeine or tramadol, and experience side effects rather than analgesia. For this reason, codeine has fallen into relative disuse in pain management practice.

- Genetic variation in CYP450 expression alters opioid pharmacokinetics and may contribute to bimodal distribution in opioid response, along with pharmacodynamic variation and other factors.

- Codeine and tramadol account for most (80.8%) oral opioid comparisons to NSAIDs or acetaminophen, and nearly all (91.6%) in acute low back, musculoskeletal, and dental pain. This needs to be stated clearly in the report, perhaps in this form:

"Weak Prodrug Opioids Accounted for >80% of Oral Opioid Comparisons to NSAIDs or Acetaminophen overall, and 91.6% in Acute Low Back, MSK and Dental Pain."

- Obvious, yet repeatedly ignored in this and other AHRQ reviews authored by Chou et al., is that meta-analyses are unsuited for evaluating the efficacy of opioids, which require a tailored approach to balance response and side effects.

Additional Discussion

From the AHRQ Report Background:

"The key decisional dilemma in acute pain management involves selection of interventions to provide adequate pain relief, in order to improve quality of life, improve function, and facilitate recovery, while minimizing adverse effects and avoiding overprescribing of opioids.8 Evidence also suggests that adequate acute pain treatment may mitigate factors that promote the transition to chronic pain.3,9,10 However, shortcomings in acute pain care have been documented.11,12 In addition to the underlying cause of pain, patient factors that impact acute pain management include age, sex, race/ethnicity, pain severity, comorbidities (including mental health and substance use), genetic factors, pregnancy, or breastfeeding status.13-16 Timing of presentation and clinical setting can also influence acute pain management. For example, postoperative pain occurs at a specific point in time and is often managed with multimodal strategies in a monitored setting prior to discharge, whereas in outpatient clinic settings, timing of presentation of acute pain is variable, and assessing treatment response is often not feasible. Additionally, access and care options may vary.2,8 Different acute pain conditions (e.g., musculoskeletal pain, neuropathic pain, or visceral pain) may respond differently to treatments. Therefore, a treatment that is effective for one acute pain condition and patient in a particular setting may not be effective in others." [Reference numbers in the original report]

Author's Comments: It is highly revealing that despite this acknowledgement of the complexities of evaluating pain therapies, the AHRQ authors proceed to merge data of doubtful quality and to generalize their conclusions using terms such as “probably” and “might be”. A section on “Research Gaps” in both the draft and the final report briefly mentions a wide range of confounding factors – which are then ignored as the authors race to their pre-ordained conclusions, attempting to disqualify prescription opioid analgesics from use in acute pain. A far more supportable conclusion from this review is that the present state of medical literature lacks sufficient rigor and repeatability to arrive at any conclusions at all concerning best practices.

In this context, the following observations apply:

1. While the investigators’ desire to limit the scope of their “comprehensive review” is understandable, exclusion of German language studies from the AHRQ review is a significant omission. The German government has invested major resources in evaluating opioid and non-opioid therapies.

2. Ketorolac has strong analgesic potency that may be predicted to surpass that of Codeine or Tramadol in four comparative trials reported. Such a match-up seems inappropriate.

3. Due to risks of GI toxicity, use of Ketorolac for longer than 6 days is contra-indicated on the FDA information label for this medication. How these patients with persistent pain should be managed is unclear. This significant limitation in "real-world" clinical practice is obscured by meta-analyses and similar big-data methods, and should be highlighted as a basis for disqualifying the selected studies.

4. Likewise, all NSAIDs, even with acute use, are associated with potentially serious GI toxicity. Such side effects are nowhere discussed in the published Review.

   For acute post-operative pain, it is unclear from the AHRQ report how or in what sense the performance of opioids is “no better” than that of NSAIDs. The Review notes an abundance of limitations which are then ignored in its conclusions:

   -- “Evidence on how comparative effectiveness and harms of opioid therapy for postoperative pain vary according to patient and prescribing factors was lacking. The number of trials was small for each comparison and most trials had small sample sizes... No study [was] conducted within-study or across-study evaluations of subgroup effects. Evidence was too limited to determine effects of different opioid doses (converted into morphine milligram equivalents) on comparative effectiveness and harms. The trials did not evaluate how effectiveness varied in subgroups defined according to the amount of opioid used."

Also of note, no trial permitted opioid refills despite study durations up 15 days. This omission increases the potential of poorly or uncontrolled pain at final assessment, improperly biasing conclusions toward opioids being ineffective.

5. Two large retrospective studies are interpreted in the Review to claim that compared to persons not prescribed opioids, opioids for acute post-op pain impose "risks" of long-term opioid use – in one study 7.7% of patients at 1-year follow-up. The other study described the proportion of patients with opioid fills 90 to 180 days post-surgery (7.1%); opioid use lasting 90+ days in the period from 180 days post-surgery (1.0%) and either 10 or more opioid fills or 120 or more days' supply (0.46%). As noted in the Review, such studies cannot ***"**adjust for factors not available in administrative claims, such as pain severity, functional status, level of psychiatric distress, or other measures of clinical status following surgery*." [*emphasis* by the author] These omissions are essentially disqualifying in the context of the AHRQ Comparative Outcomes Review

6. That retrospective evidence was allowed for opioid harms, and disallowed for opioid benefits, is telling. Post-surgical pain is a prevalent origin of chronic, life-altering pain. The discourse in this review stigmatizes patients experiencing persistent pain who require opioid analgesia. The Review section using retrospective data needs to be deleted.

7. The author suggests that post-operative use of opioids at one year is ***not*** a "risk", but rather an "incidence" related to emergence of chronic pain from failed procedures. Long-term pain is often a consequence of poor analgesic control in the peri-operative or acute post-operative setting. In most patients, pain that becomes chronic is perpetuated by CNS alteration, divorced from peripheral nociceptive input from the original tissue injury. This makes prevention of chronic pain through aggressive analgesic control -- which may include opioids -- an imperative of practice.

Chronic pain resulting from inadequate control of acute/post-acute pain is no less iatrogenic than recklessly exaggerated claims of opioid use disorder following prescribed opioids. For individuals with OUD, efforts are made to ease access to opioid agonist maintenance. By sharp contrast, patients with chronic pain are punished for needing opioid pain control in the hostile regulatory environment fostered by CDC's 2016 guideline on opioid prescribing in adults with chronic non-cancer pain.

Contrary to the insinuations of the AHRQ report authors, prescription opioid analgesics *do not* "cause" addiction in patients who are not already predisposed by other factors. **[Ref 4]** When pain in the peri-operative period is sufficient to require opioid analgesia, it is to be expected that a diminishing proportion of patients will need opioid pain control over time, with a smaller subgroup in whom pain has become chronic being continued on opioids as the only therapeutic measure that provides sufficient pain management. This reality of practice is ignored – or perhaps deliberately suppressed – in the AHRQ comparative review.

8. Genetic polymorphism may be a sufficiently strong effect to account for the bimodal structure of patient responses to opioids. It is at least plausible that poor metabolizers and hyper-metabolizers can explain the low effectiveness of low-dose opioids in millions of patients, while "normal" metabolizers experience significantly better outcomes. Although the AHRQ authors reference two papers that address these effects, they exclude any serious discussion of findings in those papers. Other papers they do not reference are also pertinent. **[Ref 5 - Ref 9]**

Conclusions

The published version of AHRQ Comparative Effectiveness Review 240 incorporates multiple and disabling errors of analytic methodology. Arguably, the authors of this review have also cherry-picked and misinterpreted data in a manner that reflects a profound and unjustified bias against treatment of either acute or chronic pain by means of prescription opioids. For these reasons, the report must be withdrawn immediately for an independent review by professionals qualified in statistical methods and epidemiology. Given the checkered history of this document, representation of patients and their advocates should be considered mandatory. The revised AHRQ Review should then be submitted to the Federal Register for a 60-day public review and comment period, followed by a published AHRQ summary of comments.

References

[Ref 1] Roger Chou, Jesse Wagner, Azrah Y Ahmed, et al, "Treatments for Acute Pain: A Systematic Review", Agency for Healthcare Research and Quality, AHRQ Publication No. 20(21)-EHC006, December 2020.

[**Ref 2]** Richard A. Lawhern, PhD., AHRQ correspondence by email, subject "Courtesy Copy – Comments Submitted to AHRQ", September 13, 2020, with attachment.

[Ref 3] Haeuser W, Toelle TR, "Meta-analyses of pain studies: what we have learned," *Best Practice & Research Clinical Rheumatology* (2015), http://dx.doi.org/10.1016/j.berh.2015.04.021

Abstract

> Meta-analysis is a statistical procedure that integrates the results of at least two independent studies. The biggest threats to meta-analysis are publication bias due to missing studies with negative results and low-quality evidence due to methodological limitations imposed by included studies. Tools to improve the quality of meta-analysis have been developed by the Cochrane Collaboration and by the Preferred Reporting Items for Systematic Re-views and Meta-Analyses (PRISMA). Meta-analyses of trials have demonstrated that pain responses in patients with chronic pain, following treatment, are not normally distributed but have a bimodal distribution with the majority of patients having either very little or very good pain relief. The benefit can be detected within 2-4 weeks following drug administration. Further, the efficacy of drug and physical treatments is hampered by high placebo response rates, with modest average benefits with active treatments over placebo in both parallel and crossover design trials.

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[Ref 8] Howard S Smith, MD, “Opiod Metabolism” *Mayo Clinic Proceedings,* 2009 Jul; 84(7): 613–624. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704133/

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[Ref 9] Bhushan A Kapoor, Prateek Lala, Julie L.V. Shaw, “Pharmacogenics and Chronic Pain Management” *Clinical Biochemistry,* 2014. http://dx.doi.org/10.2016/j.clinbiochem.2014.05.065

Author Note: Richard A Lawhern PhD is a technically trained non-physician patient advocate, with 24 years experience as a medical literature analyst and forum moderator for social media and peer-to-peer support groups for chronic pain patients and care providers. He has published over 100 papers, articles, and public addresses in a mixture of medical journals and mass media, some of them co-authored with medical professionals.

This paper has benefitted from research assistance provided by Mark Edmond Rose, author of “Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts”, *Pain Medicine*, Volume 19, Issue 4, April 2018, Pages 793–807, https://doi.org/10.1093/pm/pnx048 . However, any remaining errors herein are those of the author.

From: Rhonda Lewis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 10:55:15 PM

I am writing in response to your Updated Draft Opioid Prescribing Guideline. I am concerned about the lack of consideration for different diseases where pain is one of the symptoms. The current guideline attempts to suggest all diseases/illnesses for pain be treated the same when each disease/individual is different. As a person born with a rare genetic disease (XLH), I have spent a lifetime in treatment of this disease. Symptoms include fractures, osteoarthritis, bone demineralization, muscle wasting, enthesopathy, tendon & ligament calcification, dental issues. I have had 11 surgeries related to my disease, with more in my future. I have mobility issues related to this and am always in pain. I have been treated with opioid's on & off my whole life. I have tried all alternative methods of treatments, injections, anti-inflammatories, portable ten's unit, heat/cold, physical therapy, different non narcotic therapies including LDN, lidocaine patches, CBD, acupuncture. All with limited success. Unfortunately, opioid medications have helped the most for keeping me mobile and working. Since your 2016 guidelines were put into effect, I have had more trouble getting opioid medications when they were needed, causing missed work and inability to build strength through exercise and physical therapy. I am hearing the same thing from others within the XLH network. Your guidelines are creating a lot of unnecessary suffering. As a suggestion, you should revamp the pain scale as it doesn't accurately reflect pain. I also suggest maybe people who do need to use opioid medication for a chronic disease use a fitbit or something like that to help hold them accountable and show they do increase a person's activity level. On opioids my activity level is approx. 4 miles a day. On LDN/Tylenol it is approx. 1.5 mi.
Thank you for your time.

Sincerely,
Rhonda J Lewis
Rhonda_lewisf@hotmail.com

From: Rima McFarlane
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 9:27:54 PM

PLEASE help and NOT hurt Chronic pain patients. WE are SUFFERING and WE use the medicines the correct way. So we can have
somewhat of a life. Without the help Pain Doctors and Pain Medicine there are of people suffering. Some who can't get any and those
who can't get enough to lesson our pain. Our doctors are the ones who should be able to make these decisions. THEY are the ones who
ACTUALLY see us. There are a lot of Pain conditions and most pain Patients have more than one. I was in terrible pain before I found a
doctor that actually sent me to Pain management. It is a very sad world when you go to a doctor and the first words out of there mouths
is "I DON'T TREAT PAIN". So why are they doctors?? Also the other things they actually ask us is "Have you ever tried OTC medicine?"
Do you even think we haven't?? Doctors who no longer treat pain are totally useless. It is YOU who are causing people so much pain and heartache.
What about our families who have to WATCH us suffer, our children our parents?? It is not a life we want for them. One other thing, WHY make us go
to the pain doctor EVERY MONTH? That causes more pain because some of us have hard times getting to them. Not to mention the added cost
to us. Even if we have insurance it really adds up, there is no reason why we can't at least every three months. I would think some of you know
people who are have Chronic pain, probably for years. Please be kind and think of the people who are hurting terribly. We are all different and have
different pain conditions. It is not our fought, we did not ask for this kind of a very sad life. WE have tried OTHER medicines, therapies, without relief.
PLEASE LET OUR PAIN DOCTORS DO THEIR JOBS AND TREAT US WITH WHAT THEY KNOW WILL HELP!!
WE ARE NOT DOING ANYTHING WRONG!! WE ARE SUFFERING!!

PLEASE HELP!!

Rima McFarlane
Middletown Va

From: Rob Nelson
To: NCIPCBSC (CDC)
Subject: Chronic Patient
Date: Friday, July 23, 2021 12:52:48 PM

I am a care giver for my wife, who is a Chronic Pain Patient.

It is quite disheartening to follow her treatment path. As if her conditions don't cause her terrible pain, stress etc. She/We also have to deal with being denied medication on 0 basis by either pharmacy or Insurance even sometimes both.

Her Primary care physician at this time is very attentive & aware of Adhesive Arachnoiditis, of which she suffers.

He has prescribed her a certain regimen to follow, per her examination as well as very detailed records, however she has been UNABLE to get the scripts filled without grief from any other party involved. The State sponsored insurers actually sent a denial letter on the basis that My wife is not in medical need for such medication. One look into her file will prove them to be negligent.

That's just the current events.

Thank You
Robert Nelson
603-921-7825

From: Robert Pierce
To: NCIPCBSC (CDC)
Subject: Re: Opiate guidelines ...
Date: Wednesday, July 21, 2021 9:34:05 PM

To whom it may concern:

I just wanted to weigh in on your deliberations regarding the forthcoming new opiate guidelines for physicians. As a 5 ½ year sufferer of "Intercostal Neuralgia" (IN), please bear in mind that many of us with IN have severe chronic nerve pain and after multiple surgeries, procedures and injections, the only thing that helps us get through the day (and sometimes evenings) is the careful use of opioids. In fact, they are a God-send to many. There are far too many physicians out there (including pain management folks) who don't appreciate the very real pain that our condition elicits. If you take a few moments to peruse the Intercostal Neuralgia room on Facebook, you will be able to appreciate how many people (from around the world) suffer from this painful and often puzzling condition.

I also invite you to peruse this article from popular, *NY Times* best-selling author and lecturer, Dennis Prager, with regard to the suicide of his stepson's father. His "not being believed" by the medical establishment led to his being denied the continued, highly-scrutinized use of opioids. Sadly, it took his autopsy to prove the rectitude of his assertions.

Thank you for your attention.

Sincerely,

Robert Pierce
www.robertpierce.com

From: Rebecca Sirmons
To: NCIPCBSC (CDC)
Subject: CDC Opioid Prescribing Guideline revision
Date: Thursday, July 22, 2021 5:41:23 PM

To whom this may concern, Due to the “opiate crises” Many chronic pain patient’s as myself have been tapered down ,mistreated or abandoned or have been taken off pain medications because CDC guidelines. Doctors, pharmacies and insurance companies treat us terribly. I have neck ,back disorders ,nerve disorder ,muscle spasms Fibromyalgia and other disorders which causes chronic pain. My life has been turned upside down ever since the Opiate crisis arrived. I’m a mother of 2 and was super mom. due to false accusations about the opiate crisis I am suffering in chronic pain daily. I go from my bed to couch and am basically bed written. I barely sleep and on verge of another breakdown. I take my medications as prescribed ,never failed a urine sample test and have followed doctors orders but suffering because I’m on low doses of medications and have been denied medications from insurance. Low doses barely touch my pain. My children don’t have a mother right now. Please re advice Opioid prescribing. Please don’t punish chronic pain patients we don’t deserve this. I hope and pray there is a change,Change for the good.

Thank you,

Sent from my iPhone

From: rockstarinart@gmail.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 5:29:27 AM

I am a gulf War veteran. I am actually about to go into have a second lamanectomy done today. The first was done at the VA 10 years ago and nobody scheduled me for p.t. and when I told them I was worse three Mos. Later they said oh well, now it's too late. I have on top of that fibromyalgia, bilateral neuropathy, sciatic scar tissue, I have to self cath, I have 3 plates in my neck, I hVe had left killer replacement, I have osteoarthritis, ploylyalgia rheumatic, carpal tunnel in both wrists and I get severe migraines. I have major depressive disorder and IBS, COPD, and sleep apnea. For years the VA was controlling my pain with Ms continued 15 MG twice a day and Norco 10 MG for breakout pain up to 4 a day. I was not abusing them and never did. Iwas taking them as prescribed. I do not drink and did not use Marijuana although I really could not see why but after the military I learned to follow orders. I so do not want to die young. But in 2012 I was cut off completely by the VA. I was given no alternative so obviously my depression and my life got quite terrible. Some how I was able to hang on to my sanity but I barely sleep and I make use of ice packs and heating pads but living in the Midwest as I do it is very hard when it rains or snow. When I have had surgery the options allow me to sleep and rest but I should not have to have surgery just to get some relief from the .any ailments I have and that is not my intention. But it is a reminder of how different life was before.

I have also been very bitter and have mood swings and attempted suicide after breaking my shoulder on ice. I hBe been discriminated against many times. I am a walking reminder of what could happen so I see the fear in people's eyes. That is when I can use my walker. Most days it's the scooter if I can even leave my house. When I used to get opiates I would fish and do my AR r and some online work. I am a writer too but now I just sit in bed watching TV. I try to do p.t. but it makes me worse.

My neurologist suggested ketamine injections and botkx for the migraines. I have not start r d botox but nobody will pay for ketamine and at 500 per injection a d 300 for a consultation and another 300 for therapy that is a joke.

Soon I am expecting a large back pay check and I am seriously thinking of moving to a country where ny rights as a person will be respected and ny pain will be controlled. If people did not take them as prescribed then that is not ny fault but I pay for it every day and I am disgusted with the cou try I went to war flusing my life down the toilet as if I am a nobody.

This morning I asked ny medicaId doc office if I could u kd get some stool softeners and because I was given Norco before the surgery the nurse said if you are unwilling to work than that's what you get. You know opiates make you constipated so eat more greens and drink more water. The only reason why I have not left or committed suicide is because I love my grandkids. But if I can't even play with them than what is the point.

From: Robin Stitt
To: NCIPCBSC (CDC)
Subject: Prohibition of Opioids in treatment of pain
Date: Monday, July 19, 2021 11:11:21 AM

I am one of the victims of the Anti-opioid movement which has been in place in the last several years.
For many years I was able to take a Tramadol 50mg every day for Arthritis, Bulging Spinal Discs with Neuropathy, and a Benzodiazepine daily for Anxiety Disorder, then in later period, Ambien for persistent Insomnia.
These conditions resulted from a serious car accident in my teenage years, then a lifetime of heavy work as an RN, and shift work disturbing sleep, and stresses of being a single mother raising children and working fulltime.
There was NEVER any risk that I would abuse or overdose with the use of this med regime. I never took more than prescribed or abused in any way. Yet, because of the pressure being put on Physicians by the CDC guidelines and the scrutiny of Doctors and Pharmacies by the DEA, I was suddenly treated like a drug seeking addict and force tapered off of these life- improving meds.

I was placed on Antidepressants and Psych meds and suffered severe reactions to these. I went 2 weeks without sleep. I was fearful to go to bed at night because of the torture of lying awake in pain, and experience the horrible anxiety attacks which no one should ever have to go through.

I was mercifully allowed to resume the sleep med, or I don't think I would have survived. I have to treat myself using large quantities of OTC meds, which are less helpful and more harmful to health, plus CBD and other Homeopathics.

My experience is not unique as many, many people have been forced to go through this, and nothing has been done to permit Drs and Pharmacies to get back to treating patients with the medications medical science has provided.

It is well known now, that prescription meds are not the cause of the increase in overdoses, and that overdoses are caused by polysubstances and/or illegally obtained substances. Yet the prescription pain meds, and now including Benzodiazepines, continue to be blamed.

The overreach of the DEA has to be restrained. Unless the goal is to perpetuate human suffering which could be relieved, (such as from trauma or surgeries,) or as many feel, to eliminate the disabled (from chronic painful conditions,) the mayhem that has resulted from the attempted prohibition of compassionate pain treatment, needs to end.

From: Robert Vangelisti
To: NCIPCBSC (CDC)
Subject: Pain
Date: Monday, July 19, 2021 4:11:21 PM

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72 years old disabled vet. In 1968 for degenerative bone disease. My life is nonexistent. The past 5 years I haven't left my home except to go to the store and doctors. The USA is life liberty and the pursuit of happiness???????? Happiness is not being in incurable pain with the doctors saying I'm sorry I can't do anything because I'll lose my license. The DEA will take it away.

Sent from my iPhone

From: Ronna Watson
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:57:02 AM

The proposed new guidelines are little more than a few words changed here and there.
The 2016 guidelines were put together with erroneous data and the CDC lost my respect there and then. I used to teach nurse practitioner students and the CDC was a sacred source. No more. I am extremely saddened, and angry that you have not sought to take this opportunity to correct a grave wrong.
As the CDC said, the guidelines were misapplied. That is an understatement and a little too late. Laws have been put in place to allow legislators to tie doctors hands when trying to help their patients. Doctors have been threatened with loss of license and loss of jobs, and even prosecution, just for trying to take care of patients.
Patients have been harmed. Harmed. Whatever happened to, " first do no harm?" Patients with chronic pain, just trying to continue working, were appropriately using medication.
Patients in severe pain have committed suicide.
Some patients have just lost all ability to function.
Patients, and the vast majority of doctors never were the problem. The percentage of patients becoming addicts after surgery were in the single digits. People who are inclined to abuse substances will always find something to abuse, like alcohol, which is usually where they start. We do not treat people who drink recreationally, the way we treat patients in pain. There is no good reason for depriving patients pain medication. These patients are not the problem. They are the victims of this egregious assault.
Patients have been stigmatized. We have been treated with suspicion and treated like criminals.
I was in the hospital two weeks ago in horrible pain. I was offered a one time dose of toradol, 15 mg. That dosage is laughable for the kind of pain I was experiencing. I didn't eat or sleep for the 4 days that I was there. That is criminal! What did I do to deserve that neglect? People cannot heal without sleep. People in pain cannot sleep.
I am afraid to have surgery. I keep hearing of patients being released after surgery on tylenol! Why? Why are you punishing innocent people?
Pharmacists should not be able to refuse to fill pain meds. I could give you many examples of situations where post op patients couldn't get their pain meds filled!
There is a place for treatment with narcotics. As long as patients are properly screened, addiction is not really a problem.
You have created a monstrous problem for patients and doctors.
This tracking system that allows any doctor to see what pain medications someone may have taken is stigmatizing and a violation of HIPPA.
As a chronic pain patient, new doctors often think you are going to ask them for pain medication and often won't accept you as a patient, particularly pain doctors who know they nothing to offer a patient with fibromyalgia or interstitial cystitis, except narcotics. Let me say that as a patient with interstitial cystitis, it has been compared to the same pain as bladder cancer but the difference is, cancer patients can be treated. I have to live with this pain much longer than a cancer patient. It is cruel and inhumane.
Has this war on drugs worked? No! More people are overdosing than ever before in spite of this horrific act of depriving legitimate pain patients a life worth living.
When it became evident that antibiotics were being overused, creating resistant bacteria, doctors were made aware and they started being more vigilant about their prescribing. They did not deny patients with infections antibiotics. Why weren't pain medications treated the same way?
Doctors are smart. They go to school for a long time to learn how to take care of patients. They know how to critically think and I have never personally known a doctor to overprescribe. Those who do are few and far between. These guidelines treat doctors like they cannot think for themselves. Rigid guidelines are harmful.
You owe it to us to turn things around. You must right this wrong.
Please, I beg you; go big. It's not right.
Ronna Watson

Sent from my iPhone

From: rhonda simmons
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:46:37 PM

Greetings,

Since the 2016 opioid regulations your agency set forth I've gone from a productive member of society working anywhere between 60-80 hours a week as a welder to nothing. I was on a strict regimen of one 10mm hydrocodone four x daily. I was able to stand and walk in steel toed boots on concrete floors for the 60-80 hour weeks besides that I was able to go places with my friends and children. But thanks to the CDC recommendations I was taken off the only thing that helped. I have scoliosis (double curve), multiple slipped disc, degenerative disc disease, pinched nerves causing pain in my leg from sciatic nerve also I have no cartilage in either of my knees. Now I'm unable to work because the pain is so intense that I can't stand long enough to work or enjoy any kind of activities or even drive. I sit at home and waste away now we can add depression and anxiety to my list of ailments. I want to thank each and every member of the CDC who had anything to do with these recommendations. It has truly ruined my life. And by the way I was on that dosage for 11 years and once cut off I had no withdrawals what so ever the only thing I had was the return of the severe pain from my hips to my knees.

Your agency needs to rethink what you've done to honest hard working people and their quality of life. I understand there are addicts who misuse anything they can find eg: gas,butane, shaving creams, paint thinner what ever the ingredients people are going to find a way to abuse it. It's not legitimate pain medicine fueling this epidemic it's the fentynol that is in drugs that are killing people. If legitimate pain patients were left on their medicine and not cut off from doctors then they wouldn't be going to the streets to find their pain relief. More people medically prescribed = less people on the streets looking for relief = less people dying. Pain patients need to sue your agency for the pain and suffering you have inflicted on us. My situation : I can't work now and I've sold almost everything I've ever owned to semi stay afloat. Utility bills still come in even if you can't work.

Sincerely
Rhonda Y Simmons

Sent from Yahoo Mail on Android

From: RB
To: NCIPCBSC (CDC)
Subject: CDC guideline revisions
Date: Wednesday, July 21, 2021 2:03:20 PM

The new and continued guidelines for prescribing pain medication for chronic pain patients, has all but crippled me and has severely limited my doctor's ability to properly control my pain levels.

I have been sharply "tapered" on the strength and amount of pain meds my doctor can prescribe for me. And he is unable to prescribe in accordance with my pain levels, but for the guidelines that the CDC has dictated he must follow. It does not matter what my pain levels are. If not controlled by the lowered dose, then his hands are tied and I am going to suffer. He has told me to my face..bluntly and directly, that he is not losing his license for anyone. When I expressed my hope for change with the new congressional legislation for prescribing for chronic pain patients, now happening in Rhode Island...my doctor told me "then you need to move there". I found this very disheartening and so against the healing premise that medical personnel have promised to uphold.

Additionally, I have been denied the filling of my legitimate and legal prescription from my pain doctor when presented at my local pharmacy due to them stating that they have already met their allowed quota of narcotic to non-narcotic ratio of dispensing for that period. I have also been denied when the pharmacist did not feel my condition warranted a narcotic for pain relief. I have multiple painful medical conditions and have been under a doctors care for my issues since 1998.

I also find that HIPPA laws are all but non-existent when it comes to pain patients. The pharmacist is asking for my medical information. The government is looking at my personal files without my permission. I am being medicated by the CDC...not my qualified medical doctor.

The insurance company is also dictating what narcotic meds they will and will not cover merely based on government interference. Additionally, my pain meds used to be a "tier 2" coverage and were relatively readonably priced. Now they are a "tier 4" and the prices have increased by as much as 200% or more.

It seems that my medical care has become the business of any and everyone who has an opinion about the direction in which the "war on drugs" needs to go. The doctors are no longer assessing the patient and prescribing after close examination of the in person being. We are being medicated by "Big Brother" and by people who have never seen me, may not even have a medical license and who have confused the chronic pain patient with the addict.

The addict and the pain patient are two different patients. The addict has a mental health issue. The chronic pain patient has a physiological condition. No other physiological illness is regulated by senators, insurance companies and other laypeople...so why are we?

Please turn the business of medical treatment of the chronic pain patient back to the trained specialist....and let the sacred patient doctor relationship return to the private one it was and should continue to be.

It may be thought that these new restrictions are the answer to the record high drug abuse problem..but it is not. First of all, you cannot legislate sobriety. No law ever made has made an addict suddenly stop using. These guidelines have only served to hinder and harm the suffering chronic pain patient who can longer obtain their meds and who must now suffer in silence.

Please look at the pain patient as a legitimate patient and let their doctors treat them for their pain, using their educated talents to do so.

Thank you for listening,

Wendy Narum

Sent from AT&T Yahoo Mail on Android

From: Rita
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:19:51 PM

The opioid guidelines are hurting people with legitimate need for pain control and who are not abusing them or taking more than prescribed. I am one of those people. I live with constant arthritis pain that interferes with routine daily tasks. It takes the joy out of life.

Please refrain from punishing those of us who play by the rules because you want to control other people who just want to get high.

From: squeue42
To: NCIPCBSC (CDC)
Subject: CDC Opiate policies
Date: Monday, July 19, 2021 8:06:07 PM

DearCDC: Ever since the crackdown on opiate pain meds, I was made to try many drugs that did not work with bad side effects. Even when I was finally able to go back on oxycodone My dosage is half but I used to get 5 years ago, yet my RA and OA are worse and now I have degenerative disc disease as well. I was completely unable to work or do anything until I did get some of my old prescription back...it is still inadequate, and causes me to not be able to work most kinds of jobs nor more than 4 to 6 hours a day a couple days a week.
I had a full-time professional job when I was receiving 100 mg a day.. Now I have to subsist on $750 SSDI changed to SSI .
When I moved from New Mexico to Colorado it was very difficult to find a new doctor for over a year I had to drive 200 mi over the Rocky mountains to Denver every month. Doctor's here said things like, I refuse to be your legal drug dealer, or we don't prescribe opiates, or said I needed to see a pain doctor.. The only pain doctors that do medication management are in Denver, 4-hour drive away.
My whole life has pain as a backdrop, whereas when I received adequate pain medication, I had a completely normal, enjoyable life. Now, I struggle to not be depressed and complain, before I was a completely happy person!
Not to mention how I can't get things done in a timely manner.
This demonization of opiates is unscientific, and has nothing to do with addiction. Opiates have been used safely for centuries, when taken as directed. Addiction is a completely different problem, And from what I have seen addicts will search out drugs regardless of the source, and ABUSE them to escape from life. I use drugs to be part of life!
I never needed more than my old prescription...nor did I develop tolerance -the drugs always worked even after 6 years at that level.
The fact that you consider doctors' clinical experience and our lived experience not high-level evidence, shows that you have an agenda that has little to do with reality. I believe you have sold out to the addiction business, and the DEA, that needed a new easy target after they lost their War on Weed.
If you want to gain the Publix trust back you are going to have to actually care about the hundreds of thousands of pain patients like myself that believe these policies are akin to genocide. Indeed taking quality of life and the many who have committed suicide due to not being able to get pain relief is the govt not caring about its fiduciary duty to those who put you in the position you're in, pay your salary and benefits... But the influence of special interests has the corrupted the CDC at the top levels. And until the CDC starts listening to the people who their policies affect, it will be an illegitimate government.
Sincerely, S. Quarto
Carbondale, CO

Sent from ProtonMail mobile

From: sbalsamo3235@gmail.com
To: NCIPCBSC (CDC)
Subject: Public Comment
Date: Friday, July 23, 2021 3:28:15 PM

To Whom It May Concern,

I am writing to provide my voice to those speaking out about the damage done by the CDC guidelines. I come with a unique perspective - I have an extremely painful medical condition and yet I don't use opioids. Why? Because they don't work for me. Like many people, during my diagnoses and treatment, I tried a multitude of drugs and drug combinations. Nothing is 100% but I found something that provides some relief. I now speak for others who are having their only opportunity to live lives of some function, capacity and normalcy taken away.

Being in pain all the time is not normal. It shouldn't be treated as such, yet during the entire process of developing the opioid guidelines nobody considered us. There are people for whom opioids are the best available treatment and patient outcomes for stripping these people from their treatment have never been measured. It is likely some retreat, go back to the bed or the sofa or wherever they go that provides comfort, even if psychologically. Others may end up on disability. Some will try street drugs. Some will die by suicide. And it won't have saved a single person.

This epidemic was never about Rx opioids. New data from the CDC shows as much. What is happening to increase OD rates is not an explosion of drug users. It's because while the CDC was torturing patients and destroying doctors, no one was looking at illicit fentanyl. Without attention, it has just continued its upward trajectory which someone with any analytical sense could see. And those with OUD? The CDC let them down too.

The rise in overdoses should never be measured on the backs and bottles of people who take opioids for intractable pain. It should be measured based on the glut of fentanyl and the CDC's lack of action to stop when it all started rolling in. Years ago…per the CDC.

Sally Balsamo

From: Steve Barker
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 7:37:01 PM

To Whom It May Concern.

It has come to my attention that you have arbitrarily decided that pain medications (and particularly opioids) are unnecessary for the treatment of pain. God forbid YOU should need them yourselves. Your uninformed view is reprehensible. Please reconsider your narrow position before the final draft of your recommendations. A combination of minimally invasive techniques i.e. RFA, facet injections, nerve blocks and opioids are the ONLY things that keep me from becoming suicidal due to intractable pain. And I am NOT alone. Let pain management specialists and other physicians involved in the management of pain do their jobs. Don't allow politically motivated phobias and the popular view that people don't really have pain that responds to pharmaceuticals, cloud what should be your courageous judgement re pain management. It is true that opioids have been abused, but DO NOT punish the people with actual, horrible, life-altering pain, along with the weak-minded that misuse them. Please reconsider.

Sincerely,

Stephen Barker, R.T. (R)

Steve Barker
470 669 0759
lightspeedsolar@gmail.com

From:	Sara B
To:	NCIPCBSC (CDC)
Subject:	Comment on Updated Guideline
Date:	Friday, July 23, 2021 11:29:13 AM

The 2016 CDC guidelines were fully embraced by the medical community as if it were law. As the DEA intensified prosecution of physicians, patients were pulled off medications with little to no tapering causing illness and even deaths. People with legitimate pain are not being treated. Suicides are up because for many, living with the pain isn't an option. Children with cancer are denied pain relief. Our dying are refused pain relief. Dignity is no longer an option for anyone who suffers from pain that cannot be eased with a Tylenol or aspirin. The CDC has taken their guidelines to extremes. They have harmed significantly more people than they have helped. Anyone already abusing prescription drugs moved to illegal drug dealers, while the responsible chronic pain patients were left to suffer needlessly. They aren't prisoners of war. They aren't murderers on death row. Yet they are treated as such. They are guilty even before a crime has been committed. People rely on pain relief so they can work, care for their families, clean, bathe, even sit up or simply breathe. We are willingly allowing a large segment of our society to suffer this torture. We don't live in the middle ages, we have pain relief that changes lives for the better yet we are making it nearly impossible for a responsible physician to prescribe it to a law abiding patient. If this was yourself, if you broke your back, had rheumatoid arthritis, bone cancer, M.S. severe degenerate disc disease.. or if perhaps if it was your loved ones, your child or your elderly parent helpless and screaming in pain as you call each doctor with no help in sight. If this were YOU instead of US (the public) perhaps you would rethink these ruthless, draconian guidelines.

Sincerely,

Sara Baskins

803-553-6377

From: Shirley Buck
To: NCIPCBSC (CDC)
Subject: CDC 2016 Guidelines and 90 mme MALFUNCTIONING DISASTER.
Date: Friday, July 23, 2021 3:11:35 PM

Thank you for the opportunity to comment on the above issues. I'll begin with the 90 MME LIMITS! You may have put down as suggestions, however, you all knew very well the suggestions would begin limits for ALL CPP'S. Now given that there is absolutely ZERO SCIENTIFIC SUPPORTING PROOF THAT 90 MMEs should be the highest limit. How do you all look at yourselves in the mirror. Anyone with any medical knowledge knows very well that tolerance and INDIVIDUAL GENETIC METABOLIZING FACTORS prove that a ridiculous one size fits all doesn't work in Healthcare and YOU ALL KNOW THIS. I highly suggest that you remove the 90 mme and allow each physician to treat each patient on an individual basis as required. Do you do this for Radiation or Chemotherapy treatments? Absolutely not, this was only another tactic to torture pain pts more. Many cpps are unable to obtain any help from physicians. THE CPP SUICIDES ARE NOW UP TO 27% AND CLIMBING DAILY NOW. DO YOU EVEN CARE ANYMORE? ILLICIT DRUG OVERCDOSES ARE UP OVER 1,406% WHILE OPIATE PRESCRIPTIONS ARE AT A HISTORICAL LOW. OBVIOUSLY NOT PRESCRIPTION OPIATES.N

Would you want anyone telling your doctor they can't treat you appropriately for something which is completely out of your control absolutely not. I highly recommend to you from speaking with thousands of GPs, IM and pain management physicians that the CDC completely retract the 2016 Severely Medically Inappropriate Malfunctioning and False Guidelines. Possibly have the FDA run this, at least they know what they're doing, especially since a bunch of Rehab/Addiction Psych, PhDs or MDs don't know anywhere near as much as the tens of thousands of pain mgmnt doctors do, that I would challenge you all on.

AMERICANS WILL NOT STOP FIGHTING TO HAVE THEIR RIGHT TO APPROPRIATE PAIN MGMNT TREATMENT THERAPY BACK AS ANY HUMAN BEING SHOULD. I hope you all realize you aren't getting any younger, your one illness or bad accident from being one of us and you should be forced on the same toxic drugs your trying to force us on. OH THAT'S RIGHT YOU WONT PUT YOUR FAMILY MEMBERS ON THE DRUGS YOU PUSH TO PUT US ON. I HOPE YOU NEVER FIND YOURSELVES OR FAMILY IN NEED OF OPIATE PAIN MEDICATIONS.

God Help All Chronic Pain Pts with the group of Addiction doctors, NOT EXPERTS AS THEY SELF PROCLAIM ON THE BOARD TO CONTINUE LIMITING OPIATES. FUNNY HOW NONE OF YOU TREAT CHRONIC PAIN THOUGH.

SINCERELY,

JUST ANOTHER ADDICT AS YOU REFER TO ALL CPPS AS.

"We'll have to let them die off." A.K.

Pop

From: Stephen Chappell
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:44:05 PM

Hi,
My name is Stephen Chappell and I am a chronic pain patient. I am: a Air Force veteran, a retired science teacher with 4 college degrees, married to the same woman for 37 years. I also have 2 daughters and 5 grandkids. I have responsibly used opioid pain meds for the last 7 years through my primary care docs, neurosurgeons, pain docs, podiatrist, and orthopedist. A total of at least 10 different doctors have approved of my use of pain meds. I pay for drug testing 1-2 times a year out of my pocket $150 each. I have signed opioid use agreements with all doctors and taken meds as prescribed. There is no way with current prescription monitoring practices for me to abuse these drugs unless I went to street drugs and I don’t do that.
Why do I use opioids? I have DISH syndrome (Diffuse Idiopathic Skeletal Hyperostosis) which means my body calcifies the connective tissue in and around joints. Our spine has 364 joints. I had to have a c5-c6 discectomy with a Mobi C artificial disc implant. I have also had a L4-L5 laminectomy, removal of bone spurs in both big toes, plantar fasciitis, dysphagia, knee, foot, and wrist pain all due to DISH. All of these conditions cause me continuous pain and the only medication that helps me live and move are opioids. I tried: chiropractic twice a week for 8 years, non-opioid pain meds, and physical therapy, without success. The only thing that provides about a reduction in my pain levels are opioids. They allow me to bend some, move, and live my life independently.

I had one opioid taper back in 2016 by a paranoid nurse pa, it was later reversed by a physician. I was also sent into withdrawal by the same primary care office when my regular physician was out of town, and I ended up in an Er in withdrawal.
Why am I and others being punished for having pain. My doctors agree I benefit from it, I follow all my contracts and take meds as prescribed. I don’t sell my prescriptions or buy them on the street. I have no criminal record, I am a veteran, a retired teacher with a Masters degree, married to the same woman for 37 years, and have 2 daughters and 5 grandkids.
What is criminal about trying to remain a productive contributing member of society?

Sent from my iPhone

From: Sandra Coyle
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 12:45:49 PM

Do not revise this horrible mistake of a guideline that has resulted in the deaths and abandonment of patients with painful conditions!

No matter what our conditions, from cancer to inoperable spinal tumors, we are being accused of having Opioid Use Disorder, being denied pain treatment, our doctors are being harassed by medical boards, patients with pain continue to suffer from the undertreatment of pain and the stigma of having pain. Please rescind, apologize and let doctors continue to treat us, without the threat of prison!

The opioid epidemic is now and was before, fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin, methamphetamine and cocaine.

More than 35 states and many health insurers, pharmacies, and pharmacy benefit managers made the CDC’s 2016 arbitrary dose and quantity thresholds hard law and inflexible policies!

Stope the abuse of patients with painful conditions and their doctors now! The solution is in your hands!

Sandy Coyle

From: Shara Danziger
To: NCIPCBSC (CDC)
Subject: CDC Opioid Prescribing Guidelines Revision
Date: Wednesday, July 21, 2021 9:45:13 AM

I am sending this email to you as a chronic pain patient. My livelihood is dependent on my ability to go to work. Without my opioid medication I would be unable to function as the pain would be overwhelming. I was forced tapered from my original dose and that proved to be a terrible experience. I am concerned that at any moment my pain specialist could cut off my medication without warning. This is always a real possibility for anyone on long term opioid medication. The facts are clear that overdoses in this country are due to illegal fentanyl and heroine on the streets. It is NOT from prescription opioids. Moreover studies have shown that chronic pain patients are extremely unlikely to become addicted. As a result of these harmful guidelines chronic pain patients are made out to be drug-seeking criminals. What other patients have to prove with a urine test and medication counts that they are taking their meds? It is degrading and insulting. Chronic pain patients live healthy, functional lives when they are allowed to live with the opioid medication that they need. If taken away we live our life in pain, that is all our life becomes. Its is unfair, cruel and honestly barbaric that patients are treated this way. The CDC 2016 Guidelines must be rescinded or at the least revised. We are patients who have a condition, we are not criminals.

I am happy to provided more information if you would like.

Sincerely,
Shara Danziger

From: Scott Deddo
To: NCIPCBSC (CDC); Scott Deddo; montygoddard@msn.com
Subject: Life of pain
Date: Friday, July 23, 2021 2:20:15 AM

CDC,
To whom it may concern,
I'm writing this email to you, in regard to the debilitating pain you have caused our family.
My wife and I are professional people. She is a critical care, ICU, recovery nurse.
I am a retired fireman, medic, with 21plus yrs on the job. We have 3 children, have always worked hard, pay our taxes and thought we had some type of quality of life.
Each of us has had multiple back, hip, and shoulder surgeries. Not just one, but many.
We have been seeing our pain Doctors for 30 plus years. The pain medicine he prescribes works for us. Until!!! Until some committee decided to mess with the dosages and peoples life's. My wife spends most days in bed. The pain is unbearable. Only because someone decided she was taking to much medicine. She truly had quality of life then.There is no Opiate crisis for patients in pain that receive the proper dosages for there
specific ailments. Not the dose that the government says, but what the Dr. says.
One size does not fit all. After working with our Dr. for years, to get the right amount of medicine, we finally get that quality of life, with minimal pain. I personally take 4-5 pain pills a day.
NO more NO less. The same dose year after year. I can make life work then.
I just don't understand why a person or persons on a committee would overrule a Doctors prescribing of the proper dosages.
These guidelines are out of touch with what is truly needed. Let the Doctors do there job.
The Opiate crisis that the media has hyped up is about the street people, drug addicts,
not about prescriptions for patients in pain.
Do you think that my wife or I want to overdose? Hell no. We just want a quality of life.
The articles I've read from the CDC said that 97% of the Opiate overdoses were from
drug addicts on the street. And the remainder of the 3% were from stronger drugs like Heroin.
I believe the current death rate from Opiate drugs is approximately 46,000 per year.
And the media and government is calling that a crisis? What a joke.
The current death rate for alcohol is 95,000 a year. Now that's a problem.
So why isn't the government sitting at the liquor store telling the patrons that because of
all the deaths, we need to take 2 beers out of your 6 pack or dump out some of the whiskey.
The current death rate for smoking is 480,000 a year. Now that's a problem.
But again the government isn't sitting next to the tobacco sales area telling patrons that
we need to take 6 cigarettes out of your pack because to many people are dying.
Again, one size doesn't fit all.
So, there needs to be some work done. With scientific facts. Not media hyped hearsay.
We are asking you to put together the proper people on the committee. Ones that are familiar with the types of pain people are in. Committee members that can make intelligent decisions based on scientific data. And let us get back to our quality of life days.
Days we can enjoy with family and friends. Not days of ongoing pain without the proper dosages of medicine. We are only a few of the millions of pain suffers.
Please work on updating the guidelines. It truly is life or death.

Regards
Scott and Jody Deddo

From: Shannon Mchenry
To: NCIPCBSC (CDC)
Subject: statements on cdc guidelines
Date: Thursday, July 22, 2021 5:29:13 PM

I am requesting exception to any dosage recommendations in the new opioid guidelines for patients suffering well documented, long term chronic pain patients. I am asking that my statement include the following article about an attorney who committed suicide due to the misapplication of the 2016 cdc guidelines. Her name was Erin Gilmer, and she "couldn't do it anymore". I am also requesting that it be noted that there is NO absolute Medical Morphine Equivalent information that is correct due to the multitude of variables that exist with each individual.

Enough harm has been done to chronic pain patients since 2016 as a result of the original CDC guidelines, written by people who were not objective. Suicide should not occur when treatments are available.

Thank you, S. Evette McHenru

The beloved advocate, lawyer, & activist Erin Gilmer has passed on. She was suffering in #IntractablePain.

Her doctors ignored her to death.

How many must die to prove there is a TREMENDOUS problem in American Healthcare?

She begged for help for years, and no one listened. No one. When there is no end in sight, no relief, the #livingdeath of constant pain can literally lead to #suicide.

In her haunting words, she couldn't do it anymore. "This is not survivable", she shared.

Sent from my iPhone

From: Stacey Fields
To: NCIPCBSC (CDC)
Subject: Guidelines, OWG Report
Date: Tuesday, July 20, 2021 1:10:22 AM

Hello,

I am writing to you in response to the meeting on the OWG report on JUly 16th. I created a group called The National Chronic Pancreatitis Support Network, we have over 4000 members. Chronic pancreatitis is an EXTREMELY painful disease that can cause a myriad of other severe health issues. There is no cure and often results in death. Pain care is an important part of proper medical care for this disease. The guidelines have created barriers to care as we are "complicated patients" who often require high dose opiates. Because the pain mechanisms are poorly understood, treatment is often empirical and insufficient. The lack of proper pain care for chronic pancreatitis has led to patients suffering with some turning to street drugs or alcohol seeking relief from the relentless pain and others have ended their lives in order to end the horrific pain this disease causes. Tylenol does not touch this pain and no amount of exercise, yoga or any other alternative is going to control the pain from chronic pancreatitis.

I have had chronic pancreatitis for 18 years, have stones in both the head and tail as well as atrophy and I am an active colon cancer patient. I can assure you that the pain is the same if not worse than the pain from my cancer, stage 3C. It seems to me that specialists who know how to treat different diseases were not consulted at all. Patient voices have fallen on deaf ears at the CDC who only seems to be listening to Prop who have all profited from this travesty against the American people. The evidence is low grade at best and the CDC has neglected to look into the patient harm the guidelines have created

This has also caused undue financial strain on many patients with some being charged over $2000.00 per drug screen as well as being forced into expensive invasive procedures such as the celiac plexus block that only works 50% of the time. Patients are afraid to have surgery and or procedures as they know their pain will not be controlled. I have spoken to two women who had double mastectomies and were given tylenol after, they both suffered through severe pain as well as a woman who had a hysterectomy and was forced to suffer through severe pain with ony tylenol afterwards.

It is unethical to force people to suffer needlessly in pain (your bioethicist is NOT a medical bioethicist) and Prop has made many untrue statements to help perpetuate their agenda. This seems to be about MONEY instead of lives. Please really consider what you are doing to peoples lives with your over aggressive guidelines that have already CAUSED suicides and massive suffering!

https://gut.bmj.com/content/57/11/1616
https://www.sciencedirect.com/topics/medicine-and-dentistry/pain-in-chronic-pancreatitis

Stacey Fields

From: Sara Gehrig
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:13:47 PM

To Whom It May Concern,

Thank you goes without question for all the time, effort and continuous fight against the war on the opioid crisis. As there has been gains made in this fight, there have also been steps taken that have caused havoc on those with disease or pain that use opioids in a controlled environment. Pain is pain and I want you just not to read these words but roll them around in your mind for a while. People living in chronic pain from migraines, chronic low back pain or people living with cancer, there is pain. So their pain control is no different. All of these things NEED to be taken into consideration.

I urge you to consider my words, pain is pain.

I appreciate you!

Peace,

Sara Gehrig

From: Sheila Bell Gilmer
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:16:02 PM

I am I permanently disabled due to chronic pain I have been on disability since the year 2000 my condition has worsened in 21 years I was doing fine and functioning well on the medication I was prescribed by a good doctor in Anderson South Carolina for 13 years she knew exactly why my body was getting worse I also have 3 autoimmune disorders..well.. a new dr.came in from New York that didn't know me and had the financial lady call me before I ever met him to let me know he was not going to treat me the way I have been treated by my other doctor ..I asked is every patient getting this phone call? She said yes...well ..I go to my first appointment and this doctor tells me he's going to cut my medication back Blah Blah Blah by the guidelines and I'm working with him I even went to my family doctor and got my anxiety medication decreased .which I'm also disabled with anxiety disorder its bad.. and migraines and depression rheumatoid arthritis a history of Lupus four bulging disc in my lower back degenerative disc disease .one bulging disc in my neck .sciatica .a nerve root wrapped around a disc on the left side now I've just been diagnosed with Ankylosing Spondylitis and spinal stenosis n. the neurosurgeon sd. Everything is. inoperable.. so back to the office that dismissed me....the second appointment when I went back to this new doctor he got mad because he had prescribed a new headache medicine and my insurance which was Aetna would not pay for the $600 new medicine and I was already on.fiorcet for years prescribed by my family.dr. and an. Er. Dr in the 90s because of preocurrance before migraines..I went blind so I needed that med ..I could not afford the $600 medication he changed me to..I picked up my regular $4 medication for headaches and did not do one thing wrong. He. The. New. Dr..then is saying which was a lie. i didn't do what he told me to n. Wrote. Oud. N. Referred me to rehab. they said. No. I deserved a drs Avenue the records he stated he didn't even have my records from my other doctor who had took a break and hung up for hat she came back to neuro studies only ..part-time well after that he said I was oud but he had prescribed medicine and said I was worse he never sent me for the MRI promise to now I have found out I have Spondylitis and stenosis I have asked them nicely to bring me back in there and treat me and. The day that happened I was crying because he told me in my face when I said I will be suffering if you dismiss me I have not done anything wrong he looks at me and said I know you will !! Suffer@!!well ..another doctor in the office went and got the office manager and she told me this doctor the new doctor is doing this to everybody. I asked two other patients I know he is not doing that to them..and one works..I was picked out cherry-picked I would call it and I don't know why my family doctor has seen that I have not done one thing wrong I have never failed a drug test or pill counts and now that I'm worse after taking care of my dad God Rest his soul he was in a wheelchair me and my older brother took care of him at home which took a lot of work and then I was in a car accident and hit head-on was not my fault then another one I was rear-ended not my fault I'm in bad shape on the inside and I have chronic severe pain everyday now it's hard for me to even go to the grocery store I can barely walk now. But with the meds I was on. I could function..cbd doesn't help. I suffer now. Mostly in bed. ..I only can get. 37.5. Mg. A day w this kind of pain..four doctors have tried to get me in the pain managements..and they're saying no I have asked this doctor to remove oud from my record he said no he would not I said it's been reported to Medicare I said my family doctor said to ask you to get that off my record because he stated he wanted me to go to rehab rehab said I needed a doctor I am on disability I have reported this to the South Carolina DHHS Medicare and I am trying not to send it to the medical board I need a good doctor to treat me and I have been denied treatment by two or three pain management and one time I was being treated real good at a second one and my car broke down.. my spine was getting worse and was doing tella.. appointments due to covid. could not get there for a pill count and this nurse said I'm dismissed ..I've asked for the dismal papers w the truth about this and they wont send them. By. Certified mail. She was so mean. over the phone I said why? Because I kept calling well I had an appointment that day with my dr. I had called because they were calling in my meds and different drs and decreasing it. Very confusing. over the phone it's been crazy what Ive.had to endure emotional pain and physical pain on disability for chronic pain and put up with this ? Help me I have contacted the CDC and they told me over the phone to get a lawyer.. I'd rather have a good dr again that knows what he or she is doing. and the chronic pain guidelines please..I cant live like this. Belbuca didn't help me either because it didn't work on my back pain and I had anxiety and went to the er...

From: susanguida1
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:26:47 PM

Dear CDC,

Hope this email finds you well .
I agree with the US pain foundation. I use pain management to function daily.
I am Not addicted to any pain medications.
Why ?
Because I do not have an addicted brain .
I wish I could take no medications and live a normal life like I did before.

"This is spiritually humiliating for me to have to take pain medication to barely function."
I grew up with the thinking that you take the pain and go to school , work , etc...and do not complain .
Complaining is for weak people!!!
Then I got psoratic arthritis, but did not know this at the time.
I had swelling , crippling pain, fatigue, that I could not walk to my bathroom .
Without the pain medication, with my injectable medication, I would have killed myself from the pain .
Death was almost better at times .
Right now, I take pain medication as needed.
My injectable medication sometimes is not enough .
I work as a clinical therapist, but can only work part time right now.
I am barely hanging on, but only because of my pain medication.
It is hard to describe unless you go through this yourself.
I barely have a quality of life and it is living in hell .
I remember when I was well and a young family member got rheumatoid arthritis - I could not understand her pain, feelings, emotions she had from this disease .
I could only understand from my own healthy experiences .
How bad could this be ?
She seemed ok .
She went to law school and traveled.
I now understand.
Think of the worse flu and it is 100x worse. It never goes away and you Never have a good day ever again .
You may have to cancel plans with family, friends, clients , weddings etc... because you never know how you will feel.
This isolates you .
People stop making plans with you .
I do not blame them but I am all alone . There are no support groups where you meet other people. It was suggested I start it. I need the support not run the group.
I am lucky I can see people on zoom for work.
"If you take the pain medication away , you will be murdering me .
I am barely alive physically, emotionally , spiritually .
This would kill me ."
I would never wish this on anybody .

I thank you for your time to read this .
Please feel free to contact me .

Warmly,
Susan Guida

From: suzannehellums
To: NCIPCBSC (CDC)
Subject: Comments to the 7-16-21 OWG meeting
Date: Tuesday, July 20, 2021 7:15:16 PM

Dear Captain Houry, CDC BSC Opioid Work Group, and to whom it may concern:

I am writing you to address the CDC Prescribing Guideline re-write, as a former M.T., (ASCP), with an M.S. in biochemistry and molecular biology. After reading the letters sent to you by HP3 in 2019 and the AMA; as well as reading the low-value studies involved in the 2016 Prescribing Guideline; plus the AHRQ's recent research into changes in pain scale with non-opioid therapies (decreases of 0.5 - 1.5 points on the 0-10 pain scale); other research into MMED; as well as limited moderate to severe pain treatment options; plus hard limits imposed by clinicians/pharmacists/insurers; forced tapers and suicides of patients with painful diseases, and the attack on physicians and other clinicians causing law enforcement to define care our medical community; not clinicians -- it has become evident that the MME recommendations cannot be considered any grade other than "B" -- nor should MME's be part of the final report on CDC's Opioid Prescription Guidelines. I do feel other professionals have weighed in on these harms to your group, with appropriate citations.

The Prescribing Guideline has been misapplied to the patient populations that they were not meant for - palliative, hospice, cancer, and debilitating pain patient populations (regardless of acute, subacute, or chronic). Because the quality of the studies and research in the 1-12 (graded) recommendations, I pulled the research papers and quickly noticed that any study evidence typed 2-4 have extremely weak, anecdotal evidence, but especially in types 3-4; to the point that the evidence is not clinically strong enough. These evidence type recommendations are beyond concerning as a guide for use to apply to all patients and should not be. A quick review of the research alone creates concerns for multiple ethics violations and human rights abuses, at minimum, given the personal nature of pain. These recommendations have/will negatively impact everyone, currently, and in future clinical decisions/conditions, as well as further compromise and degrade medical treatment, medical tourism, and this country as a leader in medical innovation.

While an exercise in futility, I have summarized my thoughts on some specific challenges in the recommendation sections, and placed them all as category grade B due to poor evidence, and are as follows:

Recommendation 1 - category must be grade B; because treatment should be considered based on patient severity and individual health.

Recommendation 2 - category must be grade B; because quality of life, ability to perform ADL's, patient function, and individual treatment goals need to be foremost.

Recommendation 3 - category must be grade B; This needs to be based on pain severity and recovery/healing process goals.

Recommendation 4 - category must be grade B; Paragraph/sentence should end at "risks when considering increased dosage."; law enforcement are lurking in the PMDP to prosecute clinicians based on algorithms that should not apply to hospice, cancer, palliative, and debilitating pain care; especially during a pandemic when medicine and treatment is a large job creator and factor in sustaining work for millions. MME cut-off values must be removed due to poor research quality.

Recommendation 5 - category must be grade B; The paragraph mentions harms to patients, however larger harms are caused to families and patients. One in 7 people in the U.S. report mobility issues. In 2009, the Journal of Pain reported in a study that there were 100 million Americans with chronic pain. In recent publications, that number has decreased to 50 million, however, one has to wonder with the increasing aging population; which of these statistics are correct. Are the Guidelines responsible for more harm for these population sets? By these counts, I would consider who in your life is already impacted negatively by these poor treatment outcomes. Again, MME should be avoided, removed, and repealed (and renounced) as a measure of care.

Recommendation 6 - category must be grade B; In a country where no PTO is available across the board, along with poor support in returning to work (such as encouraging lighter work duties until healing has occurred), and no actual public health treatment options, it seems the 1-3 or 7 days should not apply to all patients, but instead be due to the nature of the pain caused. Insurers are already using this as a hard limit and are "rewarding" physicians that treat patients with non-opioid therapies, even at the detriment to the patient post-operatively; including, but not limited to, more than 1 organ removal, and are defining large organ removal as 'minor surgery' for opioid sparing (as in, NO postoperative opioids. Please read that again.)!

Recommendation 7 - category must be grade B; Clinical meaningful improvement must remain patient centered.

Recommendation 8 - category must be grade B, Due to poor medical evidence and should include shared decision making [given that >120 MME is the current consensus for what is considered "higher dose" by any other research, but not always, considering the opioid medication], the problems with MME conversions vary from receptors initiated, bioavailability, height/weight of patient, and cytochrome P450 metabolism pathways.

Recommendation 9 - category must be grade B; PMDP algorithms were created from a software that used criminal records, and therefore clinical decisions made by PMDP's are criminal in nature, and are a 4th Amendment violation, at minimum.

Recommendation 10 - category must be grade B; Unfortunately, point of care, CLIA waived UDT screens are only ~86% accurate and precise. Verification testing expenses, based on accuracy, are an order of magnitude more in cost and should not be the only factor in making these clinical decisions.

Recommendation 11 - category must be grade B; A subset of patients will benefit from benzodiazepines and opioids depending on the conditions. These urine drug toxicology screens, which are point of care, CLIA-waived, and even FDA-approved, are notorious for not screening positive and screening false negatives or false positives. Definitive laboratory testing in this area is also lacking. Clinical decisions in this area must remain patient centered.

Recommendation 12 - category must be grade B, unless you can include expanded treatment decisions and remove buprenorphine as the only recommendation. While buprenorphine may be available in some areas, the gold standard in availability in treatment (and most understood) is methadone, but in some situations, other treatment modalities are used. By creating wording which specifies one medication, punitive decision making may be made against a treatment clinic or patient and should be avoided.

Overall, based on the weak category of evidence, specific wording with lack of scientific evidence, punitive decision making, and negative clinical outcomes; it seems the graded category of B must be placed on each of these recommendations, MME must be avoided, and forced tapers must not occur.

Thank you so much for your time, consideration, and attention to detail.

Best regards,
Suzanne Hellums, M.T. (ASCP), M.S.

From: Sheryl Henley
To: NCIPCBSC (CDC)
Subject: Public Comment
Date: Friday, July 16, 2021 1:07:38 PM

Failure of a UA is very much being used to cut people off of their medications. I would like to specifically mention a certain type of UA test called the EtG UA. It is NOT approved by the FDA because it is super-sensitive and picks up trace amounts of alcohol from over 400 household products. These products include hand sanitizer, hair spray, perfume, fabric softener-the list goes on and on. I was cut off of my pain medicine for failing this test, even though I had never failed a UA in 23 years. I had been prescribed pain medicine for multiple medical issues since 1995 and in consequence of taking pain medicine, I have not had alcohol since 1995. They cut me off 2 days after Gamma Ray Radiation Brain Surgery. I had a head like a basketball and 6 weeks of very painful recovery. I have been red-flagged in my file, and have been unable to get any doctor to prescribe pain medication or even discuss the problem, since October of 2019. I have never had a drug or alcohol problem, but this UA has cost me my pain medication-seemingly permanently. It is very difficult to survive with the level of pain I endure 24/7/365. For any questions or discussion, you may reach me at shenley55@gmail.com - Thank you.

From: Sheryl Henley
To: NCIPCBSC (CDC)
Subject: Re: Automatic reply: Public Comment
Date: Monday, July 19, 2021 11:59:49 AM

I cannot emphasize enough, the long-term damage that the CDC MME limits have done to the approximately 100 million chronic and intractable pain patients. So many of us have been drastically reduced or completely force-tapered off of our pain medicine. It is extremely difficult, if not impossible to find a doctor to prescribe them. Because of your limits, we are treated by our doctors, ER's and hospitals, like addicts. They try to force us to take Suboxone, try to force us into rehab. They've cut back acute pain medicine for post-surgeries, often not prescribing anything but Tylenol-even while the patient is still in the hospital! Why not just tell us to bite on a stick? Your limits have taken away our ability to function relatively normally. We used to be able to work, take care of our families, do chores, and socialize. Now, most of us are unable to do those things that make life worth living. Many of us are confined to our beds, unable to function. Many of us have chosen suicide because we can't live with that level of pain, with no hope of functioning normally. We shouldn't have to choose between extreme pain and death. Your limits have stolen the rest of our lives and we want them back! Not only do you have to get rid of your limits, the DEA has to stop harassing and terrifying our doctors. They are too afraid of the DEA to prescribe anything. People are dying of pain stress-heart attacks, strokes, system shutdown, depression & finally suicide. Even palliative care has been affected. There are many cancer patients being left to die in extreme pain because they are undertreated or denied ANY pain medications at all. This has turned into a genocide, and YOUR agency is responsible for starting this mess. What are you going to do to fix this problem? Just saying "The limits are only suggestions" doesn't work! You'd better think of something more than that ASAP in order to reverse the terrible damage you have caused. People are dying every day because of your "suggested limits"!

On Fri, Jul 16, 2021 at 10:07 AM NCIPCBSC (CDC) <NCIPCBSC@cdc.gov> wrote:

From: Sam Incorvia
To: NCIPCBSC (CDC)
Cc: sincorvia@gmail.com; Nicholas
Subject: Comment to add to the CDC Changes on Pain management
Date: Thursday, July 22, 2021 6:53:27 PM

I need to make comment to add to your Draft Opioid Prescribing Guideline Changes.
I really don’t see any real changes to the original Guideline as was promise to change.
I feel that this is a poor set of changes. Does not in any way help or address long term Chronic Pain Patients.
The Task Force which I was a part adding comments was to make better changes. This is a Dog and Pony show effort by the CDC to say that they are making real changes. When in reality this is a very poor effort. Nothing has changed and it looks like nothing will change FOR THOSE WHO SUFFER GREATLY AT THE HANDS OF YOUR INAPPROPRIATE GUIDELINES USING 90MME DAILY. Every person is different. Not using a right across the board edict by people who most likely never had Chronic Pain. Your Agency and the HSS say you never hear from Chronic Pain Patients. Want to know why. Because they can’t deal with the pain and are trying to get through the day let alone try to fight with agencies such as yours that care more about addicts then the true people that need your help. LONG TERM CHRONIC PAIN PATEINTS!!! I wish each and every one of you that are involved in these changes could be right in the shoes of CHRONIC PAIN PATEINTS feel that pain when you wake up till the time you go to bed for 1 week. That’s all it would take for you and your agency to make some real changes that help these people.
This is a horrible attempt on your part to say you make changes when in reality you still have this ridiculous 90MME standard in there. The pain patient and their doctors are the people that should make the decision and not some agency. You have no right to put this out there. Then hide and say it’s only a guideline. Crook of Crap with that excuse. What you write becomes policy of Doctors and Health agencies trying to help people who need it. You should just sentence the Chronic Pain Patient (speaking of those long term not one just starting today) to death!!!! Because that’s what you are doing when they cannot get their proper dosage they end up committing suicide. Nobody talks about the increase of these people committing suicide without their proper medications. I bet those numbers line up with these idiot addicts you are worried about claiming Opioid overdoses. You do nothing to help Long term Chronic Pain patients by using the proper numbers of those who are long term Opioid patients that use their drugs properly. THEY DO NOT OVERDOSE> Poor use of the Data and manipulating it in the favor of these ADDICT you are trying to help. Get with the program and take a real look at what’s going on. Help all people not just a select few that really don’t deserve the help and don’t want it to be frank. Poor choices by your agency and the people that run it. Have made Long term Chronic Pain Patients suffer and or lose their

medications. Please come up with a better guidelines to help doctors and patients run their program without some stupid 90MME a day limits. Don’t Hide behind this crap of stating these are guidelines and not the Policy.

Sam Incorvia
Advocte US Pain Foundation Mo.
sincorvia@inviaresources.com

From: Suzi
To: NCIPCBSC (CDC)
Subject: Pain
Date: Wednesday, July 21, 2021 12:23:29 PM

To whom it may concern:

The specific issue is:
How do I feel about the suggested 12 revisions.

I do not like the revisions from the authors because they repeat all the errors of 2016 guidelines and make many more errors easily foreshadowed to cause great harm.

People are not made by a cookie cutter…. So to be punished with a lesser amount of medication is not humane.

From: sheryl.leonard@juno.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 10:11:35 AM

Please reconsider current prescribing guidelines which prohibit physicians from properly treating patients.
I was diagnosed with metallosis following a titanium tooth implant with resultant severe myosis. I was unable to get out of bed for 18 months which resulted in severe osteoporosis, weight loss,muscle wasting, insomnia , anxiety and depression. Pain management refused to treat me since they only want to inject steroids and not write "non profitable" prescriptions.They are also not required to inform patients of the dangers of chronic steroid use which led to the death of two close relatives. No physician should have the government dictate my healthcare.They'll no longer treat pain for fear of losing their license.
I also live with interstitial cystitis with Hunners Ulcers. The suicide rate for this is 10% (with it being the number 1 cause of suicide among woman age 20-24).l have NO quality of life or reason to live. My condition would've improved with appropriate pain medication which your guidelines prohibit. I'm a retired R.N.and have witnessed the rise of illegal drugs resulting in death due to inability to get proper pain management. My elderly neighbors manage their pain with over use of alcohol.l'm noticing marijuana odor on people whenever l shop (it's not legal in my state).
Please be aware the l've had multiple surgeries and have NEVER become addicted to opiates. Non prescribing due to abuse by drug addicts is cruel and inhumane to decent persons who suffer daily.
Please reinstate reasonable guides that allow physicians to properly treat their patients.
Respectfully,
Sheryl Leonard

From: sheryl.leonard@juno.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 10:13:38 AM

Please reconsider current prescribing guidelines which prohibit physicians from properly treating patients.

I was diagnosed with metallosis following a titanium tooth implant with resultant severe myosis. I was unable to get out of bed for 18 months which resulted in severe osteoporosis, weight loss,muscle wasting, insomnia , anxiety and depression. Pain management refused to treat me since they only want to inject steroids and not write "non profitable" prescriptions.They are also not required to inform patients of the dangers of chronic steroid use which led to the death of two close relatives. No physician should have the government dictate my healthcare.They'll no longer treat pain for fear of losing their license.

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Please be aware the l've had multiple surgeries and have NEVER become addicted to opiates. Non prescribing due to abuse by drug addicts is cruel and inhumane to decent persons who suffer daily.

Please reinstate reasonable guides that allow physicians to properly treat their patients.

Respectfully,
Sheryl Leonard

From: Sadie LoveGod
To: NCIPCBSC (CDC)
Subject: Post-Webinar Comment
Date: Wednesday, July 21, 2021 1:57:32 PM

Dear Scientific Board,

Thank you for this opportunity regarding the 16th July, 2021 Webinar on Guidelines for Prescribing Opioids.

I am Abdel-Halim SADIK AHMED from Ghana.

As an Emergency Management Practitioner, my concern is about Opioids prescription during Emergency treatments. I understood that Opioids should not be the First Line interventions in preference to NSAIDS in Acute, Subacute and Chronic Pain Management. This with all other guidelines, the rationale was very clear aside a spot I saw that: the guidelines in spirit focused on in-hospital physician practices rather than holistic commonality.

In the case of Primary Care, Pre-hospital Care has become a critical modern-day effective trend in holistic Pain Management just as nursing practice and use of Opioids for Acute Pain. Early use of Opioids is usually a temptation in severe pain management situations Out-of-Hospital. For example, in ACS and Polytrauma(Tramadol, Morphine, Fentanyl, Pethidine etc) are likely tempting for use than NSAIDS, because of NSAIDS shorter half-life.

Given the efficacy of Opioids over NSAIDS in severe Acute Pain Control, what considerations have been taken to provide confidence for pre-hospital use of Opioids/NSAIDS or their Emergency use as prescribed in the guidelines?

While I am very convinced of the rich details in the experts' presentations on July 16, I had an urge to ask this question and I will be glad to have clarity about this.

Thank you.

From: Steven Maniaci
To: NCIPCBSC (CDC)
Subject: Ncipcbsc meeting
Date: Friday, July 16, 2021 4:27:46 PM

My name Is Steven Maniaci I am 59 year old chronic pain patient and I have been for over 22 years

I have degenerative disc disease with no discs in my lumbar spine, 2 bulging discs in my thoracic spine a bulging discs in my neck & 5 autoimmune diseases including pulmonary Sarcoidosis which mimics Lymphoma.

This causes me so much pain I sometimes need to curl into a little ball on the floor and pray for a nuclear war.

On the issue of UA's which was discussed earlier my doctor has discharged me as a patient because I tested positive for an illegal substance.

He told me that would Not test me again and promptly dismissed me. When I asked why he said I had tested positive falsely for another illegal substance about 10 years earlier. The fact remains is that UA's Are not infallible they are subject to mistake and in fact 5 to 10% of them across the United States do test AS…false positives. He tefusee to offer me another test

That said he didn't even offer to wean me off my medications and gave me 1 months worth of pain medication and said "My hands are tied" and told me the DEA has been to his office 5 times and to his home once without a warrant or reasonable suspicion and he then hung up the phone.
So the DEA has been the police that have taken hundreds and thousands of lives.

After 14 years of compliance and never asking for pain medication early I had been cut off of all my medication.
So I have had to wean off my medication myself and I'm not going through withdrawals I am in excruciating pain 24/7

I have no recourse as no other doctor will prescribe me the medication that I need for quality of life.

These guidelines have been a death sentence for people in all walks of life including veteran's and people suffering from intractable pain some of whom their only recourse is suicide.
I apologize but I must say These deaths are partly on all of you. The doctors we put our trust and lives in your capable hands

I hope that my contribution to this forum will open the ears of all the medical community to listen to the people suffering and dying from untreated chronic pain.

Thank You for the opportunity to speak in this most dire situations.

Thank You

Steven Maniaci

From: Sandy Marks
To: NCIPCBSC (CDC)
Subject: BSC Written Comment on Update to Opioid Prescribing Guideline
Date: Thursday, July 22, 2021 9:35:17 AM
Attachments: image001.png
2021-7-22 Letter to Cattledge re CDC BSC Comments final.pdf

Good morning. Thank you for you help in getting the American Medical Association's comments into the official record of the Injury Center BSC meeting. Attached please find comments from our Board of Trustees Chair, Dr. Bobby Mukkamala.

Sandy

Sandy Marks
Senior Assistant Director, Federal Affairs
sandy.marks@ama-assn.org
Office: (202) 789-4585
Mobile: (202) 256-6247

From: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Sent: Friday, July 16, 2021 10:21 AM
To: Sandy Marks <Sandy.Marks@ama-assn.org>
Cc: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Subject: BSC Public Comment Period - 2:15-4:15 PM, July 16, 2021

Good Morning, Ms. Marks.

Thanks for speaking with me in reference to your email. Although Dr. Mukkamala was not registered to make public comments, there is an opportunity to speak after all those that have registered for public comments have spoken during the 2-hour period. Again, as mentioned previously this morning, written public comments can be emailed to ncipcbsc@cdc.gov by July 23. All public comments, whether verbal or in writing will become a part of the official meeting minutes.

Have a great day.

Thanks,
Gwen

AMA
AMERICAN MEDICAL ASSOCIATION

Bobby Mukkamala, MD
CHAIR, BOARD OF TRUSTEES
bobby.mukkamala@ama-assn.org

July 22, 2021

Gwendolyn H. Cattledge, PhD, MSEH
Deputy Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE, Mailstop S-1069
Atlanta, GA 30341-3717

Dear Deputy Associate Director Cattledge:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments on the work of the Injury Center's Board of Scientific Counselors to advise the Centers for Disease Control and Prevention (CDC) on the update to its 2016 Guideline for Prescribing Opioids.

A revised CDC Guideline that continues to focus only on opioid prescribing will perpetuate the fallacy that, by restricting access to opioid analgesics, the nation's overdose and death epidemic will end. We saw the consequences of this mindset in the aftermath of the 2016 Guideline. Physicians have reduced opioid prescribing by more than 44 percent since 2012, but the drug overdose epidemic has gotten worse.

The opioid epidemic is now mostly fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin, methamphetamine and cocaine.

As CDC heard from dozens of patients at the hearing, the 2016 Guideline is hurting patients. Patients with painful conditions need to be treated as individuals. They need access to multimodal therapies including restorative therapies, interventional procedures, and medications. These include non-opioid pain relievers, other agents, and opioid analgesics when appropriate.

Instead, patients with pain continue to suffer from the undertreatment of pain and the stigma of having pain. This is a direct result of the arbitrary thresholds on dose and quantity contained in the 2016 CDC Guideline. More than 35 states and many health insurers, pharmacies, and pharmacy benefit managers made the CDC's 2016 arbitrary dose and quantity thresholds hard law and inflexible policy.

CDC's threshold recommendations continue to be used against patients with pain to deny care. We know that this has harmed patients with cancer, sickle cell disease, and those in hospice. The restrictive policies also fail patients who are stable on long-term opioid therapy.

While the patient harm from the 2016 Guideline was unintended, it was not unforeseeable.

The AMA urges CDC to make all of the changes to the guideline that the AMA recommended in our June 2020 letter, much of which is also supported by Opioid Workgroup report and has been endorsed by the CDC Board of Scientific Counselors. Patients with pain need CDC to adopt the AMA and Opioid Workgroup recommendations to remove arbitrary thresholds, restore balance, and support comprehensive, compassionate, equitable care.

AMA PLAZA 330 N. Wabash Ave. Suite 39300 Chicago, IL 60611-5885 | ama-assn.org | (312) 464-4887

Patients with pain need the CDC to be their advocate and urge it to rescind the perceived limits on opioid therapy doses or days.

We have an opportunity here to care for these patients responsibly with your help. Thank you.

Sincerely,

Bobby Mukkamala, MD

From: Susan Martens
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:35:27 PM

To whom it may concern:
I am writing in response to the guidelines that have been implemented by the cdc.
For those of us dealing with intractable pain, the guidelines have become a nightmare for us. I suffer from multiple issues, I have multiple collapsing discs, osteoporosis, rheumatoid arthritis, neurological damage, fibromyalgia, and I am also a cancer patient. The stigma and vilification of patients like myself, people that use the same doctor for years, that sign contracts with their doctors, and often are looked down upon by multiple pharmacies, questioned by pharmacists, get prescription papers thrown back in their faces, get told to go to rehab (yes this has happened) and have to scramble for medication that makes the difference between having a fraction of quality of life,vs none at all. My medication does not take my pain away, it brings it down to a level where I can at least dress myself. I am a fraction of the person I once was, and have become a shadow of myself. I barely leave my home.
Please for the love of God separate your stats. Valid patients like myself are suffering from the fallout of a database that includes every street junkie out there. We are not those people. Until someone has walked in my shoes they would have no idea of how much I suffer on a daily basis. All of you need to pray you never experience the kind of pain cancer brings. There are no words to describe this kind of pain. We are not villains, or criminals, we are normal people. I am a mother, and a grandmother, I am 59 years old, and have been in chronic pain for over two decades. Each and every day my threshold for pain has been diminished. Please stop the madness, I am a patient with very real issues.
Sincerely,
Susan Martens

Sent from my iPhone

From: Shannon Mchenry
To: NCIPCBSC (CDC)
Subject: my statements on updated cdc opioid guidelines
Date: Wednesday, July 21, 2021 1:40:10 AM

I am writing to have my statements included in the updated CDC opioid guidelines. Thank you for the opportunity to be included, as a person who these guidelines have done considerable harm to. I am a long term chronic pain patient. I have 3 progressive, degenerative conditions that resulted in me being permanently disabled since 2013. I, also, have other conditions that affect my medications, including a seizure disorder.
The 2016 CDC opioid guidelines have been misapplied, and treated as law, by doctors, nurses, pharmacists, and insurance companies. They have done severe harm to patients with progressive, degenerative diseases like myself. They have even caused increased suicide among chronic pain patients.
I believe legacy chronic pain patients who have been on high dose opioid medications prior to the 2016 guidelines, and have had no problems, should be excluded from these guidelines. This would be one way to help rectify the harm done to us by the 2016 guidelines. Our lives are hard enough. Forced withdrawal, breakdown of dr/patient relationship, decreased daily functioning, trouble finding health care providers, discrimination, insults from pharmacists are now a regular occurence for us, as a direct result from the 2016 guidelines. Physicians offices now use state prescription monitoring data as a way to screen which patients they will take because they do not want to deal with anyone who has taken opioid pain medication. I was fired from my dr office after one urine screen (by a phone call from his nurse) after 14 years of perfect screens. The lab director finally found the results were done in error- but I still had to find a new provider because the doctor "didn't want to lose his license".
I went through the suggested guidelines and think these should be changed;

#3) This should state when starting opioid NAIVE patients.

#4) The specific dosages should be removed. There is NO absolute MME measurement, and it is incorrect and damaging to use this term absolutely when so many variables exist. These dosage recommendations have already done so much damage to chronic pain patients.

#5) The specific dosage must be removed. An absolute MME does NOT exist. The inclusion of these dosage requirements have caused patients with chronic pain much abuse. Any decisions about changes should be consented to by the patient, also.

#6) The number of days should be included in supporting statements, or given as an example (example: 1-3 days will often be sufficient. Many times more than 7 days will not be necessary).

#7) Any specific time frames for evaluating risks, such as 1-4 weeks, should be for opioid NAIVE patients only.

#8) This statement should end at "increased risk for opioid overdose". There are so many variables and naming benzodiazepines just adds more confusion. Remove specific dosage number!

#9) Each state already has rules for opioid prescribing and checking PDMP data. A better statement would be "Each clinician should check the PDMP data when beginning opioid therapy, and continue checking it regularly throughout treatment". Also include PDMP data should NEVER be used as a way to screen, or exclude treating patients who may have been treated with prescribed opioid medication. This happens regularly now.

#10) Urine screening tests are not infallible, and should never be used as a sole reason to discontinue treating a patient. Urine drug screen results should be discussed with the patient no matter what the results of UDS are.

#11) Clinicians should use caution when prescribing opioid medication and benzodiazepines concurrently is all that should be said.

#12) Opioid Use Disorder should be treated no differently than other diagnosable mental disorders. Suspected, or diagnosed Opioid USe disorder should always be discussed with the patient and the offer to help find treatment should be made. This will help decrease the stigma this disorder carries and build trust between patients and providers. Opioid Use Disorder should NEVER be used as the sole reason to discontinue treating a patient. Also, there may be special circumstances with any past substance abuse may need opioid pain medication.

Principle #3) Individual Variations to dosing requirements for long term, legacy chronic pain patients MUST be noted. Chronic pain can be just as severe as cancer pain, and only naming 2-3 conditions HAS excluded people with severe, chronic, degenerative disorders that have been prescribed higher dosages of opioid pain medications for years prior to the 2016 guidelines. If legacy chronic pain patients are not excluded from dosage requirements we will continue to suffer as a direct result of the CDC guidelines. Please allow us to have some quality of life.

I hope my suggestions are helpful. I hope that the parts of the first cdc guidelines are absolutely removed and patients do not have to suffer and providers do not have to fear treating chronic pain patients.
Thank you, Shannon McHenry
64O W. 20th street Connersville,In 47331 ph (765) 698-8116

Sent from my iPhone

From: Scott McMurtery
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:29:49 PM

Hello, My name is Scott McMurtery , I cannot believe that we live in a time that people are suffering are made to hurt worse than needed. I am eat up with severe degenerative arthritis, I had both hips replaced at 40, both knees at 48 and a revision at 58 on my right knee. So I've had hips in for 24 years. My body is out of alignment I hurt all over. Why can't we have so many pain doctors per capita to write what's needed as long as you have the paper work showing you have pain and someone to monitor them. People are suffering needlessly. If I fall I can't get up by myself. Pain changes you. The things you were passionate about you just don't care. I have at least 3 operations within a few years and I'm scared because of reduced meds. After your out of the hospital is when the pain is a 10 plus. I know, That revision sucked and meds weren't reduced then. Please legalize Cannabis and I believe docs will be writing less meds anyway.

From: Sandra Moore
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 2:45:10 AM

Hi,

My name is Sandra Moore. I am a Pain Management patient and have been for 8+ years.

I am writing you now because of the Draft Opioid Prescribing Guidelines being updated.

I have so much I want to say. I'll keep this short.

First, i describe my chronic pain journey....

Eleven years ago is when my pain became unbearable. Until then, I had no idea that pain could be continuous. I tried to just deal with it. Long story short, when my loved ones finally convinced me to go to my doctor, I was in a very, very dark place.

The years that followed are a blur of different appointments (Orthopedic Surgeon, Neurosurgeon, Chiropractor and Physical Therapist), different test (XRays, MRIs and CT scans), and different medicines (opioid, non opioid and OTC vitamins).

Now, I go to a Pain Management Doctor EVERY MONTH. I get Radiofrequency Ablation done 2-3x a year. I have to do stretches and exersises everyday. I get drug tested atleast every 3 months. I am prescribed non opioids and opioids THAT ARE COUNTED EVERY VISIT.

The Opioid dose is higher than the morphine equivalent guidelines. Therefore, my insurance does not have to cover the meds. Some pharmacies won't fill the prescription.

I go to bed with pain, I wake up with pain. It is always there.
I know that I could not live a productive life without relief from the pain. And part of that relief is opioids.

The fact that I'm not dying actually impeding my living is not lost on me

PLEASE consider my situation and situations like mine when updating the Guidelines.

PLEASE realize that exceptions are needed.

PLEASE do not make my journey with chronic pain harder. I already feel like there is so much I cannot control.

PLEASE remember... you set the hoops that the chronic pain patients jump through.

I will continue to hope for a day when a new procedure makes opioids obsolete. Until then, please keep Chronic Pain Patients in mind. Do not forget about our struggles. Don't let me fall through the cracks. Don't let the bad actors dictate the policies for the country.

Sincerely,

Sandra K Moore
601 Hamilton Ave
Franklin, IN 46131
317-446-4378
Pickwhateverworks@gmail.com

**Wishing good health and serenity for you and yours

From: Shirley Pina
To: NCIPCBSC (CDC)
Subject: 90MME vs what"s best per individual.
Date: Sunday, July 18, 2021 3:55:21 PM

To whom it may concern,
Ever since the Guidelines came into play, there's been too many chronic pain patient's left behind! I was included trying to figure out what happened. It's not like we were causing ANY problems. Understand:
We don't have euphoric feelings
We don't ask for more than what's needed
We don't cause trouble with our physchians
We're Not overdosing
So again, wondering why we were included in your 90MME for everyone. It's difficult for our Dr.'s to be confined to this when patients have different weights, metabolisms and needs.
In the Guidelines, if taken the way their written, we wouldn't be included as it was for acute pain patients with their PCP's up to three months then being either referred to Pain Management,(unless able to get into them due to travel, costs, etc isn't covered in their health insurances) or continued after the three months. It's understood that they didn't all have pain management in their studies before becoming a Dr.
So now why can't you just eliminate and differentiate between patients, along with stopping the DEA from threatening good physchians treating their chronic pain patients with usually dual diagnosis of untreatable or incurable circumstances.
Thank you,
Shirley
Sent from my Verizon LG Smartphone

From: Sabrina Riley
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:41:58 PM

I am 43, have two young children and suffer from Fibromyalgia and chronic fatigue. I deal with pain on a daily basis, I know it will be part of me for the rest of my life. I know once our kids are older my husband will most likely leave me because my pain is too much for him to handle.

Even though I don't necessarily take pain meds (I take Neurontin and Klonopin) I understand the impact of pain on a life, a marriage, and a parent. I taught kindergarten and I know I will probably never be able to work again. I see a therapist weekly to deal with the emotional aspect of my pain.

I know my doctors fear writing me scrips for Klonopin for example - even though they know I am a very responsible user. I want those in pain to get what they need and not be treated like a scamming addict.

At six years old I watched my grandmother die of cancer. I remember being able to see how much pain she was in - even at six years old. I never want to see someone in pain whether it be while they are dieing or in a "trying to live life" situation. I understand how it can be a life or death (killing themselves over living in pain) situation.

I feel strongly about responsible patients getting the pain meds they need and not being treated like a scamming, criminal, addict.

Please reconsider the 2016 guidelines regarding pain medications.

Thank you for your time,
Sabrina Riley

From: Sherrie Salinas
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:08:32 PM

I am a chronic pain patient. Since 2016 when guidelines were updated I have been treated horrible. My pharmacy and doctor that I have had over a decade started to say I can’t fill your medication CDC says it’s not good for you and The DEA will take my license away. They were scared because of the guidelines! Your guidelines have made my life harder and made my pain worse. My doctor lessened one of my medications. Which has increased my pain. Your guidelines have hurt me and they have scared my doctor and pharmacist. This is not right! This is wrong! My care should be between me and my doctor not CDC! My pain is real and opioids have been one of the best treatments for me along with my ice/heat and massage/acupuncture. Praise God that I am still receiving my opioids. Please understand that you have done so much harm to people in pain. I know I am one of the patients your 2016 guidelines have hurt. Sherrie Salinas

From:	Stephanie
To:	NCIPCBSC (CDC)
Subject:	Personal
Date:	Thursday, July 15, 2021 7:20:36 PM

My name is Stephanie Soblaskey; I own and operate Soblaskey Counseling Services in St Ignace Michigan. I am a year old mother, wife and counselor who takes great pride in my ability to continue to work even though I am disabled (medically.) I have chosen to continue to work versus receiving disability for numerous reasons, but mainly because having the opportunity to work with children and families daily gives me great purpose, especially in such a high need low availability area of the country. 99% of the patients that I work with are dual diagnosis (meaing having a diagnosed mental illness and substance abuse issue.)

Approximately 19 years ago while pregnant with my third son, I fell injuring my spine. It wasn't until almost a year later that I underwent a spinal lamenectomy to repari a herniated disc. Unfortunately I developed a severe staph infection which led to me fighting for my life in a hospital for two months, being sent home with a PIC line with IV antibiotics for a year. I also required a wound closure surgery on my spine. From this point forward my spinal issues and pain became a permanent part of my daily life. I am lucky to get two to three hours of sleep on any given night, waking almost every half an hour in excruciating pain.

About two years laters I went through another spinal surgery and in January of 2013 had a spinal fusion surgery on 3 levels of my lower spine which failed; I also developed another severe staph infection (although my neurosurgeon had started me on antibiotics prior to the surgery.) I was in the hospital 6 hours from home for another two weeks. For the next 6 months I underwent physical therapy as well as regular Xrays and was told that the spine did not fuse and that I would require a bone growth stimulator (also I still have the screws and plates in my spine.)

August 13th 2013 while driving the 90 miles to my neurosurgeon's office for the bone growth stimulator fitting, I was in a terrible car accident. My car rolled 6 times end over end, pinning me upside down. I was without clinically dead for close to 4 minutes before a bystander broke a window to perform CPR which of course was hindered as I was restrained and pinned in the vehicle upside down. Thankfully the State trooper first on the scene had a portable defribillator which after 7 attempts, restarted my heart and breathing. I was on life support for the next 12 hours; I suffered 7 fractures to my neck, 5 compression fractures to my upper spine, 3 to my lower spine, 12 fractured ribs and head injuries. The doctors were not positive that I would survive or if I could ever walk again? Thankfully through the grace of God, I have been able to walk however have constant pain and limitations due to the seriousness and ongoing deterioration of my spine.

I have diagnoses that include but are not limited to the following: Facet degenerative disease severe, post fusion surgery failure, severe osteoarthritis, Crohn's PCOS, endometriosis, and numerous other diagnoses focused on my spine. I have been treated by pain specialists and put on numerous different medications over the years. Due to the Crohn's disease I am not able to take NSAIDS. My dose of medications had been stable at 80mg oxyconten three times daily, 30mg oxycodone up to four times daily for breakthrough pain. I was prescribed for many years Zanaflex 4mg and konopin PRN 1mg before bed to assist with severe sleep issues. I stopped asking for the zanaflex and konopin a few years before the CDC changes as I knew I would be forced to choose either the pain medications that I depend on or the others.

Living in an extremely rural area causes myself and other chronic pain patients severe stress! We literally have to drive almost an hour just to get to a Walmart. My last 3 pain physicians retired early due to the strain the CDC recommendations were placing on them. I was always under the care of my pain specialists until they closed their practices; I had random and scheduled drug screens and pill counts and have never had an issue with either. I have 3 letters on my chart from highly respected neurosurgeons and pain specialists stating that "in the case of Stephanie Soblaskey, the higher level of narcotic medications allow her to continue to work in her private practice and participate as a wife and mother; the benefits for the higher doses far outweight any risks." Unfortunately, I like most others in my area have been left high and dry without anyone willing to even make me an appointment! I was unable for many years to even find a new primary care physician due to me taking narcotic medications (even though they would not be responsible for prescribing those medications)

About 18 months ago my last pain specialist (who had been practicing for over 50 years) was forced to give up her license as she had retired however had continued to prescribe medications for myself and two other patients. She did this out of the goodness of her heart and ended up losing her license to practice medicine because she was not performing drug screens (even though my PCP had offered to perform these drug screens and provide her the information.) Since that time my actine PCP who is a nurse practioner agreed to write my medications for me which actually led me to break down in tears! I had been praying non-stop that God would provide someone willing to help me! This nurse practioner does not typically prescribe any controlled substances however because she knows my history, diagnoses and prognosis she volunteered to help. Please keep in mind that she also knows that just in our local area we have thousands of chronic pain patients without a physician! We have 5 local pain specialists who DO NOT WRITE CONTROLLED SUBSTANCES! Like myself, most of these patients have already gone through the countless epidural injections, physical therapy etc with little to no success. Unfortunately, when the physician whom my nurse practioner found out that she agreed to write these medications he became irate! He had only been out of medical school a few years and actually told me to my face that "if I ever found another doctor willing to keep me on the same doses of the narcotics that he would end up either in prison or at the least, lose his medical license!" He has ordered my nurse practioner to reduce my dose to 1/10 of the dose that I have been stable on for over 12 years! At this point I am having withdrawals daily, have had to miss over half of the hours at my private practice and can not stand or get out of bed without assistance! I have literally no where else to turn! I can not continue to live like this and it is negatively impacting not only myself, my husband, my children but also my patients!

There is a great deal more information that I didn't feel you would appreciate me including since this is already lengthy however I am more than willing to sign releases of inforamtion if anyone would like to review my lengthy file and/or speak with my nurse practioner or her physician who she writes under.

I appreciate your time and consideration in this matter. This is NOT something that can continue to be put off by the CDC and medical community. This had already gone on too long and I can absolutely say for certain that even if changes are made by the CDC the damage has been done! How many more chronic pain patients have to die because they can not continue to struggle just to get through the day or night? Chronic pain patients and their medications has never been part of the so called drug epidemic! Chronic pain patients are less than 1% of those who abuse and/or accidentally overdose on their medications. The war should be on illegal drugs, not chronic pain patients! Please help us!

Sincerely,

Stephanie Soblaskey LMSW CSW MSW

From: Steve
To: NCIPCBSC (CDC)
Subject: comments
Date: Saturday, July 17, 2021 3:53:15 PM
Attachments: enjdkfnjcfmgoooa.png

Our bureaucracy wants us to believe that we have a opiate crisis and that current state of that crisis had a genesis of the over prescribing of Rx opiates. Legal Rx opiates peaked in 2012 and have been on the decline every year since and the DEA has reduced the pharma opiate production limits by about 50% since 2012. It is seems to be no small coincidence that followed the Decade of pain law that Congress passed in 2000 and expired and not renewed in 2009 https://www.congress.gov/bill/106th-congress/house-bill/2260
that opiate prescribing increased during that decade.

The CDC has been less than honest about the reporting of opiate OD deaths... they report the number of ALL DRUG DEATHS and then shift the conversation to opiate OD, leaving the reader with the impression that the large number is all about opiate deaths, when it has been reported that there are some 15,000/yr deaths from the over use/abuse of NSAIDS that are included in those larger numbers. How many other subsets of drugs are included in those numbers are unknown.

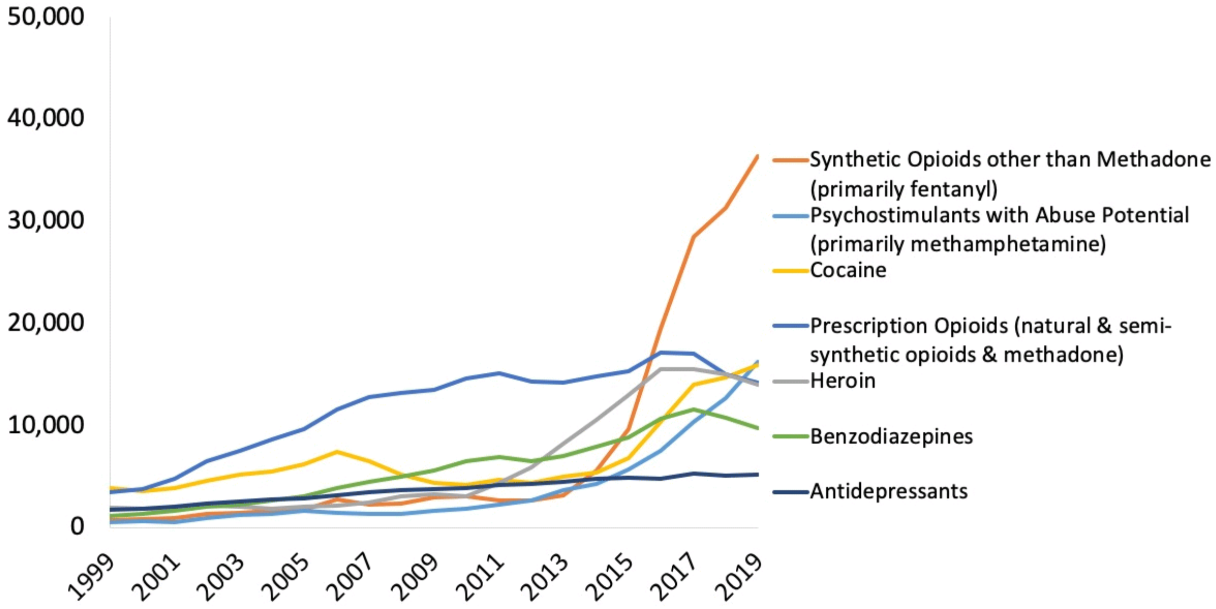
In May, 2017 the https://ndews.umd.edu reported that 99% of the OD deaths in the Dayton Ohio area involved an ILLEGAL FENTANYL ANALOG, but the exact article is no longer available on the web.

Just this month the Washington post reported that in some areas of the country, 95% of OD are involving ILLEGAL FENTANYL https://www.washingtonpost.com/local/public-safety/fatal-opioid-overdoses-dc/2021/07/08/0c50d298-db51-11eb-9bbb-37c30dcf9363_story.html

The chart below shows that just as the CDC opiate dosing guidelines were being implemented that ILLEGAL Fentanyl analogs increased from a few thousand to nearly 40,000. Once again the CDC does not distinguish the difference between legally obtained Rx opiates and illegal obtained Rx opiates.

Some have stated that a OD from legally obtained Rx opiates is most likely a SUICIDE and a very small percentage of overall OD deaths. We know that suicides by chronic pain pts, especially those designated as intractable chronic pain pts, is increasing dramatically.

Figure 2. National Drug-Involved Overdose Deaths*,
Number Among All Ages, 1999-2019



*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2019 on CDC WONDER Online Database, released 12/2020.

Our society is trying to find a equilibrium point between the push-pull between two populations that need/use controlled substances - opiates in particular. Those who have been dealing with undiagnosed mental health issue of a addictive personality and when they interact with certain substances they discover that the demons in their heads and/or the monkeys on their backs is silenced and "silence is golden" for them... and they quickly head down the path to some degree of substance abuse and/or addiction.

Then we are trying to deal with those who have been diagnosed with chronic pain... a subjective disease with no medical testing that can determine the intensity of the pt's pain. Some/many have been on a steady opiate dose for years or even decades.

The CDC guidelines also ignore the fact that as we age, many disease issues that are the genesis of pain will continue to deteriorate and the pt's intensity of pain will increase, not to mention pain associated with aging and/or activity induced pain, while trying to do just personal care issues.

We do have tests that will determine if a pt is slow, normal, fast, ultra fast metabolizer which would suggest that the pt would need high single doses and/or more frequent dosing because of their status of their CYP-450 opiate metabolism. https://www.acsh.org/news/2021/01/03/recognition-genetic-differences-opioid-metabolism-finally-15238

Then we have a newer test PGx(Pharmacogenomics) that will help the prescriber to refine the pt therapies to more align with their metabolic individualities based on DNA testing. https://pubmed.ncbi.nlm.nih.gov/31582008/

These CDC guidelines were based on MME (Morphine Mg Equivalents) which were reportedly done on pts with acute pain and using a SINGLE DOSE of a opiate. Which has no valid application to the treatment of chronic pain.

Here is a widely used opiate MME conversion prgm https://globalrph.com/medcalcs/opioid-pain-management-converter-advanced/
and here is just the first footnote: Published equianalgesic ratios are considered crude estimates at best and therefore it is imperative that careful consideration is given to individualizing the dose of the selected opioid. Dosage titration of the new opioid should be completed slowly and with frequent monitoring. Conversion ratios in many equianalgesic dosing tables do not apply to repeated doses of opioids.

In my professional opinion, these MME are pretty much MEANINGLESS, especially when dealing with chronic pain, especially intractable chronic pain.

The chart below, first published in 2011, shows the complications to a individual’s comorbidity issues from under/untreated pain. Some of the more serious is hypertension or a hypertensive crisis that can lead to eye and kidney damage, strokes or death.

The body’s response to all the stressors of under/untreated pain can cause the adrenal glands to keep producing more and more adrenalin until the adrenal glands FAIL... causing the pt to end up with Addison’s disease

Under/untreated pain can lead to increased anxiety and/or depression resulting in suicidal idealization and even suicide itself.

The CDC itself has warned about the misapplication of these guidelines, which seems to have been mostly ignored. https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html

This misapplication of CDC guidelines has caused untold number of pts - maybe tens of millions of chronic pain pts - to end up being chair/bed/house confined. Living in a torturous level of pain. This not only impacts the QOL of the pt, but their family’s as well.

The implementation of the CDC guidelines including the MME’s recommendations seem to be a excellent example of the cure being worse that the disease.

The Biden Administration is increasingly stating that he wishes everyone has more EQUITY and perhaps the treatment of the two subjective diseases, pain and mental health/addiction, has a better focus on providing a equity to access to medical care that will optimize the pt’s QOL and not rely on some “cookbook” type approach to treatment.

The Biden administration routinely states that we need to FOLLOW THE SCIENCE and CYP-450 and Pharmacogenomic testing is current best practices and standard of care for high acuity pts.

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Steven R. Ariens, P.D. R.Ph.
502.938.2414

www.pharmaciststeve.com
www.steveariens.com
CFO American Pain and Advocacy Association https://americanpaindisabilityfoundation.org/

"The fellow that can only see a week ahead is always the popular fellow, for he is looking with the crowd. But the one that can see years ahead, he has a telescope,
but he can't make anybody believe that he has it.." Will Rogers

From: Samantha Stiess
To: NCIPCBSC (CDC)
Subject: MME and chronic pain suffers we are dying because of your forced guidelines
Date: Friday, July 16, 2021 5:44:32 PM

I've been suffering from 8 chronic pain diseases since I was 15 years old, I'm now 35, over half my life I've been suffering from chronic pain. I don't remember one day that I was well.. I've tried everything natural at first, Physical therapy, cortisone shots, trigger blocks, antidepressants and started to get lumbarblocks at 16 because once you get diagnosed with a life long chronic pain illness you don't get narcotics and a pat on your back you try every step possible not to get on them until you have no options left.

At 21 I had 2 botched spinal cord stimulators that made my disease spread throughout the lower half of my body. Something that was promised to give me my life back took it away even more and caused permanent harm and damage and it wasn't a narcotic pain medication.
At 28 I found my perfect dose of pain medication along with my new and 3rd spinal cord stimulator to keep me looking like a "normal human being" and I was able to do everything with my husband and even lose 75 lbs bc yes it took 12 to 15 years to find that right pain medication. I also get violently ill from 98% of narcotic pain medications that's why it's important to realize no one size shoe fits all. From the Nsaids I took and voixxs and Celebrexs lead me to a stomach ulcers at 16 and I never fully got better from it at 35.

I never failed a drug test and did everything as told even to recently getting a pain pump put in because doctors are too scared to write for oral prescriptions but have absolutely no issue cutting your body open and put another implant in all for the sake they don't lose their licenses with no extra pain medication after the surgery. And if the pump doesn't work they will still take your medication away and go tough luck. How crazy does that sound?!?

5 years ago my life line was taken away from me by faulty agendas and misinformation by the CDC, PROP AND THE DEA I lost my best pain management doctor who gave me my life back and my pain medications who let me function like a semi normal human being. If you know what's it's like to lose your life over and over again you would understand exactly how we feel. By purposely scapegoating the wrong individuals and with absolutely no science to back up their claims. PROP and the CDC are exactly The Boy Who Cried Wolf. There isn't an "opioid crisis' However there is an illegal fentanyl and heroin crisis from drug addicts not chronic pain suffers, our country isn't helping because all agencies want to pigeonhole us together and not realize or even care that a drug addicts will always find a way to get high even make you look like a bunch of fools. A chronic pain patient just wants their lives back with regulated narcotic pain medication we got at a pharmacy. We never got high off our medication, we just wanted to live a life that was semi normal for us and we can't even have that. Can you tell me

that you know the difference between a drug addict and a chronic pain patient after 5 years of torture that you bestowed upon us? This is a human rights violation we know it, we deserve better than this hand that was dealt with. We need to go after PROP and the CDC and DEA for a moral, civil and human rights violation you have blood on your hands.
And have been on the sofa for 5 years now with a baby that I had to take care of with my pain riddled body and my blood pressure going through the roof because my pain isn't under control anymore. 75 lbs that I once lost came piling back up from my high risk pregnancy that I almost didn't make it out alive. I hemorrhaged after my csection and needed 2 blood transfusions and I still wasn't given anything extra after all that but an (Nsaids) ibuprofen that thins out your blood, smart right?

I see the number of overdoses especially since covid increasing but the pharmaceuticals have been decreasing heavily for 5 years since Prop, and it's ill informed doctors who aren't pain management doctors at all had no business deciding our fate who went and destroyed the chronic pain patients way of life and not help the drug addicts at all either mentally and physically. Why do we only hear one sided stories from the media? What are you going to do to fix it? Don't you realize it's illegal fentanyl and heroin on the streets killing drug addicts not chronic pain patients we are committing suicide then rather go on the streets? Can't all the big corrupted agencies know the difference between real chronic pain patients who are dropping like flies because you took our only life line away from us and for absolutely no reason at all?! You should know the difference between dependence and addiction. All of you are one accident away from being in our shoes and you'll finally will see why we're speaking out. the MME guideline is torture for chronic pain and cancer patients, especially who metabolize everything too quickly and has to be changed back because no one sized shoe fits all. I lost 5 years of my life because of this and my 11 month old daughter deserves her mom in her life. I deserve to live another 35 to 40 years semi pain free and with my 255mg of morphine that I was on 5 years ago. Yoga, kale,tylenol and prayers aren't going to do anything for us who's already tried everything possible to stop their pain.

Sincerely a young chronic pain sufferer who needs their pain medication
Samantha Stiess

From: Sandy Tubb
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 6:51:16 PM

The CDC needs to stop conflating addiction with numerous diseases that cause pain and allow pain patients' physicians to treat their patients as they see fit. The facts are what the CDC calls Guidelines are taken as gospel by State Medical Boards, the DEA, state legislatures, and pharmacists all who these days are practicing medicine as if they were the pain patient's physician. In the field of pain management the CDC has become the instrument to deny narcotic pain meds to those who seek pain relief not the next high. I challenge the CDC to find anyone who has overdosed from following the instructions that comes printed on every prescription bottle regardless of the the dosage or whether the pain med is extended release or instant release.

Terrorism is defined as creating an atmosphere of fear. Fear is all I hear from every Dr I have spoken to since 2016 regarding prescribing pain meds and from ALL their patients' who live in fear of losing the one thing that has worked efficaciously without causing any harm to patients who take their meds as prescribed . So congratulations to the CDC for becoming an organization that has more in common with terrorists than Drs and scientists who used to care what kind of ripple effects their policies would have on millions of people. Chronic pain is not a mental illness or psychiatric disorder, pain is physical whether acute or chronic, and only worsens with time and gravity.

Tylenol and NSAIDS are far more dangerous and harmful than opiate pain meds when taken over long periods of time to the kidneys, liver, and for older patients gastric bleeds. Opiate pain meds are much safer and far more cost effective when taken as prescribed rather than invasive procedures ie spinal injections, ablations, surgeries, and surgical implants that carry far greater risks of medical error resulting in complications that exacerbate rather than ameliorate chronic pain.

Let me be the first to thank the CDC for establishing the one size fits all MME for Drs to commit malpractice by following this flawed theory that ignores how individual patients metabolize the drugs, the length of time their pain has been untreated/undertreated and the dosage that may be needed to reach adequate pain relief and maintain relief.

Sandy

From: Steven Voiles
To: NCIPCBSC (CDC)
Subject: CDC Opioid prescribing guidelines revision
Date: Wednesday, July 21, 2021 11:12:07 AM
Importance: High

I'm writing this because I have been harmed by the current CDC 2016 opioid prescribing guidelines . I was suddenly in shock !!
As my doctor lied to me and said he was starting a practice with his wife a private practice. Lied straight to my face went from Sharp Rees-Stealy to Scripps both in San Diego no private practice wife works at a totally different site so not even the same building as his wife was, my wife's doctor before she passed and they both worked in the same building at Sharp, not really that important to this issue but it seems like this issue is also empowering doctors to lie to their patients face I had been seeing this doctor for 14 years.
The new Doctor I saw immediately wanted to start tapering down my medication, knowing good and well I was in pain from Hardware in my back a failed Fusion and degenerative disc disease eating away at my spine even now as you read this. I have been harmed by your decision in 2016 raise the numbers then go back until the real numbers and then again inflat them and make it a big issue to the point where the president of the United States Donald Trump was saying we have a big problem. Because of your policy we had a big problem...
And I was directly harmed because of that. I hope that no one ever has to go through what I went through for almost six months trying to find a doctor that would treat me with compassion. I am not going to go into all the details. All's I know is I could not wish this on any other human being especially a family member or a child. That has been laying in a bed in pain and cannot function because my pain medication was being titrated proper treatment because of inflated incorrect numbers reported by the CDC your policy has hurt thousands of patients across the United States don't make another mistake please by posting another unrealistic "MME" limit on opiate medication everyone is different with this respect everyone has a different tolerance for pain I did have a good tolerance for pain but after five back surgeries, Bilateral total knee Replacements Etc. 17 surgeries and all. I was open up like a fish time and time again. After 30 years with the Department of Defense. Serving my country in a civilian capacity I hurt my body over and over again sacrificing for the freedom of this country. And I was left without treatment with nowhere to turn after 15 years of pain management intractable pain being opened up like a fish on the operating table I hope none of you ever have to experience what I went through it was a living nightmare.
I have read very sad stories and obituaries about pain patients that have taken their own life and this is a sad story to read stuff like this day in and day out as they're taken away pain medication is if we are a communist country and can only ration pain medication to the elite or the wealthy. I am not either one so I lay in bed pain because my pain medication was my life it gave me t

From: Susan Wade
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:24:28 PM

To my fellow American's,

In Civics class in Jr. High we are taught our rights established in the United States Constitution. These rights self evidently true extend until they impinge on the rights of others.

My rights as an American with multiple chronic pain issues are being ignored. For over 25 years I've lived with a failed back surgery complication resulting in chronic pain. In 2016 I was in a 'near fatal' automobile accident resulting in a damaged foot and ankle. This also resulted in pain lasting permanently after repair surgery. Due to these extreme repeating stresses to my body I live daily with not only multiple chronic pain injuries but also Fibromyalgia. This is not a 'waist basket diagnosis' but research documented condition. These documented diagnosis's have come from not one "quack" but 3 different independent board certified Physcians.

The results of the current CDC guidelines have diminished my quality of life to the point I'm no longer able to enjoy my previous ability of daily functions. My care is delegated to others or disregarded if possible.

The upcoming guidelines as stated will continue this horrific downward spiral to not only myself but to the entire Pain Patient Community.

I also question the validity of your data that chooses NOT to acknowledge the aforementioned community. In a further note I also challenge this as even being in your jurisdiction. I believe the National Institute of Health NOT the Center for Disease Control should preside over Pain Management.

Your commandeering of this matter has not only resulted in Patients and Physcians being targeted by the DEA but willful disregard of our BASIC rights but in TERRORISM!

Data shows the ill-gotten and illegal Fentanyl is from non-prescribed street drugs. Physcian PRESCRIBED therapies are not resulting in these overdoses. FORCING tapering and terminating these is resulting in SUICIDES!

Acetaminophen and Ibuprofen are NOT the miracle answer you should be forcing on us. They and other non-opioid medicines fail to work in all cases. When all other therapies and modalities fail to offer any reduction of pain- Primary Care Physicians should be allowed discretion to provide further options INCLUDING other medicines.

All I'm asking for is my BASIC HUMAN RIGHT in AMERICA...

Life, Liberty and pursuit of Happiness. Your current and proposed guidelines alleviate all three for us that SUFFER from chronic (often invisible) PAIN

I humbly ask and pray that you will revise your proposed guidelines,

S. Wade
Tupelo, MS

From: Sue Walker
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Friday, July 23, 2021 2:00:32 PM

I have been a chronic pain patient for over 25 years, due to fibromyalgia, scoliosis, arthritis, a Shrogren Syndrome.

I have tried all of the “approved” medications for the conditions with untenable side effects for each. I cannot take any NSAID medication, due to a history of ulcers and stomach pain. Tylenol has no impact on my pain level unless mixed with codeine or narcotics.

I have taken a small dose (maximum 20/mg daily) for breakthrough pain for most of the time since my original diagnosis, with no side effects or issues with addiction. During most of that time, I worked full time, always with volunteer work in addition, and sometimes as many as three volunteer gigs and full time paid work.

The relatively small amount of narcotic pain meds I’ve taken have made it possible for me to live a productive life, and fully participate in the lives of my family. Without them, I’m frequently in constant pain, too much so to do simple household chores or family events.

I have, with help from other patients, run a chronic pain support group since 2007, and have had contact with approximately 1,000 pain patients during that time. Almost all are suffering from the restrictions on the most effective pain medication available. None, including myself, advocate these medications as a first line treatment, but there are those for whom nothing else works, and/or other medications have ceased over time to be effective.

I am in complete agreement with the following-accurate - statement from Dr. Walter F. Wrenn, III M.D.:

"The recent informationshowing a marked increase in overdose deaths in 2020 with prescrition medication found in only 28 percent of those deaths is proof that physicians who prescribed opiate pain medication were never responsible for the opiate epidemic. Illicit drugs then and now are solely responsible for those deaths."

Please stop punishing compliant patients because of the actions of those with the disease of addiction. Addicts should be treated as well, not punished.

Thank you for your consideration and attention to this critical issue.

In hope,

Helen Sue Walker, President
Richmond Fibromyalgia and Chronic Pain Association (Richmond, VA)

Sent from my iPhone

From: Samantha "Throttle" Bonsack
To: NCIPCBSC (CDC)
Subject: A Patient"s Comments on Updated Draft Opiod Prescribing Guideline
Date: Thursday, July 22, 2021 5:29:50 PM

Hello.

First, let me thank you for the health and safety concerns you've shown for the misuse of opioids by both end-users as well as the medical field. As we know, these drugs are far more powerful, and addictive, than originally marketed. This resulted in a dangerous lack of awareness which has had tragic impacts on many lives, unfortunately, a large number of them are now gone.

I am a surviving pain patient. I live in a rural community with very limited medical care and an even more limited understanding of the pain process within the body. I was literally bedridden for over a year with no hope of anything changing as I could barely get to the kitchen, let alone a doctor's appointment 2-hours away. I was prescribed opioids. I took them as directed, both the 24-hour slow-releasing and the 4-hour breakthrough dosage. I was on them around the clock for months, slowly developing opioid hyperalgesia but in denial that it was from the pills prescribed by my doctor. My pain increased, causing an endless cycle putting me in more and more agony.

We tend to think of suicide as something that happens to those who are depressed. Who's life isn't full, without supportive loved ones, and no future to look forward to. That was not me. I had a wonderful husband, a beautiful family, and a motorcycle event company that was flurishing. But the pain was so great, and so utterly relentless, with no medical options and no end in sight. Before I knew it or could stop it, my mind grasped ahold of the concept that I had could make all it stop and gain blessed relieve. With one, little bullet.

I am unsure how I survived that period of time as it took more than what I knew I had in me to get through it. But I got through it, stopping cold turkey. Slowly, I became clearheaded which allowed my strength of will to return and I began searching for alternative pain relief in every place i could. This lead to a new understanding of how the pain system functions in the body, and how it can malfunction and become the sole source of dibilitating pain despite no discernable tissue damage.

My story sounds like an example of why opioids should be banned, or at least extremely restricted. However, it is not.

I am here to ask that you re-consider your proposed guidelines to ensure you do not swing the pendulum too far in the other direction, throwing the baby out with the bathwater.

A realistic reflection on my story is accurate for so many, - opioids were the appropriate prescription. The issue at hand comes from it being the ONLY solution that the medical community turns to, which then has patients believe that these little white pills are their only hope for pain relief. They are not. They are a temporary phase of the journey, allowing patients brief relief as they explore the plethora of other options. A note that many patients have exhausted traditional options *before* they accept pain medication and are eager to *not* be on medication at all, but they are viewed as a last resort and their only hope.

To truly help the opioid crisis please, do not discount the positive potential of the drug by enacting such extreme restrictions that will deny many deserving patients life-saving relief. Instead, turn your focus toward what patients are screaming for - *are dying for* - which is supporting new alternatives to address the core reason for a large majority of chronic pain. Consider funding research and creating materials to help educate our current medical community on the discoveries on how the pain system functions *and how it can malfunction,* so that prescribers can better direct patients to solutions and gain a higher degree of compliance. The discovery and acceptance of the third pain descriptor, nociplastic pain, should not be overlooked but should be front and center when opioid relief is being removed from a patient's ability to combat pain.

There is hope in a patient understanding their pain process. Hope which currently is often only contained in these little white pills that you are being taken away from them with nothing to replace it with. Essentially, removing all hope from their lives.

Redirecting a patient's mindset is just as important as prescribing medication, and the CDC has one of the loudest voices to make an immediate, positive difference.

If not you, then who?

And if not now, then when?

Thank you for the time to consider my thoughts. I was close to dying for them and ask that you keep others from the same, or worse, fate.

Kind regards,

-Samantha.
(435) 220-0676

Samantha 'Throttle' Bonsack
Nut-up or Shut-up Motorcycle Events

From: Ted & Janie Cole
To: NCIPCBSC (CDC)
Subject: Chronic Pain Management
Date: Thursday, July 15, 2021 7:27:00 PM

My name is Ted W.Cole 108 Brady Street, Council Idaho 83612, Tele 2087396171

I would like to make a comment to the NCIPCBSC about Chronic Pain and Opioids. I'm 68 years old and during my teenage years I suffered from unrelenting back pain. I was taken to a doctor Who said I had Spina Bifida Occulta. I didn't mean much to me at the time, but recently I found that there is much pain related to Thalidomide. My mother who was stationed at Camp Pentleton Where my dad was a Marine was given samples of Thalidomide for nausea. I was born with spina bifida occulta and a congenital fusion of the C2 C3 cervical spine. As long as I can remember my spine hurt. In 1977 working at a local saw mill I had a serious injury to my lumbar spine. I was treated with most of the pain treatments of the time without much luck. Again in 1994 I injured my L1 spine. Every once in awhile I would go in and get a shot of Demerol and a muscle relaxer and go back to work the next day. This was fairly common at the time about once every 3 or 4 months.
In 1990 my neurosurgeon warned me I was in a very precarious position with a severe cervical narrowing that could either kill me or render me a quadriplegic. I eventually had the surgery in 1995 and have suffered until 1997 when I went to the University of Washington Multidisciplinary Pain Center in Seattle, Washington. By happenstance they detoxed everybody off of their pain Medication and put us on a methadone cocktail. This was the first time in many years that my pain was in control. This lasted until 2016 when the CDC Opioid prescribing guidelines came out And all the doctors simply quit prescribing Opioids for pain. I have been through withdrawal 3 to 4 times since then and almost committed suicide. I am receiving a small dosage of opioids now, that leaves me in constant unrelenting pain. I did in the mid80s shoot myself because of the unrelenting pain but unfortunately survived it to live in more untreated pain. My pain was treated successfully from 1997 to 2017 and people that had no idea about me and my doctor destroyed that treatment. WHY????

My wife of 30 years also has a wedged disc with constant back pain, and also has 2 very bad knees. The right knee is as bad as any doctor has seen, but we can't get it fixed because she has lymphedema
And needs to get it in control, all the while uncontrolled pain. Her left foot has now deformed to where the bone on top of her foot has slid around to the bottom of her foot and she is now painfully walking on it. With two of us in uncontrolled pain, this is a household of insanity! Pain controls this house since the 2016 CDC guidelines. I have eaten a truck load of psychotropic medication that does less than nothing and the cost is prohibitive let alone very aggravating!
Thousands of Legitimate Pain Doctors and Pain clinics have been shut down and hundreds of doctors locked up since these disgusting CDC Opioid Guidelines.
The Washington Legal Foundation found the collection of information by the CDC was illegal! So how can we trust the CDC to do the right thing?
Thank You for taking the time to research this miscarriage of justice and humanity!

Ted W. Cole

Post Office Box 675
Council, Idaho 83612
twcole@ctcweb.net

From: Tim Cook
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:37:23 PM

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15 year pain patient (Opiods): No other method will give relief to my rare diseases of all major joints and spine. Further reduction of pain methods will cause complete immobility, Please come look at my case, I encourage you to assess my situation and say my medication is not necessary, Gtxtimothy@gmail.com, please contact me. Most illegal opioid use is from criminals, Not hardly ever patients. Your shooting in the wrong direction with the wrong weapon.

From: Terri Couls
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:24:21 PM

I have had chronic pain due to a car accident that has left me disabled. At one time I was on very high doses of opioids and am currently trying to exist on 90 mg of morphine a day. I wish you could experience one day of the pain I deal with 24/7. To hear that "there are no benefits to opioids" is absolutely ridiculous. I understand it doesn't take the pain away, but blocks your brain from recognizing it, but either way, it is of GREAT benefit to me. As it is I have been treated for possible suicidal tendencies, and definitely would not be here today without the help of opioids. I understand some people become addicts. I am, no doubt, physically addicted, but I have taken them since October 2011 and have decreased, not increased, my use. The pain doctors seem to know who is an addict to drugs and who is taking it for reasons that are helping a quality of life. Why not trust the pain doctors and monitor the legitimate doctor vs. the "pill mills"? There are people who drink and drive but that doesn't mean we should all have our privilege of driving taken away!

I have tried every other Avenue from holistic approaches, Accupuncture, physical therapy, etc. I am in such pain that after trying everything, the only relief I get is the morphine. Please consider that (from what I have read) 2/3 of the opioid users are not those looking to get high but NEED the medicines to exist. I have a very limited life even on the morphine, so I beg you not to take what little quality of life I have now away.
Don Couls
1000 Rock Springs Dr.
Melbourne, FL 32949
321-831-2999

Sent from my iPhone

From: T Grady
To: NCIPCBSC (CDC)
Subject: Chronic pain denial to appropriate care
Date: Friday, July 23, 2021 1:58:11 PM

Greetings. Being a chronic pain patient for over 24 years has had a huge impact on my life. In 2016 things came to a crashing halt because of these newly unfounded guidelines. I started to do some research on the guidelines imposed across the United States. The data that the CDC used was unscientific and unfounded. It was still used to convince a lot of people that this was the best thing to help stop the opioid crisis. These findings were unfounded and Cherry picked data was used in its place. This has turned out to be a disaster for millions of chronic pain patients. The suicide rate has grown by more than 50% and almost 60% in veterans because of lack of proper pain care. Knowing that the new data backs up these findings the CDC still denies the chronic pain patients what they need just to have some normalcy back in their lives. I asked myself why a government agency would use data that was unfounded to actually hurt it's good people of the United States. Has this become a politically motivated agenda? Are a lot of these people that are making decisions being influenced by outside sources? Their job is to look out for the best interest of the citizens of the United States not the interest of their politically motivated hidden agendas. Their job is to look after the best interests of the people that are paying their salaries. But it seems this is not the case anymore. Certain people should be removed in all aspects of CDC decisions because of their own personal hidden agendas. If politicians aren't allowed to do this where does it say that these officials at the CDC are allowed. I employ you to help the citizens of the United States and not violate their 14th amendment rights to adequate care. This is where there is a huge failure to actually do your jobs and not be politically driven by outside sources. This has gone on long enough and it's time that the right thing should be done. Thank you for your time sincerely.
Richard.D.G.jr.NH

From: TY GREEN
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:20:18 PM

I have been living with pain since I was about 11years old, and at age 55 today it has gotten worse. I have Fibromyalgia and chronic pain. I have been to the mayo clinic in Minnesota to figure out why I am suffering to no avail. I was basically informed that there are some medical conditions that cannot be diagnosed as to why a person is suffering.

I totally get that physicians are not Gods. Physicians cannot know the answers to all the medical conditions out there until enough people report it and there is research to figure it out.

That being said there were times I could not move, I spent weeks in depression because of the severe pain. Nothing could give me relief but Percocet. For many like me that has never misused my prescriptions, I hope that a consideration will be made for chronic pain sufferers. To live day in and out feeling like your life is over because of the severity of the pain. Completing daily task for yourself is not an option. Again I hope this is considered when determining how to allocate pain medications.

Thank you for listening

Tynnetta Jackson

From: tgunnard
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:32:15 PM

Life of a chronic pain patient

Dear Sirs and Madams,

I am a 58 year old disabled RN in SW Florida. I have been suffering from chronic intractable pain since my early 20's due to chronic autoimmune disorders such as Lupus, Rheumatoid Arthritis, Spinal Stenosis and Sjogren's disease. I have been on opioid pain management, steroids, steroid injections, have had over 60 surgeries, accupuncture, massage therapy, PT and many other treatments. I have my knees, hips, back and neck regularly injected to help with the pain.

I am not sure if you are aware of the side effects of steroids but there are many unpleasant ones. One that bothers me the most is the incredibly disfiguring bruising it causes, as well as Buffalo hump, Moonface and what it does to your insides. I look absolutely terrible!

I have 35 years experience in Nursing, mostly in Hospice care and children. I haven't been able to work regularly due to the amount of pain I suffer and recoveries from all the surgeries I have had.

About 7 years ago, my doctor increased my opioid to Fentanyl patch 125 mcg's, and a short acting opioid such as oxycodone as needed. At that time, I felt so little pain I was able to work full-time with over-time, and even volunteered at my local Sheriff's office in Crime Prevention. I was able to get off disability for a while and enjoyed life immensely!

Fast forward to 4 years ago...

My opioids were cut in half. I had to quit the job I loved more than anything, stop volunteering and spend life mostly in bed or on the couch because of the pain. I have lost my identity and wish that my life would end sooner rather than later.

This is No Way To Live! I am so depressed and feel worthless as a human being, relying on my 27 year old daughter and 78 year old mother to help care for me and my home. I should be taking care of THEM!

My pain management physician checks my opioid levels monthly to make sure I am taking it correctly and obviously not selling it. My medications are locked up in a safe. I am now on 75 mcg's of fentanyl patch and my physician is trying to decrease it to 50 mcg's which the DEA prefers because I am above some score they have that prescribing physicians have to stay under. I am even told Medicare is likely not to cover the current dose of opioids I am on and that my pharmacy may stop filling my medication at any time. This stress does not help my current outlook on my future.

During your meeting, I feel a representative of the DEA should attend, as well as a congressman from each state. We need to get the CDC's new Best Practices report through to congress so chronic pain patients can live the life that everyone else is living, productively and comfortably. Physicians only follow the DEA recommendations on opioids, not the CDC's.

I am 58 years old and had many years left as an RN. I made enough money to live comfortably. Now poverty has also become part of my life and my daughter has to support me.

I am pouring tears as I write this, feeling as though I will spend the rest of my days with pain of an 8 or 10.

Thank you for reading this. I pray something good comes from your meeting. God Bless.

Sincerely,

Trish Gunnard

Punta Gorda, FL

Sent from my Verizon, Samsung Galaxy smartphone

From: Tom Hayashi
To: NCIPCBSC (CDC)
Subject: Revision of 2016 Guidelines/July 16th meeting
Date: Friday, July 23, 2021 3:02:55 PM

Hubert Humphrey spoke about the treatment of the weakest members of society as a reflection of its government: “the moral test of government is how that government treats those who are in the dawn of life, the children; those who are in the twilight of life, the elderly; those who are in the shadows of life; the sick, the needy and the handicapped.”

First and foremost, it should be acknowledged that the primary strategy pushed by PROP, Kolodny, Chou et al. which is decreasing opioid prescribing has been an epic failure. Of course, doctors that prescribe with no safety considerations need to be educated. But the vast over reaction in cutting down prescribing has produced the exact opposite of the intended result, with both OUD and chronic pain communities paying, far too often, the ultimate price. As prescribing has fallen, precipitously, it has been accompanied by skyrocketing drug overdose deaths, precisely the opposite of what Andrew Kolodny predicted.

The unwillingness of the CDC and state governments to acknowledge this failure points to a critical lesson that is becoming painfully apparent. Our American health institutions are in need of a drastic overhaul - greatly improved self awareness and self examination. The present structures (too political?) are, apparently, cowed by popular attitudes that preclude genuine consideration of research, facts and basic regard for the humanity of fellow Americans. CPPs are now commonly treated as “drug addicts” have been - unkindly, with suspicion and looked down upon simply because they depend on opioid pain medications, also a consequence of noxious popular notions. It is certainly not unusual that anti-opioid attitudes which have found a home at the CDC have resulted in treatment of CPPs that the director of Health and Human Rights at Human Rights Watch (Diederik Lohman) has said is identical to that of victims of police torture.

Perhaps the first paragraph of a revised Guideline should be a clear statement that CPPs are human beings, deserving of compassion and NOT objects to which “red flag” metrics are applied and then handled from a law enforcement perspective. This is how CPPs are treated today, across the board. Their opinion about how they are being treated can not compete with state regulatory and law enforcement views on MMEs. Doctors know that their careers are in the hands of the state, not patients. Crafting of Guideline language needs to be far more carefully considered, clear and direct, protective of CPPs humanity.

The failure of the PROP/Kolodny/Chou strategy needs to be recognized. How can CPP care move forward in a substantive way if reality does not play a part. Last Friday’s meeting (July 16th) and words spoken indicate that CDC plans to proceed, basically, with the 2016 Guidelines mostly intact with OWG opinions possibly considered as some little extras. OWG concerns really need to be incorporated in a serious way.

CDC needs to address reality directly and then see to it that state governments do the same. CDC needs to repeatedly inform state governments in terms of both science as well as basic human rights. CDC needs to follow through with a lot more involvement of CPP input and insist that state government follows suit. The Medical Board of California has made some interesting moves in this direction, taking direction from Bridget Gramme and Center for

Public Interest Law at UC San Diego. At the first of a new format of Public Stakeholder Meetings for the CA Medical Board, Ms. Gramme opened with a talk entitled “Amplifying Voices: Transforming Public Comment Into Meaningful Change”.
https://www.youtube.com/watch?v=Zcyx-9Ic2Ic

Discontinuing current harms to CPPs is the top priority.

From: Ted & Janie Cole
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 6:21:27 PM

To Whom this Concerns

The 2016 CDC Opioid Prescribing Guidelines have killed thousands of Pain Persons and rendered millions more severely harmed and left without a means to remain active citizens of the United States. Many have worked productive lives only to be injured through no fault of their own, and many born with painful disease of no fault of their own. There has been for thousands of years, medications that people are intitled to live relatively pain free instead of condemned to a life of suffering. Yet we have people who are determined to leave people in pain. These people unless people of severe chronic pain, have no idea of what pain is about. It would be like me determining what pain they are in and completely idiotic. People who don't have pain have no business
deciding how to treat my pain.

I was born in 1953 in Oceancide, California. My Dad was a Marine station at Camp Pendlton. Mom was very sick and was given Thalidomide for nausea. I was one of the lucky ones and only had a congenital fusion at the C2 C3 cervical spine and Spina Bifida Occulta. As I grew I had a constant pain in the back. In 1978 I was working in the local sawmill stacking green lumber when I was severely injured. I had a extruded disc fragment at the L 4 region. This is pain like non other, it knocked me unconscious for a short time. I went though all of the physical and medicated treatments
they did at this time. I went for years of treatments that barely helped reduce the pain. They even tried the immediate release opioids that help more than the original treatments, but still failed to reduce most of the pain. I spent once every 3 or 4 months in the emergency room getting Demerol shots which worked quit well. It reduced the pain and let me sleep and I was ready to go back to work the next day. I was diagnosed with a severe narrowing of the C3 C4 spine in the early 90s and was told I would become a quadriplegic or end up dead if bumped in the head. I had surgery in 1995 and started the very long process of finding pain control. Pain is very unforgiving!

In 1997 I was invited to attend the University of Washington Multidisciplinary Pain Center and one of their classic studies along with ten or fifteen other patients. Here I learned that there was a Medication that reduced my pain down to a very minor roar. That was a pain cocktail of cherry syrup and methadone. After a months stay they decided that I did not work for their study and tried to kick me out because all of the non-opioid treatments caused me more pain and crippled me. I found me a doctor in Idaho who was willing to treat me with Methadone and for twenty years I lived relatively free of severe pain until the CDC run off my pain doctor in 2017 when the DEA tried to look up my pain doctor who did nothing wrong and they acquitted him.

Since 2017 pain is my constant companion, he lives with me while I try to breath, he poked and prodded me as I tried to sleep and he really got rough when I needed to do something physical. There is probably no one at the CDC who has had a companion like mine. I don't understand and I know these people who made these guidelines don't have a clue in the world what we go through! How would they like it if all pain patients were in control of these doctors medical aid???? They absolutely would not like it and pain patients medical guide of doctors would without a doubt kill a few, Cripple a few and accidently cure a few. These doctors are not our GOD but our literal pain in the ass. I have suffered more than anyone of them could ever understand. Please let me guide the CDC These Guidelines are so far off!!!!!

Ted Cole
twcole@ctcweb.net

From: Tanna Jones
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:26:28 PM

To whom it should concern,

Despite the CDC having received thousands of letters and emails showing the harm caused, and the deaths of compliant chronic pain patients, for whom every other interventional therapy has been exhausted, they still have not acknowledged that the arbitrary 90mg Morphine equivalent dosage is not effective for every individual. Rather than make this acknowledgement, they are implying that the quality of life of those that have, through no fault of their own, devastating injury, is of no concern to them. The role of the highly trained pain physician is limited by this lack of concern on the CDC's part, and actually a violation of their Hippocratic oath, first do no harm.
There is an ILLEGAL Opioid crisis in this country, and rather than focus on the legislation in place that allows Fentanyl, and Heroin to flood the streets, they tie the hands of physicians that treat those, that break no laws, and seek all forms of therapy available, using Opioids as last resort.
I hope it does not take a class action lawsuit, using the Federal Tort Claims Act, to show how detrimental these "guidelines" have damaged Americans.
It is my sincere wish that no member of The CDC have to experience this pain, literally and figuratively, ever.
Sincerely,
Tanna Jones

Sent from my iPhone

From: Tiffany Kinney
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:15:36 PM

Before the changes made to the guideline for opiate prescribing, I was in a successful scientific career while my pain from a genetic and other chronic condition was well managed with opioid medications. Once the fear was sparked in the medical community with the change in guidelines and the pressure and convictions from the DEA who used the guidelines as permission to go after clinicians, my well treated condition was suddenly barely treated and I had to go on medical leave and eventually quit my PhD because of uncontrolled pain. I had taken my meds as prescribed, did all of the other things like maintaining good nutrition and exercise to battle my pain, and yet I was suddenly at risk because of arbitrary MME limits. Shortly before the official changes were made, I noticed a change in practices as physicians and pharmacies became increasingly fearful and that only worsened over the years since the guidelines were released. A number of studies have shown that the guidelines are harmful and that chronic pain patients are not at increased risk from taking prescribed opioids. What has harmed me are the guidelines and the fear in the medical community that they have caused. Untreated pain has at times landed me both in the hospital and in inpatient psychiatric care for periods because of suicidal thoughts brought on by unrelenting pain when I had no or not enough medication. I IMPLORE you, these guidelines must be changed to protect patients. The current guidelines and the current draft don't even discuss the benefits of opioids for treating pain. The MME guidelines are not based on science and don't allow for differences inpatients such as weight, gender, genetic responses to meds, tolerances, etc.Also, they ignore many painful conditions, somehow implyin some conditions are worthy of being treated and others are not or implying they are not painful enough to merit treatment. I have Ehlers Danlos Syndrome and Complex Regional Pain Syndrome (often called the Suicide Disease) and I certainly deserve and need proper opioid pain treatment.

It's ok to admit the guidelines were wrong, science is meant to be constantly questioning and looking at the results. The results are that patients were harmed, now that needs to be factored in.

--
Tiffany Kinney

~I hope life isn't a big joke, because I don't get it. ~Jack Handey~

From:	Tony Mckissick
To:	NCIPCBSC (CDC)
Subject:	Comment on Updated Guideline
Date:	Thursday, July 22, 2021 3:22:26 PM

Please consider the best practice benefits for opioid use in your guidelines.

As a chronic pain patient for over 20 years hydrocodone has been the only medication that best works for me. Other medications have adverse effects I cannot accept. For ten years before my back surgery and the ten years following I have been on hydrocodone for managing my chronic pain. I only use what I need for pain any given moment and taper off any day my pain is lower. Before my back surgery this meant many days I came off completely of pain medication. After my back surgery I completely stopped my pain medicine in one day. I was off it for two years and still working before my failed back surgery. The effect of pain medication as far as addiction never happened. Largely because if taken correctly my pain is using the medicine not my body and emotions I believe. Therefore when I lost the need for pain medication I could immediately stop taking any medication. Please consider hydrocodone for other patients as well, such as cancer patients, post op patients, end of life pain patients, and so forth. For me, oxycodone diminished my drive and therefore caused me to "not care" about practicing my physical therapy daily and other practices to help curb my pain. Morphine is much worse as it requires increasing doses more often and for me eventually caused hallucinations. Other pain medications especially things like mood enhancers only make me more happy while I hurt. Chronic pain untreated equals torture. The mind can only take so much. I was forced into having my medications stopped because my doctor was frightened into stopping my treatment because of the new opioid laws and before a pain clinic took care of my pain. During a time of uncontrollable severe pain that went up to a 10 in a 1 to 10 pain scale I experenced torture pain. This almost led to a psychotic event. Fortunately for me that pain event ended before I had a mental breakdown. I have had one 25 years ago and had simulare symptoms that preceeded that event during this more current time of torture pain. Even lesser pain if gone untreated has an additive effect on the nervous system such as multiple small partial blockages in the arteries add up to a severe blockage diagnosis. I have a degree in Cardiopulmonary Science and am a registered respiratory therapist and a registered cardiovascular sonographer. No I am not a doctor but my board exams required me to know diagnosis according to symptoms just as well.
Please consider best practices therefore in your guidelines for hydrocodone at least.
Currently my pain has gotten so high I have been increased to 4 - 10 mg tabs per day. In the past week I have been able to go to 3 and may get to 2 per day. I only take medication if pain requires and this best practice means my medication is used by my body and I believe my soul (or my mind, will, and emotions.) is medication free. This equals no addiction effect for me ever from my pain medication, I can simply lower my dosage and stop taking it in the span of the current day. Simply put, I can stop taking my medication in 1 day if I have no pain. This best practice of taking only what I need for pain and not excluding the physical therapy which includes stretching, walking, and use of a tinge unit and use of an iceman circulating ice water pad for my pain management. I believe hydrocodone has been a very positive tool in my pain management and has significantly increased my quality of life over the past 20 years. Please stop marginalizing it as a killer to pain patients. If these best practices are in place it saves lives. I know! It absolutely saved mine.

Thank you,

Joseph Anthony McKissick

From: Tina Mitchell
To: NCIPCBSC (CDC)
Subject: CDC Guidelines Meeting Comments
Date: Tuesday, July 20, 2021 12:31:41 AM

The new CDC guidelines are very detrimental to chronic pain patients. They have effectively made it very difficult for the patient to have any quality of life. What life we do have left is very miserable. There have been patients that cannot take the forced tapering or the sudden not being treated and those patients have commited suicide,forced out of jobs because they could not handle the added pain and some have been forced to seek illicit drugs from the street because they are being abandoned by their doctors who are being forced not to write pain prescriptions. Through no fault of their own the doctors are being harassed if they prescribe opioids to their chronic Pain patients.The CDC is doing a huge disservice to the chronic pain community. If you dont believe it then I wish that you get any of the incurable diseases or accidents or surgerys that leave you with chronic pain,not for life but just 6 months and are unable to get access to the meds that will help you be able to do most of the things that you can do now. Believe it or not there are people that are having to give up being a productive member of society and file for disability because of these messed up guidelines and the DEA coming down on the doctors that prescribe the meds that help people to still enjoy the pursuit of health and happiness. The DEA needs out of the relationship between ethical doctors and their pain patients. These guidelines need to be re-written without the input of people that have their hands in both pots. (suboxone/methadone clinics) and also getting money to be an expert witness against big pharma. This is doing a big dis-service to law abiding citizens that just want to still have some quality of life despite having multiple painful conditions and still want to/can be employable citizens instead of having to become extremely poor,lose insurance and be dependant on the government for the rest of their painful life!

From: Tom Norris
To: NCIPCBSC (CDC)
Cc: pcowan@pacbell.net; ksapp@theacpa.org; sfarmer@theacpa.org
Subject: Personal comment on Observations on Updated Guidelines for Prescribing Opioids
Date: Friday, July 23, 2021 2:50:05 PM

Dear CDC,

Thank you for this opportunity to provide some of my personal experiences and thoughts about the observations on the updated guidelines for prescribing opioids. My thoughts on the observations are based on the on-line discussion of these guidelines on Friday, 16 July 2021, and the documentation provided of that discussion.

I am aware that my comments are addressing the observations only – not the actual updated guidelines themselves.

I have lived with chronic pain for over thirty years. The pain started because of being over-irradiated during treatment for testicular cancer. This pain now includes all my spine (from the coccyx to the nape of my neck), all my abdomen, both hips, my groin, and my left leg.

I have tried almost every therapy and therapeutic for chronic pain management. I was prescribed Fentanyl for ten years. I did not like what Fentanyl and other opioids did to my mind and body. I took myself off all opioids and other medications and now exist on my faith, the love my wife and I have for each other, the lessons I have learned through my support groups, Virtual Reality, epidurals, and my attitude. Regrettably, my situation is the exception rather than the rule. Most people with chronic pain must have the help of medications to be able to have a life of even minimal quality.

I speak daily with people living with chronic pain who have been cut off from their medications and those who are terrified that they will lose access to their opioids as opioids are the only medication effective in minimally controlling the pain they live with constantly. These individuals are not opioid abusers; they are people with chronic pain who are trying to have lives with dignity. This fact should be recognized and appreciated when giving guidelines for opioid utilization.

General thoughts:

<!--[if !supportLists]-->1. <!--[endif]-->Patient centered healthcare/shared decision making should be used in any decision concerning therapies and medications.

<!--[if !supportLists]-->2. <!--[endif]-->We need to take action to ensure the correct interpretation is made of these and any “guidelines.” “Guidelines” have become the law of the land – not guidelines.

<!--[if !supportLists]-->3. <!--[endif]-->There appears to be a distinction drawn between cancer pain and chronic pain. I believe “pain is pain” and individuals with pain should not have their options for relief curtained by the distinction of cancer pain and chronic pain.

<!--[if !supportLists]-->4. <!--[endif]-->People with pain should be allowed access to the medication/therapy that helps them live with pain. Otherwise, we are allowing people to continue to hurt or be in pain needlessly.

<!--[if !supportLists]-->5. <!--[endif]-->The benefits of opioid therapy is not discussed or considered.

My specific comments are provided on the attachment.
Again, thank you for this opportunity and thank you for including my comments in the upcoming report.
I am available for any questions
Sincerely,

Joseph T. Norris, Jr., Lieutenant Colonel, USAF (Retired)
1656 West 25th Street
Los Angeles, CA 90007
323-775-2311
tomn482171@aol.com
jtomn482171@gmail.com

Attachment: Specific Comments

Specific comments on the recommendations

!--[if !supportLists]-->1. <!--[endif]-->The biggest problem I have encountered with the 2016 Guidelines is the interpretation that the guidelines are law.

<!--[if !supportLists]-->a. <!--[endif]-->I have not figured out who is at fault in that outcome: DEA, federal government, state government or local governments.

<!--[if !supportLists]-->b. <!--[endif]-->Who would be the one to ensure that does not happen again?

<!--[if !supportLists]-->c. <!--[endif]-->If we do not address that issue, how can we prevent these guidelines from being used to scare people?

<!--[if !supportLists]-->d. <!--[endif]-->What is going to be done to preclude any misinterpretation of new guidelines by national legislative bodies, state legislative bodies, and the media?

!--[if !supportLists]-->2. <!--[endif]-->I believe we should continue to stress patient centered healthcare in all matters dealing with chronic pain management.

<!--[if !supportLists]-->a. <!--[endif]-->This is not consistently addressed in the comments.

!--[if !supportLists]-->3. <!--[endif]-->I also believe that people with pain should be able to use the therapies that work for them.

!--[if !supportLists]-->4. <!--[endif]-->Education of both clinicians and people with chronic pain continues to be of upmost importance.

<!--[if !supportLists]-->a. <!--[endif]-->This is not addressed in the comments.

!--[if !supportLists]-->5. <!--[endif]-->I am concerned the inequities of access to chronic pain management for all people with chronic pain.

<!--[if !supportLists]-->a. <!--[endif]-->Not only is there often a dearth of chronic pain management doctors in some regions (racial and economic barriers), but many people with chronic pain do also not have access to medications or treatment due to their insurance.

!--[if !supportLists]-->6. <!--[endif]-->I am concerned that the use of opioids for post-operative pain is not specifically addressed.

<!--[if !supportLists]-->a. <!--[endif]-->Are opioids not to be used for post-op pain?

!--[if !supportLists]-->7. <!--[endif]-->I am concerned that use of opioids by dentists is not addressed.

!--[if !supportLists]-->8. <!--[endif]-->There appears to be no mention of paying physicians for the time required to perform an individualized assessment before the prescribing of any therapy.

!--[if !supportLists]-->9. <!--[endif]-->Recommendation #1*: Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient. (Recommendation Category: A; Evidence Type: 3)*

<!--[if !supportLists]-->a. <!--[endif]-->Person with pain is not involved in decision making process. (Patient education would be required to be included in decision making process.)

<!--[if !supportLists]-->b. <!--[endif]-->Post-surgery pain doesn't seem to be considered.

<!--[if !supportLists]-->c. <!--[endif]-->Recommend removal of "only."

<!--[if !supportLists]-->d. <!--[endif]-->As pain and reaction to medications (including opioids) is individual to each person, how is the risk assessment to be standardized.

!--[if !supportLists]-->10. <!--[endif]-->Recommendation #2: *Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate. (Recommendation Category: A, Evidence Type: 3)*

<!--[if !supportLists]-->a. <!--[endif]-->Here again it appears that the person with pain is not involved in the decision-making process.

<!--[if !supportLists]-->b. <!--[endif]-->Do the revised guidelines indicate how the person with pain is informed or educated to be part of the decision-making process?

<!--[if !supportLists]-->c. <!--[endif]-->How are the goals for pain and function established and made part of the partnership of doctor and person with pain?

<!--[if !supportLists]-->d. <!--[endif]-->If the person with pain is unable to communicate, does this mean that opioids are not considered as a possible therapy the

<!--[if !supportLists]-->e. <!--[endif]-->Suggest reordering of sentence: Clinicians should consider initiating opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the person with pain.

<!--[if !supportLists]-->f. <!--[endif]-->Since pain and reactions to medications are specific to each person with pain, how is the risk assessment standardized?

!--[if !supportLists]-->11. <!--[endif]-->Recommendation #3: *When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. (Recommendation Category: A and Evidence Type: 3)*

<!--[if !supportLists]-->a. <!--[endif]-->When are extended release/long-acting opioids considered?

<!--[if !supportLists]-->b. <!--[endif]-->Is the person with pain involved in making the decision to move to extended release/long-acting opioids?

!--[if !supportLists]-->12. <!--[endif]-->Recommendation #4: *When opioids are started for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to =90 MME/day or carefully justify a decision to titrate dosage to >90 MME/day. (Recommendation Category: A and Evidence Type: 3)*

<!--[if !supportLists]-->a. <!--[endif]-->As each person with pain is different and has different interpretation of pain and different tolerances, doesn't the inclusion of specific, seemingly arbitrary limits, preclude helping individuals live with pain?

!--[if !supportLists]-->13. <!--[endif]-->Recommendation #5: *For patients already receiving higher opioid dosages (e.g., >90 MME/day), clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation Category: A and Evidence Type: 4).*

<!--[if !supportLists]-->a. <!--[endif]-->This in an important area for patient involvement in the decision process.

<!--[if !supportLists]-->b. <!--[endif]-->Are the benefit and risks assessments arbitrary or standardized?

!--[if !supportLists]-->14. <!--[endif]-->Recommendation #6: When opioids are used for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. One to three days or less will often be sufficient; more than seven days will rarely be needed. (Recommendation Category: A and Evidence Type: 4.

<!--[if !supportLists]-->a. <!--[endif]-->It appears that the person with pain is not involved in this process. Patent centered healthcare would require this involvement.

<!--[if !supportLists]-->b. <!--[endif]-->I believe the last sentence of this observation is too defined and limiting and should be removed.

!--[if !supportLists]-->15. <!--[endif]-->Recommendation #7: *Clinicians should continue opioid therapy for subacute or chronic pain only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. (Recommendation Category: A, Evidence Type: 4)*

<!--[if !supportLists]-->a. <!--[endif]-->How is "clinically meaningful improvement in pain and function measured and standardized?

<!--[if !supportLists]-->b. <!--[endif]-->How is "risk to patient safety" measured and standardized?

<!--[if !supportLists]-->c. <!--[endif]-->Where is the person with pain involved in this decision-making process?

<!--[if !supportLists]-->d. <!--[endif]-->How are "benefits and harms "measured and standardized?

!--[if !supportLists]-->16. <!--[endif]-->Recommendation #8: *Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should incorporate into the management plan strategies to mitigate risk~~, including offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (=50 MME/day), or concurrent benzodiazepine use, are present~~. (Recommendation Category: A, Evidence Type: 4)*

<!--[if !supportLists]-->a. <!--[endif]-->Recommend excision of "including offering naloxone . . .are present" as too specific.

!--[if !supportLists]-->17. <!--[endif]-->Recommendation #9: *Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages ~~or dangerous~~ combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for acute or chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. (Recommendation Category: A, Evidence Type: 4)*

<!--[if !supportLists]-->a. <!--[endif]-->Recommend removal of "or dangerous" as judgmental, not specific.

<!--[if !supportLists]-->b. <!--[endif]-->The person with pain needs to be involved with this decision.

<!--[if !supportLists]-->c. <!--[endif]-->Is this recommendation for both chronic pain and acute pain?

!--[if !supportLists]-->18. <!--[endif]-->Recommendation #10: *When prescribing opioids for chronic pain, clinicians should use drug testing before starting opioid therapy and consider drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. (Recommendation Category: B, Evidence Type: 4).*

<!--[if !supportLists]-->a. <!--[endif]-->The definition of illicit drugs is not standardized.

<!--[if !supportLists]-->b. <!--[endif]-->Who would bear the cost for repeat verification tests for possible erroneous testing?

<!--[if !supportLists]-->c. <!--[endif]-->When is this discussed with the person with chronic pain?

!--[if !supportLists]-->19. <!--[endif]-->Recommendation #11: *Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible and consider whether benefits outweigh risks of concurrent prescribing of opioids ~~and other central nervous system depressants~~. (Recommendation Category: A, Evidence Type: 3).*

<!--[if !supportLists]-->a. <!--[endif]-->Delete “other central nervous system depressants” as too general.

<!--[if !supportLists]-->b. <!--[endif]-->How are the benefits and risks validated on a person-to-person basis?

<!--[if !supportLists]-->c. <!--[endif]-->When is the person with pain brought into the discussion?

!--[if !supportLists]-->20. <!--[endif]-->Recommendation #12: *Clinicians should offer or arrange treatment with medication for patients with opioid use disorder. (Recommendation Category: A, Evidence Type: 2).*

<!--[if !supportLists]-->a. <!--[endif]-->Who defines opioid use disorder?

<!--[if !supportLists]-->b. <!--[endif]-->When is the person with pain involved in the decision-making process?

From: Ted Nowicki
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:23:29 PM

I am one of the many who have pain. Mine is from small fiber neuropathy and back problems. I was prescribed Norco for awhile and I decided to take myself off of it. However, since then there has been nothing to take away the pain to a level that would be consistently manageable. Now I take Lyrica and it does not do what I would like. I know that some people in pain would benefit from taking opioids, if they are managed appropriately. I also think that alternative therapies should be covered by insurances. Furthermore, all painful conditions should be taken into consideration, pain is pain. Thank you.

Marilyn Nowicki

From: Tavia Palmer
To: NCIPCBSC (CDC)
Subject: CDC opioid prescribing guideline revision
Date: Wednesday, July 21, 2021 5:50:56 PM

Hello,

My name is Tavia Palmer. I am 45 years old. I live in Kingwood Texas 35 minutes outside of Houston. I have three kids & seven grand babies.
I suffer from CRPS/RSD & full body neuropathy. It started in 2015 when I was hit from behind going 45 mph by a drunk driver. I no longer can wear a hat on my head, no glasses for my poor eyesight, even laying on a pillow is excruciating! I can't get out of bed, I can't think, can't function at times. In 2019, I was talked into getting a spinal stimulator implant. It seemed to work a little bit for the headaches at first, but then my feet started having the same exact pain in them & begin to discolor & swell. In 2020, I was meeting with my Medtronix Rep after my first Spinal Stimulater Implant & I was explaining my symptoms to him, and he asked me if I had ever heard of CRPS? I looked up the symptoms online, I had every single one of them! I was officially diagnosed with CRPS & full body neuropathy by my nurologist & my pain specialist when I moved to Houston. The pain with CRPS & neuropathy is so intense that I cannot walk most of the time. When I walk it feels like I am stepping on glass and my feet, legs, and pelvis feel like my bones are being crushed. My left thigh feels like it's being cut, if you picture a knife filleting your muscles. Like when someone fillets a fish. Imagine experiencing that & having to feel it every second of every day. There is no reprieve, no relief at all. The burning I feel throughout my body is like somebody has poured gasoline in my veins & lit me on fire. At the same time, my skin feels numb, as if you were standing in a block of ice. If you've ever been out in the snow in subzero temperatures, how it begins to burn... Take a moment to think of how that would feel & you can NEVER get out! It feels so cold at the same time feeling as if I'm burning & on fire. It is unrelenting, freezing, burning, crushing & slicing pain, that never goes away. For a lot of chronic pain sufferers, pain comes & goes. But CRPS patients, we feel this pain non-stop. There is no getting out of it. It is the most horrific pain a person could ever feel. They say the pain is worse on the pain scale than cancer, amputations without anesthesia, & childbirth. Being a mother of 3, they're not wrong. I know it's much worse than childbirth! I've never experienced cancer or an amputation, so I couldn't attest to that pain. But I can take a pretty good guess that it is right up there or worse and wears on me every minute of every day. It is dubbed the suicide disease because the agony is so unbearable & there's no hope out there for getting better for someone who has it & it goes undiagnosed & untreated for years. Because it goes untaught to those in the medical community & not taught to every doctor, as it should be in school, it went undiagnosed in me for four years (there are thousands out there that go undiagnosed to this day). It is at a stage in me where it is just about keeping me as comfortable as possible until the end of my life. Which is not being done because of the 2016 CDC guidelines. (Dr.'s should

be the ones to decide whether to prescribe and how much a patient requires for adequate pain relief.)

There is no help in anything over the counter. I have had 2 spinal stimulator implants put in, which have done absolutely nothing for me. It actually made things far far worse & the CRPS had spread to other places in my body eventually becoming full body CRPS. I have tried injections, nerve blocks, nerve ablations, & countless medications. You name it, I have most likely tried it to no avail. I understand the “Opioid epidemic.” I get why the system needs to have checks and balances in place. But taking away opioid pain medication from the people who desperately need them to be able to live as comfortable of a life as possible is NOT the answer! We need to have our doctors treat us by whatever means necessary so that we can live life & be there for the ones that we love so we don’t have to be miserable & in so much pain that we don’t want to go on living. There has been a rise in suicides because doctors are scared to treat their patients. The government should never presume to know what’s best between a doctor & a patient. A doctor should be able to treat a patient as they see fit to have some semblance of a life. I can understand a system where one can look and see if patients are doctor hopping or hospital hopping to score drugs. That should be done. But there also needs to be some history put behind a score in the machine given to you without knowing the reasoning behind the score. For instance, for me, I have had to go to several doctors in the past few years. Number one, because I couldn’t afford to live on my own so I had to move to live with different family members until I was able to receive a car accident settlement which gave me enough to purchase a home & a car. My plan was to stay in Houston for at least the next five years. My parents are here & they’re getting older. But I can’t even spend time with them, because I am in too much pain & it’s hard for me to get out of bed. It’s difficult if not at times impossible for me to spend time with my children and grandchildren whom I love deeply. I finally had found a doctor who was willing to treat me & out of fear, he cut my meds down & informed me he would no longer be treating me. Yet again, I am forced to go to another doctor. Not because of anything I did, but because of them being to afraid to prescribe. I assure you, it will be counted against me in the system. I have done everything I can to go to the same doctors & Hospital when needed. But they all have become indoctrinated with the thought that is being pushed on so many doctors across the United States. Doctors, congressman & senators. They’re all being fed the same lie about the “opioid epidemic” this is not due to prescription opioids! Less than 2% of all overdose deaths have anything to do with prescription meds. The opioid epidemic is because of illicit street drugs. People who suffer chronic pain are not addicts! They are just people suffering that are just trying to get relief from the hell we are living in. We are instantly labeled “drug seekers” since when is seeking pain relief a crime? Our pain is not temporary! It is lifelong & it is relentless! It can happen at any age young or old. It does not discriminate! Hospitals & the doctors should be able to discuss their patient’s options openly, honestly, & freely. Instead they are instilled with fear & false information. Instead they have their hands tied. They need to be encouraged to feel free to assess & treat each individual patient’s needs. Hear each & every individual situations, as we are all different. Doctors are being indoctrinated with thoughts the government has put in their heads by people who have other agendas behind the “opioid epidemic”. People like Dr. Kolodney the leader of “PROP” and countless others who have made millions of dollars off pain patients who are desperate for relief & have been severely punished due to an epidemic that has been due to the illicit street drugs that are pouring into our country from China, Mexico etc.. NOT from prescription pain medication! Opioid manufacturing and prescribing is down by 43%, yet we continue to see an increase in overdose deaths. Why? It’s because PAIN medication is not responsible for the epidemic, opiate pain medication is meant for PAIN patients to treat PAIN. Addiction is a completely different disease & should be treated differently. There should be addiction therapies, psychotherapy & medications available to them but pain patients are not drug addicts! We are sick! Pain should be treated with pain medications that have been proven to work for many years and give people back some semblance of a life. Don’t let people who abuse it ruin it for the ones who truly need it & choose to use it responsibly. We are forced to go on the streets to get relief or worse; take our own lives! Why is my mothers pain any less important if I were to die due to my body finally giving out due to untreated pain or by suicide, than a mother who has lost their child to addiction or overdose? Help us pain patients that need it! Please help us get the word out. please tell the truth to the public, our doctors, and pharmaceutical companies. We need them to know the truth! We need you to know the truth! One more day of suffering is too much for those suffering inhuman unimaginable pain. Many of us have been suffering for years. It has to stop! Something has to give! Every day this subject gets swept under the rug is another day someone suffers or dies. Please don’t put this subject off any longer! People are losing hope and they’re giving up. People are losing their jobs because they can no longer work. That is costing taxpayer money that is unnecessary. I would think the government would want people to have the pain relief they so desperately need so money the government is having to pay out for those people can be put to better use. Pain patients want to work! We do not want to live on a measly check we get from the government each month. I have heard comments from people like Andrew Kolodny from (PROP) and Judy Rumler from (FedUp) saying people are lazy and wanting to sit back and live off government money. Who in gods green earth would want to live in poverty? We are not lazy! We want to get back on our feet and back to work! At the very least, we want to stop suffering! Please stop this insane attack on the chronic pain community! We don’t deserve this! We are not criminals! We are not addicts! We are sick! And we need help! Please!! For the love of God! Help us!!

Sincerely,
Tavia Palmer
(469)494-7699
22304 Misty Woods Ln
Porter, TX 77365

Email: taviasbox@yahoo.com

From: Terry Putnam
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 2:44:44 PM

My pain is unbearable at times.

From: desertsnake2002@gmail.com
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 3:23:07 PM

Hi,

I have chronic back pain. I feel like I’m being treated as an addict instead of treating my pain or getting the pain relief i deserve. Something has to be done with people who has severe pain.

I would be willing to talk about it more to try an give doctors and politicians a perspective of how hard it is to live day to day with severe pain.

Thanks
Terry Putnam

Sent from my iPhone

From: Tracey Rice
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:50:13 PM

Hello

I am a long time sufferer of chronic back, hip, and leg pain due to a sports injury.

Legislation is desperately needed to protect people in my situation.

I currently have switched to taking methadone after taking morphine sulphate for years and the results are tremendous. Plus there is no craving for the medicine at all.

People should be offered these safe alternatives to the other drugs.

We also need our civil liberties protected as well. For example, if a pain patient has a car accident we are almost guaranteed to be found guilty of a DUI. The long term consequences of DUIs can result in inability to get life insurance and certainly car insurance.

It is possible for a pain patient to be in a traffic accident and it have nothing at all to do with the medication.

Thank you for your work on the behalf of pain patients everywhere.

Tracey Rice

From:	Tom Riggs
To:	NCIPCBSC (CDC)
Subject:	Comment on Updated Guideline
Date:	Thursday, July 22, 2021 12:25:06 PM

To Whom It May Concern,

My name is Tom Riggs and I have Ehlers-Danlos Syndrome, Type III. This is the hypermobile type and is very painful. I endure pain 24/7/365, and some days are absolutely unbearable. For a very brief understanding of my background, let me tell you that in my younger years I was a competitive gymnast here in Colorado. Later I took up running and continued doing that very regularly for more than 30 years. In that time I accumulated more than 30,000 miles, ran (and completed) 30 marathons, including the Boston Marathon three times (though I qualified several times in addition to the three times I participated). I was never what you would consider an elite runner, but I was good enough to place 4th overall in a high-altitude marathon (Estes Park, Colorado), and won my age group several times. I absolutely LOVED running. I would go out on Sundays and just run, wandering around our city for hours at a time. I ran at least six days a week.

EDS begins to affect males later in life than it does females. Typically, a male will begin to suffer from EDS in their early-to-mid forties. Being a late bloomer, I was "okay" into my early fifties. I first attributed my increasing pain levels to the amount of running I was doing. While 40-50 miles a week is not excessive, it is above average. Eventually, my body started breaking down at an alarming rate. I sought help from physicians and physical therapists, but nothing was having any lasting effects, and my pain got progressively worse. Eventually I no other choice but to seek help from a pain clinic.

I am a very responsible patient and never take more than my prescribed doses of ANY medication. I log my medications by date and time and have those logs dating back several years.

Just over two years ago I had to apply for disability because I was no longer able to qualify for any work outside the home. I am still a freelance artist, but my pain limits the amount of time I can spend working, even at something I love dearly.

As I said, I am a very responsible patient and have never abused, and never will abuse, my pain medications. The problems occurring in our country and around the world are predominately related to the abusive use of opioids by people who have attained those medications through illicit means or are producing/purchasing illicit drugs that are not of the controlled variety that we pain patients are prescribed. Most pain patients are responsible and careful just as I am about the doses and the times that we take our medications.

My use of opioid pain medications is in no way about getting high or, as the old song goes, to "take a trip and never leave the farm!" I use pain medications so that I might have at least SOME quality of life! I've had to give up SO much of what I love because of chronic pain caused predominantly by Ehlers-Danlos Syndrome, Hypermobile Type. Please understand that I take pain medication so that I might still function and be productive and contribute, rather than be bed-ridden or confined to my home or a care facility.

Please look at the legitimate uses and users of opioid pain medications before you decide to take away any hope that we have of leading a productive, (semi) comfortable life! All sides of the issue need to be looked at, and all people need to be considered. There are probably hundreds of thousands of us who rely on pain medications to get us through the day, not by choice, but by the bad luck of (in my case) an unlucky draw from the gene pool.

Thank you for your time, and I sincerely hope you have read this email and will consider my words carefully as they are written from my heart with the best of intentions to help not only myself, but the many thousands of sufferers just like me.

Sincerely,

Tom Riggs
Fort Collins, Colorado
Tom@tomriggs.com
(970) 223-3657

From: Thomas Siders
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:32:33 PM

Hello CDC,

I will keep my comments short. The opioid guidelines that you unveiled in 2016 has caused irreparable harm to both chronic pain patients and to addicts as well.

While I hate that diversion, over prescribing and faux prescriptions of opioids helped fuel this issue. The changes forces those seeking opioids illegally to only illicit manufactured and supplied synthetics which have increased the death toll to a previously unprecedented number.

For those who use pain medications to be able to function on a daily basis, these guidelines have either curtailed or abruptly ended their access to medications that allowed them a semblance of life. In many cases we are just talking about lowering the degree of pain a little. If you give it a number, going from an 8 1/2-9 to a 7 is all it takes to allow a person to function in life. But your guidelines were not taken as suggestions and you know this) but as gospel and led to new laws, regulations, legislations, reductions in prescribing, the loss of licenses to many professional physicians, the forced tapering or or abrupt ending of prescriptions to patients. Patients who managed their pain successfully were either cut off or in many cases had their physicians decide not to care for these patients any longer due to the fact that they came under pressure from the FDA, DEA, FBI and other such agencies at local, state federal levels.

The abrupt, without notice ending of both service and prescriptions with zero tapering forced those who are physically dependent (not addicted) to the illicit market and this has been at the cost of hundreds, if not thousands of lives.

There have been enough studies of the unintended consequences of your 2016 guidelines to have you reconsider and release guidelines that are patient focused. But the rumors that we are hearing is that your new “committee” is no more diverse than your last and still contains no one who is well versed in pain management and that you are still not patient focused. I hear that these new guidelines may be more restrictive and will cause further harm to those who live in chronic pain due to either a disease with a major pain component, an injury with lasting pain management needs or deteriorating bodily functions that cause severe pain.

I hope and pray the rumors are incorrect and that you all find the wisdom to correct the damage inflicted through the issuance of the 2016 guidelines and recommendations.

Thank you,
Thomas T Siders
66 Trinity Avenue
Worcester, MA 01605

Sent from my iPhone

From: Thomas Siders
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 11:36:02 PM

And the MME equivalents are arbitrary at best and do immense harm due to the fact that it is impossible to relate every opioid prescribed to 90 MME's of Morphine Sulfate. These comparisons do not exist in the manner in which you intend them to be applied.

Sent from my iPhone

From: Teresa Stillwell
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 5:00:46 PM

These guidelines and rules are killing those patients like myself who have chronic widespread pain. We suffer 24 hours a day 375 days a year with no relief and no way to get pain medicines now due to the guidelines and laws. We've been taken off meds and sent through dangerous withdrawals, tapered down to doses that don't help and the opioids are completely off the lists because of drug abusers. The abusers will still get their illegal drugs just as they always have and the ones left to suffer are us chronic pain people that have been forsaken and forgotten and swept under the rug.

Do you realize how many of us have committed suicide from the suffering, a lot more than have overdosed. We should be considered the same class as palliative care so we can get relief and pain management just like hospice and end of life patients. I contemplate suicide regularly from my intense suffering and all because some druggy overdosed on opioids off the street. Your committee doesn't understand or see the big picture. You are killing us and we have no way to stop it or fight it. It's shameful with all the drugs available and resources that something can't be done for our incomprehensible pain we have daily. It has ruined my life and countless others and we have no hope because there is no end or solutions on your part to help us. All of our blood is on your hands.

Teresa Stillwell
NC

From: opr.1@juno.com
To: NCIPCBSC (CDC)
Subject: From: Terressa Sundstrom re CDC Prescribing Guidelines
Date: Wednesday, July 21, 2021 9:29:29 PM

To whom it may concern:

I have been in chronic pain for 3+ decades (from a no-fault, on-the-job injury accident). My life changed forever when I was 33 years old. I was athletic the day before the accident, but since then I have been in such debilitating pain that I could no longer hold down a job.

My provider of 15 years suddenly disappeared when the CDC came out with its new prescribing guidelines. He said he couldn't deal with the stress of what that was going to do to his patients. I was suddenly without ANY PAIN MEDICATION(S), and as a result, I:

-can't stand up;
-can't walk;
-can't take a shower or a bath;
-lay horizontal 23 hours/day;
-have no reason to live.

This is not living. This is just existing. I have been an Advocate for more than 40 years, and if I saw someone else living like this - - - well, it's very cruel, to say the least.

I know the CDC has to deal with the pandemic, but PLEASE, PLEASE DON'T LET US FALL BETWEEN THE CRACKS!!!

Our providers need to be our life-blood to some form of treatment. Please give them back their power to prescribe opioids, so they might save a life. Mine.

Electronically signed,
Nealy Tynes

From: Tamara Weisser-Martin
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:12:21 PM

Since the ,CDC ,WITH it seem like a blink of an eye,no warnings just took opioids away a couple I new who got hit by a simi truck decided to end their life as they were into much pain. I,myself had,Breast Cancer,the worst treatments ever called,THE RED DEVIL. (CHEMO),7Weeks of radiation.and surgeries.That was back in,2o12.3-5-2012,it all started and the afar effects I'm going thru right now,Degeneration,hard going up and downstairs ,etc.My life is worse as time goes by I don't get out much as the pain is disable.at least when the pain was being controlled I could do a few things and not feel isolated.U do window sometime is it worth it??

From: Tina Whitney
To: NCIPCBSC (CDC)
Subject: pain pills to live!
Date: Thursday, July 22, 2021 8:59:47 PM

I am 54, with fibromyalgia, fractured back and anxiety. I work 2 jobs to survive..food.gad and pay for home..I am on a small amout of pain pills..noy narcotics but still...they could be taken away from me by you guys. Please dont take my life...I want to work!! Not live off disability..sitting around. Let me be a part of society..give me my purpose...please..for me and all the others who responsibly take their meds. What kind of life without my meds? not a life worth living purposely . Give us back our lives! We have a right to talk to our doctors and let them decide , tests every 3 months..personally talking to dr...

SIncerely TW

From: treycvee
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 1:17:20 PM

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dear cdc,

I have never had any problem with using opiates responsibly, despite this in my medical history I am treated like a drug seeker and I have a lifelong sentence to pain. doctors use the excuse that it's only for acute pain and I beg to differ. my entire spine is destroyed and i do not wish to become reliant upon opiates either, but theyre the only thing that provide relief when I am in extreme pain. i cant handle sitting in an emergency room just to be labeled a drug seeker and given 3 days of pain meds when i have a bad flare up or relief PRE-SURGERY, only post surgery. this is torture for those who use these medications responsibly and sparingly due to the side effects. this only happens to the poor and people with bad/cheap insurance because my friends who are engineers are handed them like candy. i have 10 times their physical issues and i have to literally fight with doctors to get help. it is not their fault but the rules that you make for us. i was made permanently disabled by a drunk man and you all have punished me for it ever since, as if i deserved the pain because i'm poor. my history is on paper and plain to see for all doctors accessing it. ive never had issues weening off meds when healing from the FOUR major surgeries i have either had to my spine or my full hip replacement. you drive me to suicide, you also drive me to seek illegal drugs from people who could potentially give me fentanyl. so, maybe i could see a pain management person, right? WRONG. the waiting list of a 6 month minimum kind of seems useless when you're done with surgery and even post surgery meds so that makes that program useless. i'm tired of being punished for others lack of control of the medications. i shouldnt think my life is so worthless because my government doesnt give a crap about how much i suffer on a day to day basis. i have asked for a minimum amount per month for my flare ups, but no, i suffer through the pain and the fact im sitting home crying and unable to sleep or rest because nothing is helping my suffering. it is unconstitutional as it impedes on my right to LIFE, LIBERTY AND THE PURSUIT OF HAPPINESS.

sincerely,
Traci Van Zandt

From: TS WARTKO
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:38:23 PM

To Whom It May Concern,

I am very familiar with chronic pain suffered by a family member and two close friends. In all three cases, the pain is caused by muscular/skeletal issues, not the pain conditions you exclude from your Updated Guidelines. All three people are accomplished, productive citizens with strong family and community ties. The use of opioid medications by chronic pain sufferers, under careful medical supervision, can make the difference between living a productive life and spending one's life in bed with ice bags to dull the pain. Without opioid medicaitons, for many sufferers, the pain is so severe that suicide becomes the only way out.

Please trust the research strongly indicating that the overwhelming percentage of chronic pain sufferers use these medications appropriately. These are critical medicines to restore quality of life for chronic pain sufferers.

I would hope that you would use your influence to argue strongly for much more medical research into new, more effective pain medications that don't form dependencies. Chronic pain sufferers need better medicines, as do all of us who suffer even occasional painful injuries and conditions. The amount of research in the NIH budget dedicated to pain is shockingly small, given the magnitude of the problem.

Sincerely,

Anthony and Sanny Wartko
7 Trails End Rd
Hilton Head Island, SC 29926

From: Vicky Cathey
To: NCIPCBSC (CDC)
Subject: My thoughts on the CDC Guidelines
Date: Monday, July 19, 2021 8:40:49 PM

Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids

To whom it might concern,

I am a chronic pain patient and would like to give some insight if I may. I have been on pain medications for 14 years with the same pain clinic. I was stable and doing well until the forced tapering was required. I was working, volunteering, and enjoying my life. I am 60 years old and my plans were to continue working until 65 (at at job that I love) and continue my volunteer work with hospice (which I also enjoy). My medications were reduced over 60% and I was unable to function at that amount and was discharged from my pain clinic.

I tried everything to help with my pain-injections, physical therapy, etc. The pain medications helped me to lead a normal life and once they were stopped my life also stopped. I now face early retirement with having to live the rest of my life being in pain. I never would have dreamed that this would be where I would be at. I feel that I should be allowed to have a happy life just like any other person.

I am not an addict, I am dependent on medications that help me to live. I now have no trust in the medical field at all-I see no reason to ever see a doctor again after how I have been treated. This has all gotten out of control and there are too many people like myself who have been harmed in the process. There are so many who are to blame and they should be ashamed of themselves.

Chronic pain patients should be heard and treated. The CDC guidelines in 2016 took away any concern for pain patients and many lives have been lost because of it. I have little faith that a change will be made, but wanted to put my two cents in anyway.

Thank you,

Valerie Cathey

From: Veronica Clark
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 4:25:50 PM

Hi. I've been in pain for over 20 years. I got fired because of it. I've never been fired in my life.

Here's my story. In the 90's, while working at the local casino (it's in the boonies of WI), things started happening. I'm not, nor ever was, one to complain about pain. My hands would go completely numb and I would drop all of the cards on the blackjack table. Then my right shoulder hurt like heck. After unsuccessful physical therapy, I was diagnosed with Fibromyalgia,an autoimmune disease.. I really thought that meant no one could figure out the real cause so they slap a label on it.. I couldn't even hold a can of soda in my hands without dropping it. It was embarrassing.

Then, one morning (I was separated from my unfaithful now ex husband), I got up for work and my right leg completely gave out. I couldn't get up. My dog was trying to help me, and eventually I went to work. I could barely walk without severe spinal pain. Cause: degenerative disc disease. I was told I would be in a wheel chair by the time I turned 40.

Next, I noticed my mouth was severely dry, to the point that people couldn't understand me. And my eyes were unusually dry. Cause: Sjogrens, an autoimmune disease one is born with. The more I researched it, the more my life up to that point made sense.

I was also getting really bad headaches. Physical therapy said they were migraines, and to talk to my doctor. They also only worked on my neck from then on. I saw a neurologist, and she confirmed the migraines.

I was sent to 4 different pain clinics. I was also on oxycontin, along with other medications. One to keep saliva in my mouth, eye drops that are very expensive, heart medication, and muscle relaxants. Mind you - not one of them made me 'high', sleepy, or slow. They helped with the pain a lot.

With the last pain clinic,, he refused to see me unless I stopped the oxycontin immediately. I did. Then, he had me see an in-house psychologist. It was supposed to be a 6 week deal. After 3 weeks, he said "I don't even know why you're here. I know you are in pain, and never abused any medications. We are done." Sent me back to the pain doc. He then injected something in my back/spine that made me high and had rubbery legs. He said he wanted me on methadone. I told him no. I refused to take that. When I got home, pain started shooting down the back of both legs. I called them and was basically told to deal with it. I told them I'm done with them.

Next, my eyes started hurting like someone was poking needles in them, especially the right one. They were also dripping, like tears, but it was oily. I can't cry, but this happens?
Cause: cysts on my corneas, caused from an autoimmune disease.

I'm also retaining fluid in both feet and lower legs. It's very painful to walk. I can't find shoes to fit me. The heart doctor refuses to continue with anything until it's figured out why the fluid is so built up. I'm on water pills and take cranberry vitamins daily. They aren't helping, even after doubling the dose of water pills.

I still have a few oxycontin. I also have a few tramadol, which my primary had prescribed after the last pain clinic.

I had one doctor tell me "If you don't regularly take the pain medications, and only take them when you're in pain, they won't do the job they're meant to do."

I've had no pain medications for, well, I don't know how many years. I'm in terrible pain, but they are told to not prescribe any pain meds to anyone, and I haven't asked.

Perhaps my next move should be to just end it all.

You shove pain patients into one large group, including those on the streets doing drugs, and selling them.

We are in chronic pain that you are making worse. You have taken away our pain medications that helped us maintain a semblance of a life. You are killing us. Figuratively and literally.

Chronic pain patients deserve to be heard, seen, and given the medications that will help them. Not thrown in the trash, but helped.

Thank you for reading my life story,

Sincerely,

Veronica Clark
3245 State Hwy 32
Wabeno, WI 54566
rice_reggie92@yahoo.com

From: victoryevermore@protonmail.com
To: NCIPCBSC (CDC)
Subject: NOTHING FOR PAIN after SURGERY?!
Date: Sunday, July 18, 2021 2:19:30 AM

In December 2017,

My surgeon released me from the hospital telling me to take IBUPROFEN for POST-OP SURGERY PAIN, due to some pain medication guidelines. I hope whoever caused that cruel, callous decision WALKS A MILE IN MY SHOES. I'm sorry, but this makes me so angry. Plus, my friend who has had 9 BACK SURGERIES after being PERMANENTLY INJURED working as a FIRST RESPONDER and is 90% BED RIDDEN has to get out and go to the doctor MORE OFTEN because someone treats him like he's a potential CRIMINAL. No, being cruel to patients like this is CRIMINAL. That's all I've got to say!!!

From: V K
To: NCIPCBSC (CDC)
Subject: BSC/NCIP CDC's Board of Scientific Counselors of the National Center for Injury Prevention and Control
Date: Thursday, July 22, 2021 9:22:36 PM

Dear CDC's Board of Scientific Counselors of the National Center for Injury Prevention and Control Members:

I attended the open meeting last Friday, July 16, 2021. Thank you for allowing us to be part of your research and for the transparency offered.

On behalf of the people who have suffered the effects of PROP's devastating war on patients, I welcome any input from the AMA. Or any other group that is willing to stand up to self-appointed opioid czars.

Intractable pain patients along with the AMA concurrently repudiates the CDC's pain treatment recommendations on opioid dose and duration for several reasons:

* Exactly who asked PROP for advice?
* Is PROP qualified to give advice?
* Who can explain how PROP, a Non Government Organization with no official capacity, became intimately involved in the CDC's misguided effort to regulate opioid drugs.
* Are there any undisclosed conflicts of interest that have played a part in PROP's involvement?
Please explain why the CDC is involved in any aspect of the regulation of drugs or what gives the agency either the authority or expertise to do so?

The "guidance" itself is medically unsound because it is based on faulty science in that it fails to take even the most fundamental principles of pharmacology into account. It should be-soundly repudiated. All PROP's responses contains the same trickery, clever words and cherry-picking of data that has characterized virtually all communications from PROP dating back to the time the group was formed.

It may be concerning to PROP but that does not make it true. A three-year 2019 Massachusetts study concluded that a prescription opioid was found in only 16.5% of people who died from an opioid overdose (the rest being heroin and illicit fentanyl and its analogs) and that only 1.3% of overdose deaths arose from the drug that matched the prescription given to the patient. How is this consistent with a prescription drug-driven epidemic?

Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing.

The recommendations were, for the most part, applied, not misapplied as strict limits. How else can PROP account for different legal restrictions of opioid dosage, number of pills, or both, in 40+ States?
Did PROP play a part in influencing state legislatures? If so, why?
If PROP were so concerned about the "misapplication" of their "advice" why have we not heard one word from the group about this misapplication over the past six years?

This is mind-boggling. PROP's "suggestions" and subsequent CDC "advice" has led to a widespread and involuntary tapering of opioid doses regardless of whether the pain patients had been functioning well for years, if not decades, on high-dose opioid therapy. Involuntary tapering sounds more like a practice that might be used in a concentration camp than medical policy in the United States.

Who other than doctors should make the determination of "the right indications?"

PROP has made sure that opioids are not available for the right indications and frequently any indications. Perhaps PROP should share with us the statistics concerning the number of physicians who have left the field of pain management and how this alone has contributed mightily to patient suffering.

"How many? Five? Hundred? Thousands? Has PROP polled a large group of physicians and collected data to support this contention?

Does this also include the physicians who have been persecuted by a runaway DEA and state medical boards because they may have prescribed more than the PROP "recommendations?"
And PROP is presumptuous to think that it represents other physicians who also want responsible opioid use.

I challenge PROP to demonstrate that a maximum daily dose of 90 Morphine Milligram Equivalents is based on any evidence whatsoever. Where did this number come from? Does it take into account rapid opioid metabolizers? Slow opioid metabolizers? Is metabolism or personal history of individual patients even considered when establishing a maximum dose? Why should government, let alone a Non Government Organization, even establish such a number, especially since it is the antithesis of personalized medicine.

Although long overdue, perhaps it can be taken as a sign that the FDA will no longer roll over and play dead when it comes to the institution and science of drug policy.

But the damage done by this rogue group will not be easily undone.

Given this, at a minimum, PROP should NO longer enjoy a prominent role in guiding future opioid policy in the United States. This is a particularly urgent concern, as Roger Chou has been linked to authorship of CDC’s New Pain Guidelines, and at the meeting he recused himself of participating. Beyond limiting PROP’s role in developing future, potentially harmful opioid policy, a reasonable individual would be justified in wondering to what extent PROP bears culpability for the harms that arose from misapplications of the 2016 CDC Pain Guidelines.

It is more likely than not that PROP’s efforts to affect opioid policy helped shape the CDC Guidelines, which CDC has admitted were misapplied harmfully. It is also more likely than not that PROP’s performative advocacy efforts contributed to misapplication of the CDC Guidelines.

Veronica Kramer
jav_chaho@yahoo.com

From: Veronica Noechel
To: NCIPCBSC (CDC)
Subject: Please consider the lives of chronic pain patients when drafting the Updated Draft Opioid Prescribing Guideline
Date: Thursday, July 22, 2021 2:44:07 PM

Dear committee members,

Please make an effort to change the 2016 guidelines to improve pain care in our country. The American Medical Association, and numerous other pain management specialty organizations and medical personnel guilds have come together to voice their concerns regarding the damage these guidelines have caused to people suffering chronic intractable pain. Since these guidelines were released there has been a disturbing increase in suicides among chronic pain patients who were stable prior to having the changes inflicted upon them. Many others have lost significant quality of life at the behest of these guidelines. Others have sustained, but gone through hell to regain their lives after the guidelines hit, causing their doctors to drop them, insurance companies to suddenly refuse to cover effective, safely monitored opioid medications they've relied on for years, had pharmacies refuse to fill legitimate prescriptions or simply stop carrying those medications altogether. Desperate patients have been forced into trying dangerous and invasive treatments, including absolute quackery, in an effort to find some relief from the debilitating pain they live with. Some have even turned to illegal drugs when their doctors have failed to help them. Human Rights Watch has noted that these guidelines are a terrible violation of patients' rights--surely being accused of such horrific human rights abuses is an international embarrassment to our country. How can we continue to treat our citizens with this sort of callous disregard for their most basic needs?

As a person with chronic intractable pain, I live in constant fear since the 2016 guidelines were released. I am terrified that I will have my life destroyed a third time...the first time, it was by the diseases and disorders that attacked my body (Ehlers-Danlos Syndrome, degenerative disk disease, with suspected TMJ and slipping rib syndrome). I had to rebuild my life into something very different from what it looked like before the symptoms hit. I lost my life as a dog trainer, my love of bowling, yoga, and other physical activities, and I lost my life's work running an animal rescue organization, my way of making the world a better place. I lost my ability to do artists' residencies and live poetry readings. My life collapsed. With help from my doctors and opioid medications, I was able to build a life again. Yes, it was lived from a 45 degree reclining position most of the time, but I could still do my writing, I took up paper crafting, and I could still foster an animal or two for rescue in my home. I could go out of the house maybe once a week to see a movie or go to a card making class.

Then the 2016 guidelines were released. That was the second time my life was destroyed. I can't begin to cover all the details here, but I became bedridden. I could no longer do physical therapy, or even take care of myself without great assistance. I vomited from the pain. I suffered allergic reactions to the meds they tried replacing my regular opioids with. Through all of this I had to try to find new doctors, new pharmacies, again and again as the rules kept changing. I learned of new suicides each week as people in support groups I relied upon took their lives when they couldn't find any relief without the medicines they'd been stable on for decades. It took a lot of trial and error, research on my part, some risky, invasive procedures I never should have had to endure, some quackery I also never should have been exposed to and wouldn't have been without the desperation caused by the 2016 guidelines, hiring a patient's advocate (I was one of the lucky ones who could afford this pricey service.), and eventually finding a doctor who was willing to fight for me. It took years but gradually I rebuilt my life, though I still lost a lot. Being able to resume some of my opioid meds and finding some other meds that had a lot more side effects than the opioids I used to be on, gradually allowed me to return to physical therapy, occasionally get out of the house (though mostly just to lie on friends' couches), and do some socializing when friends could come see me, and do a bit of professional writing from home. It’s expensive. I have to pay out of pocket for some of my meds now. I had to hire house cleaners to regularly come into my home because I can no longer do basic chores. It's hard, it's not even the life I made after the diseases took so much from me, but I can live with what little quality of life the CDC left behind. If I have to lose more a third time? I just don't know. How many hits can the chronically ill and pained take? How much have I left for the CDC to take from me?

Please. Revise the guidelines with effective pain management in mind. Stable chronic pain patients who have safely been utilizing opioid medications for decades should not endure risky, ineffective alternatives that simply do not work. Controlling pain is like a game of Jenga. You build your pain management plan out of many pieces, many therapies, many meds, many treatments, many day to day tricks that help a little. When you restrict opioids arbitrarily, you pull the base out from under this carefully constructed, elaborate structure that has been working to keep the pain at a level that stops the screaming, the vomiting, the spams, and allows the patient to read, to write, to focus on a television show, or a computer screen. We aren't asking for a lot. We just don't want to have to choose between incessant torture and dying. My bones dislocate regularly. Could you suffer that sort of injury without effective pain management? Could you do that on a daily basis, in several parts of your body at the same time? Could you read a book or write a novel while that was happening to you? Opioids save lives. They saved mine.

Thank you for reading to the end. I know this is a long letter and I appreciate your time and concern. I hope you will help.

Veronica Noechel

Raleigh, NC USA

CV, publication, sample works, my blog, and more:
http://www.evnoechel.com

From: Vance Snyder
To: NCIPCBSC (CDC)
Subject: Vance Snyder
Date: Thursday, July 22, 2021 8:04:12 PM

I am a 70yo husband of a severe intractable pain patient. I am a Berkeley grad and a U.S. Army-trained physician assistant. I was Forest Tennant's physician assistant from 2004 to 2006. I am so disappointed in the constant roadblocks placed in the way of pain patients trying to effectively treat their pain. I spent 15 years in the direct treatment of heroin addicts, so I believe I understand addiction better than most medical professionals. It seems to me that that addiction and the risks of addiction are poorly understood in regard to effective pain treatment; nearly all severe, intractable are not "addicts" and they are not going to become "addicts". Some people abuse opioids (actually many people) and their travails have made it very difficult for real pain patients to achieve relief of their pain. Frankly, I am very pessimistic about any resolution of these issues; the opioid crisis is very real and it will probably continue to prevent pain patients from receiving their needed pain medications in amounts that will relieve their pain. I hope I am am wrong.

Sent from my iPad

From: vickyvulc vulc
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:08:58 PM

The Opioid Prescribing Guidelines have done nothing but harm.
Within a year of Guideline publication, there was evidence of widespread misapplication of some of the Guideline recommendations.
Many doctors and regulators incorrectly believed that the CDC established a threshold of 90 MME as a de facto daily dose limit.
Soon, clinicians prescribing higher doses, pharmacists dispensing them, and patients taking them came under suspicion.
Patients have endured not only unnecessary suffering, but some have turned to suicide or illicit substance use.
Others have experienced preventable hospitalizations or medical deterioration in part because insurers, regulators and other parties have deployed the 90 MME threshold as a both a professional standard and a threshold for professional suspicion.
The CDC has a moral imperative to uphold its avowed goals and to protect patients.
A dedicated effort must be made to undo the damage from the misapplication of the CDC Guideline.
The CDC must acknowledge that many patients experience pain that is not well controlled, substantially impairs their quality of life and/or functional status, stigmatizes them, and could be managed with more compassionate patient care.
The CDC must urge state legislatures, payers, pharmacy chains, pharmacy benefit management companies, and all other stakeholders to immediately suspend use of the CDC Guideline as an arbitrary policy to limit, discontinue or taper a patient’s opioid therapy.

Vicky Vulc
Caregiver and Pain Patient Advocate.

From: BUTTERFLY FREE"SPIRIT
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:48:15 PM

My name is Ms. Venessa Walker, I am a 66 yr. Old Southern Lady , I have multiple disabilities an all are 'SERIOUS' 'PAIN' ALL THE TIME, of which I did not inflict upon myself. The scariest is the fact that they can Comatose me at any given time. I have to beg for pain medication, & then my pain meds were cut from 120 tablets a month to 90 per month, from 100mg tablets to 75mg tablets. I only have one pain tablet , one tube of Emmla Cream , that's it. My whole body hurts , but because some people abuse pain meds I have to suffer. REFLEXOLOGY , Body Massages, COMPOUND PAIN CREAM ,would help tremendously, but Medicare & Medicade don't cover those things, an I can't afford what could benefit me because my income is $840.00 a month. SO, my request to is is on the grounds of "MERCY" , I ask you for that, do not take away what little I have , and I ask for 'GRACE' TO SUPPLY WHAT I NEED" , to stay on this side of the dirt , a little while longer. Please feel free to contact me , or, better yet, come an sit with me an see an hear what pain life Looks & Sounds like. My telephone # 609-251-9566, or e-mail : pookielovesyah@gmail.com. May THE' SOVEREIGN' TRINITY' BLESS' you as ONLY' THEY' CAN'. IN' CHRIST' NAME' AMEN' . . 7/22/2021.

From: WILLIAM ARENDT
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 2:20:40 PM

I realize the value of the use of opioids for chronic pain, from such conditions as Ehlers-Danlos syndrome which one of my daughters deals with. Taking opioids when you are dealing with chronic pain does not make you an addict; it gives you the chance to have a normal life.
Sincerely,
Sarah Arendt

Sent from my iPad

Wendy R. Burnett
Certified Occupational Therapist
215 West 98 Street
New York, NY 10025

July 23, 2021

Re: BSC/NCIPC Comments

IPS, Intractable Pain Syndrome, is defined by Forest Tennant MD of the Intractable Pain and Education Project of the Tennant Foundation is "Constant Incurable Pain causing measurable cardiovascular, endocrine and autoimmune complications." One of the syndromes listed as causing IPS is arachnoiditis. I have the misfortune of having an intimate relationship with it and high dose opioids as well as other medical therapies which enable me to control the pain and to function.

My life was inexorably changed in 1972 as the result of an auto accident, when a contrast medium, Pantopaque, was injected into my spinal fluid before surgery. It caused an inflammatory response where the nerves floating in the cauda equina began to adhere together and subsequently to the walls of the dura. Pain in both legs gradually increased as did the milligrams of hydromorphone and oxycontin needed to control it.

I am fortunate to have an excellent medical team and pain management doctor (Chief of Pain Management at a major NY research hospital) who have managed my care for many years.

Although my medicines are prescribed by and monitored by my physicians, I have periodic problems when dealing with some drug dispensers. As an example, when recently hospitalized with a fractured femur I had a problem when the hospital pharmacy unilaterally refused to dispense the opioids required to control my pain -- presumably fearing that I would overdose. I have had to use an oximeter to make sure that my oxygen level was sufficient.

Every year I am required to have my pain doctor write a letter of medical necessity to justify the high level of opioids that he prescribes to control the pain. I have no idea what my end point is if rigid limitations are placed on use of these drugs. Like all people with IPS, I live with fear everyday -- fear that well-intentioned regulators will establish guidelines that will make it impossible for me to function and have a passable quality of life.

Wendy R. Burnett, OT

Wendy R. Burnett
Certified Occupational Therapist
215 West 98 Street
New York, NY 10025

July 23, 2021

Re: BSC/NCIPC Comments

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Every year I am required to have my pain doctor write a letter of medical necessity to justify the high level of opioids that he prescribes to control the pain. I have no idea what my end point is if rigid limitations are placed on use of these drugs. Like all people with IPS, I live with fear everyday -- fear that well-intentioned regulators will establish guidelines that will make it impossible for me to function and have a passable quality of life.

Wendy R. Burnett, OT

From:	wendy costa
To:	NCIPCBSC (CDC)
Subject:	Chronic pain patient
Date:	Monday, July 19, 2021 10:43:55 PM

Good evening,

My name is Wendy Costa, I have been living with RSD/CRPS (Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome) going on 18yrs. I was on extended release Morphine and Roxycodone for breakthrough pain for at least 14 of the 18yrs. I am now stuck taking Suboxone, because too many drug addicts are overdosing. Drug addicts who are mostly overdosing on Fentanyl, Heroin, and Methamphetamine. Since I've been removed from my regular pain med regimen, I've been having to frequent the ER more than I'd like. (The hospital has to administer 2mg of Dilaudid to lower my BP (Blood pressure). I'm not a drug addict, I'm a loving mother, who has a beautiful 1yr old son to take care of. I have enclosed the MC Gill pain scale, in hopes you can understand the pain I'm in 24/7. I have also included a photo of my right foot. Last, I've attached the difference between a drug addict and a pain patient. If you have any questions, feel free to contact me at 401-414-9565.

Thank you

Wendy Costa

From: William Newman
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 12:17:28 PM

I’ve lived in constant pain for over 25 years now. No one could figure out why for the longest time, and treated me like a drug seeker.

An MRI of my neck, after ten years of this, showed why. The disks we damaged (all but one), and yes the pain was real.

Patients are individuals, each with different situations you have no idea about. What makes you think you know best? You don’t, and for the decades you’ve left me stranded in pain: “Go Fuck Yourselves!”, all of you.

Sincerely,
Ssgt(fmr) Wm C Neman Jr
3rd Generation US Veteran
Gold Star Family Member

From: Walter Strickland
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:15:42 PM

Hello, my name is Walter Ray Strickland, I had a car accident in April of 1972. There was damage to my Cervical Spine and after 49 years of all kinds of treatments for chronic pain as well as all kinds of non opioid pain medications I still suffer from chronic pain due to Cervical Discs Desiese in my Cervical Spine at c3-c4-c5-c6-and c7 locations. The quality of life for me would be pretty dismal if it wasn’t for having the opioid pain medication my pain management dr prescribes to me. The constant stabbing and gripping pain in my Cervical Spine won’t stop, it never stops. I am here to tell you that if you have never had to suffer thru your days without any relief from this terrible chronic pain there is no way in the world you could even know how awful it can be to constantly moving your head from side to side and also moving your head around and around to only get that one or two seconds of some kind of a fake relief and then you are made aware that the constant chronic pain is still there and will always be there to torture you for all your days to ware you start to think things you are better off not thinking about. Thank you for your time to read this and please don’t leave us chronic pain patients out of a place where no pain relief is to be found. May God bless and guide you to do the right thing. From a 69 year old Pain Warrior.
Walter Strickland
Sent from my iPhone

From: Walter Wrenn
To: NCIPCBSC (CDC)
Subject: BSC/NCIPC
Date: Saturday, July 17, 2021 12:49:25 PM

It was a pleasure to participate in the meeting but I didn't have a opportunity to express my thoughts to the group live. I recognize the difficulty encountered trying to be clear and understood. The problem is the lack of understanding the pathophysiology of opiates. Opiates like all medication has a mechanism of action and a site where it acts. Like all medication it is eliminated from the body by some mechanism in this case the liver. The pathophysiology is not dose dependent. The speed of metabolism varies from individual to individual . Regardless of whether it is a prescription opiate or street opiate, the physiology is the same. What is the process? In 1803 Morphine was synthesized. Every opiate has the Morphine molecule as part of its formulation. In 1972 the first opiate receptor was discovered. It was the Mu receptor. This receptor is found in the brain and other parts of the body and is the cause of constipation in the GI tract. In the brain it is responsible for euphoria. When opiates are taken it attaches to these receptors and pain is relieved. However depending on the half life of the opiate it leaves the receptor and is detoxified by the liver and eliminated from the body. The first time a person uses a opiate the liver is not familiar with it and detoxification is slow. However with continued use detoxification speeds up and the patient has to raise the dose or increase the time between doses to prevent withdrawal . People unfortunately believe that the individual is chasing the high when in fact he or she is trying to prevent withdrawal symptoms, called dope sickness in the street. There is nothing any health care provider or any guidelines can do to prevent this. It is the way opiates work. We have now discovered other opiate receptors, Delta and Sigma. As a father of a daughter who died at 53 from a drug overdose, I wish that were not true. I also believe that if we legalize drugs more people with substance abuse disorder would be treated. Suboxone at the right dose is the preferred treatment. The CDC has tried to make it clear that these are guidelines not laws or rules. You tried to clarify the misapplication of these guidelines in the June 13 2019 article in the NEJM. Inspite of your efforts the DOJ/DEA have incorrectly used these guidelines to arrest, prosecute, and imprison health care providers. I am such a physician. I had a patient who died in 2019. I prescribed her Oxycodone 20 mg every 4 hours and Morphine Sulfate ER 90 mg daily. She had been on the same regimen and dose for more than 3 years. I had treated her for more than 20 years. I ordered MRI's of he cervical and lumbar spines. I sent her for non surgical treatment of her pain. I sent her to a neurosurgeon as her symptoms didn't improve. She was operated on. Post op she developed foot drop,urinary and bowel incontinence and a increase in her pain. At the time of her death she was found to have cocaine in her system. I was charged with Drug Delivery Resulting In Death and involuntary manslaughter among other charges. Everyone knows that a direct cause of death cannot be determined when multiple drugs are found. Nevertheless I was arrested at my home at 7am in the morning on February 17 2021. P Since I practiced in Philadelphia Pennsylvania and lived in NJ, I was imprisoned in Camden County Jail for 7 days waiting for extradition to Pennsylvania. I was held in Philadelphia for 14 more hours waiting for a bail hearing. I was forced to surrender my medical license DEA license and passport. I also had to sign a paper that I would no longer practice medicine. My 27 patients on opiate pain medication couldn't find a physician to prescribe their opiate pain medication. My 275 Suboxone patients had to seek other physicians who didn't share the same philosophy of treatment that, I did . 2 of my Suboxone patients died of a drug overdose while I was incarcerated. My story unfortunately is not unique. This attack on health care professionals is happening all over the country and ur guidelines are the ammunition that is being used. The belief that prescription pain medication is the cause of drug overdose has been completely disproven. The data shows that opiate prescription medication has markedly diminished while death from overdose is at it's highest level.I like many physicians will be taking a plea agreement. I am 80 years old. My wife who I am the sole provider for is paralyzed on her left side. My agreement eliminates jail time. The AG of Pennsylvania who has the highest amount of charges and conviction in the country will have another conviction.

Walter F Wrenn III, M.D

215-237-4933

From: Walter Wrenn
To: NCIPCBSC (CDC)
Subject: CDC Guidelines
Date: Wednesday, July 21, 2021 9:50:13 AM

On July 16 2021 I sat in via zoom on the BCS committee meeting convened to update the 2016 CDC guidelines. The reason for the meeting was an attempt to modify the guidelines due to the widespread misuse of these guidelines. It was apparent that the CDC had no business issuing guidelines in the first place. The FDA is the agency that approves medication for use. The physician or health care provider determines how this medication is prescribed. Because the CDC issued guidelines which were misapplied patients had their medication reduced without their permission, insurance companies started to regulate medication requiring prior authorizations, pharmacy supply companies restricted the quantity of opiate pain medication a pharmacy could receive, physicians were arrested and imprisoned,patients who normally would get opiate pain medication for their condition were denied. Because health care providers who prescribed opiate pain medication were being arrested and jailed and insurance companies were requiring extra work for approval, many health care providers have stopped prescribing opiate pain medication all together. No proposed CDC guideline had consensus. There was disagreements on all 12 newly proposed guidelines. It is obvious to me and most who attended this meeting that the 2016 CDC guidelines as well as the 2022 proposed update are ill-conceived and should be immediately dropped. All Healthcare professionals who have been arrested and or jailed because of these guidelines should be exonerated. Any Healthcare professional who has lost their medical license and DEA license should have them reinstated immediately. Monetary restitution is also in order. That includes the families of those who committed suicide. We all want to do our part to address the lost of life from drug overdose deaths. The recent information
showing a marked increase in overdose deaths in 2020 with prescrition medication found in only 28 percent of those deaths is proof that physicians who prescribed opiate pain medication were never responsible for the opiate epidemic. Illicit drugs then and now are solely responsible for those deaths.

Walter F. Wrenn, III. M.D.

From: ABD 2525
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Thursday, July 22, 2021 8:45:44 PM

It feels strange to ask for help for the millions who can't get out of bed and if they can, only suffer non-stop asking for consideration from people who have never suffered. How can they know the mind numbing pain that many deal with while trying to see something good in life. Making rules to live and die by should be done by people who are going through it themselves, not rich, healthy people who have always enjoyed a comfortable care free life. The pain that people are forced to live with after being denied even short term relief to catch their breath and continue on. Individual responsibility and the freedom to choose what helps, should be a right that Americans. Not taken away because they can't fight back. Non-stop pain is killing people and driving more crazy. More care is given to animals and people invading our country than the Americans that worked to build this country and offered to die in our countries wars. When being forced to be disabled because of someone else's abuse of power is like putting sand in the wound by other's who think they can do no wrong and have never made a bad decision. When in fact you are out of control with the power that you abuse. You are ruining people's lives and their families lives. How would you like to have someone do that to you and your family? Walk a mile in our shoes, then decide to stand down and let people who are going through the worst pain make the decisions. You are not qualified to decide the fate of pain patients because you have a college degree. Forcing people to endure unimaginable pain is not humane. It's what the bad countries leaders do.

From: Zarifa
To: NCIPCBSC (CDC)
Subject: CDC Opioid Guidelines
Date: Thursday, July 22, 2021 11:59:23 PM

All CDC Guidelines must be repealed immediately! Clear evidence of malfeasance and intent to harm as well as intention obfuscation of CDC policy to create the 2016 Guidelines in secrecy as well as intentionally working outside their scope of interest demand that ALL CDC guidelines regarding opioids be repealed!! This is the purview of the FDA!
Illegal drugs are the cause of drastically increased ODs. Addiction is not casually or correlationally related to Rx opioids. ACES, trauma, poverty, lack of access to mental health care, and other factors are the reasons for addiction, substance use, and ODs. Issues that are complicated and costly, but real and demonstrated by evidence. Fight those causes! Stop harming and killing patients!!

From: Alchemy Saga
To: NCIPCBSC (CDC)
Subject: Comments on the latest Prescribing Guidelines
Date: Friday, July 23, 2021 4:43:59 PM

To Whom it may concern,

I am writing to make comments on the revisions to the CDC Opioid Guidelines and Pain Treeatment Guidelines.

I believe that the Guidelines have been influenced too heavily by individuals making recommendations for their own benefit or by abusing the power of their other positions to continue to implement. In particular I feel this way as the Guidelines are- contrary to the insistence of members of the work group- being enforced as law as lawmakers make laws based on the guidelines with no exceptions, and thus interfering unduly with medical practice.

In particular, the participation of:
Roger Chao, who did not disclose conflicts of interest until the most recent meetings, and who through his three positions has been able to effectively decide what studies to approve and what they mean.

Kolodny and Jane Balantyne who had conflicts of interest which they failed to disclose until recently and who's suggestions are still heavily incorporate into the guidelines.

Given all of these undeclared conflicts of interests, which have been present since the beginning and still influence the guidelines in their current forms, I believe they are unsuitable to implement on the general public, particularly as the board does not include any current pain patients from the general population. The fact that all approved studies that the Guidelines are based on consist solely of mild to moderate chronic pain, while deliberately excluding the reality of severe chronic pain is further reasoning to discard the guidelines.

I am a 26 year old with a genetic disorder that has led to severe daily pain, that I can expect to remain constant through my life. The causes of pain are those that cannot be treated through surgery. I do not think that it is right in either a moral or scientific sense that these guidelines are being implemented in a form that does not actually account for cases such as myself, but also does not allow accommodation as the Guidelines are enforced as law.

Nor does the groups insistence that the Guidelines are not enforced as law have any significance in face of the reality that not only are laws being written that limit opioid pain treatment, but insurance companies are enforcing caps on the amount of medication that can be prescribed based on the guidelines- particularly as insurance companies contributed to the severity of the opioid epidemic when it was actually fueled by prescription medication. Professing ignorance or innocence does not deny the reality that the Guidelines are being used as the basis of laws, which patients then suffer the consequences of- and as these laws and policies are based on the guidelines, those who write said guidelines are thus directly responsible for this suffering and deaths that occur.

Additionally, the failure of the guidelines to address that the 'fentanyl' that is currently fueling the epidemic is that of illicit origin- not fentanyl prescribed to pain patients- has increased deaths as people who use illegal, illicit street drugs are unaware of the risks they are taking.

The reality is that the Guidelines have been tainted by those who have sought to profit from what was at one time a prescription epidemic, but has long since become an epidemic fueled by illicit drugs. And yet the guideline and its writers would seek instead to punish those who received their medication through legal, medically monitored means, and who follow their doctors instructions. Also part of this reality is that the board would rather double down on their list of mistakes than admit that their guidelines did not reduce the opioid epidemic, but instead pushed legitimate pain patients into using street drugs or committing suicide, because they refused to relinquish their ableist insistence that the medication was the only reason that pain patients were not working and providing 'human capital' to the government and the corporations who pay the government to write laws that benefit them.

I request that the Guidelines be dismantled, and be admitted to have been based on flawed- if not outright fabricated- science, and the right of determining correct medical treatment of pain be returned to doctors. The board has proven itself incapable of drafting guidelines to accurately address the problem, without bias, and without causing undue harm to one demographic for the sake of another.

From: Chronic Pain Voices
To: NCIPCBSC (CDC); Chronic Pain Voices
Subject: 2016 CDC Opioid Revision Draft Recommendations July 23, 2021 comments
Date: Friday, July 23, 2021 4:43:21 PM

Hello. We appreciate your time to hear from pain patients concerning the restrictive 2016 CDC Opioid Guidelines. We strongly request the current guidelines be rescinded due to the unnecessary suffering & harms to chronic & acute patients. Instilling misery on tens of millions is unconsciousable. Whether they are "legacy" chronic pain patients patients, acute & postop surgical pts , trauma pts, cancer pts in active & post cancer patients, Sickle Cell Disease & other painful diseases/conditions/illnesses or Veterans etc etc - severe harm is being done to them in the name of the "greater good". Greater good of whom - surly not any of these people mentioned in the past present or future. This madness must STOP. While you say this was "unintended," it was not unforeseeable nor is it unforeseeable in the future.

Patients are loosing access to their life saving medications by doctors, pharmacists, hospitals etc due to the guidelines fueling this false narrative "opioids are bad " or from the very real fear they'll be arrested. Even good practitioners aren't safe if they don't follow the "volunteer" "suggested" guidelines. You MUST undue this, no matter what you do with the draft.

Saying "oh well they were misapplied "does NOT relieve you of the CDC's responsibility in the past nor future disabilites, deaths & Suicides from forced tapers. Undertreated pain can often be just as horrible as untreated. Many more have been harmed than "saved." Pain prescriptions are at a 20yr low, cut by 44% since 2011 yet OD opioid deaths are at an all time high of 93,000. Only 13,000 were related to pain medications and within that number are suicides & illegal prescription drug use. Telling us it's really a fraction of 13,000 & that OD deaths are really from illegal street drug usage. Yet your entire focus is STILL on pain patients. With this stigma, along with states passing laws based on the guidelines- its literally killing us, forcing pts to find relief from illegal street pain meds or to take their owns lives to escape the extreme pain levels. Fear of the very real possibility of losing one's meds or to 50/90MME is now wrongly connected to addiction while it fuels the stigmatizing & false narrative even more. Some states set laws LOWER. No MME/dosage limits. They aren't scientific - they have no strong evidence in their support.... only "junk science." Rescind the restrictive guidelines & make sure every state follows.

2016 Opioid Guidelines should be also be rescinded for there has been transparency issues from their initial writing along with severe conflicts of interest. Dr Roger Chou, as well of many of the writers, has very close connections with the anti-opioid prescribing group PROP Physicians Responsible Opioid Prescribing. Now we learn he is tied into the funding/payment of these studies that support the guidelines (ex AHRQ). He has not only written but is about to update these recommendations. So he choses the studies that he funds to support his own opinions- this is unethical at best. He not only needs removed from any guidance on opioids, but this puts the entire CDC GL further under a microscope. We request a full Investigation & Congessional Hearings into this unethical behavior, his removal along with the GL being rescinded.

The AMA yesterday talks about all this & the harms , attacks & stigmas placed on all pain patients.
https://www.ama-assn.org/press-center/press-releases/ama-backs-update-cdc-opioid-prescribing-guidelines

Patients aren't "drug seeking" they're "relief seeking " HUGE DIFFERENCE. This also needs told by the CDC & written if you move forward. If you continue with the guidelines we support & agree & endorse the comments & recommendations submitted by the AMA both comments, Richard Red Lawhern, PhD, Jeffrey Singer, MD, Jeffrey Fudin, PharmD, the advisory panel OWG, advocaters &/or speakers -
Kate Nicholson
Tamera Stewart
Bob Sheerin
Mike McAuley
Claudia Merandi
Anne Fuqua
Kristen Ogden
Cindy McCalester
Peter Pischke
Terri Lewis
Shirley Buck

Jessica Minerd-Massey
Andrea Anderson
Maria Higginbotham
Syndee Damrosch
Lauren DeLuca

Part of our comment we are sharing various pain patient's harms caused by the prescribing guidelines. We hear them cry, scream & share their misery and sadly even their suicidal ideations. We don't share private messages to safeguard everyone's trust. If we did - they would be even more disheartening (If that is even possible).

Comments-

"I think I have hit the end of the rope. I can't think anymore or try anymore. I am not planning to do anything to myself but I just need to vent some of this ....feeling. I am so lost in a world I don't understand, I have nightmares everyday about not finding my way or knowing who I am. Last night at 4 am I broke down and took some of the precious meds I do have, the pain was riding a 10 and I couldn't take it. That left me wondering what will happen when there are no more meds. I realized my life has no purpose, I am expendable and living in a world that just wants me gone. The general public that think they are so above propaganda has swallowed the "drugs are bad" hook, line and sinker. Even at the expense of their family, friends and neighbors they stand by and watch and say how sorry they are but do nothing. I know I will end up deleting this but I just had to say it out loud."

"Why is this so hard for politicians and people like (Andrew) Kolodny to understand. I don’t want to get high or escape. I want to control my pain enough so I can go to work and take care of my family. No one gets hurt because I get my pain meds. A lot of people get hurt if I can’t work. "

"I was told by Walgreens that I can't get my hydrocodone filled because they had given out their quota of opioids for this time of the year. They couldn't/wouldn't say when they may be able to fill it. They said the DEA has new rules that they have to follow. Kroger pharmacy isn't taking new opioid patients' prescriptions. Walmart said they can't fill it. The people who take pain meds for fun are ruining it for chronic pain sufferers."

"Warren, Klouachar and other Senators need to remove the bills they have written. These Senators got Billions in Taxpayer Funding for a Fake Prescription Opioid Crisis based on inflated numbers and flawed data. In addition to that Warren and numerous others sued everyone they
could target with a member of Prop being paid to testify as a Consultant. They knew the numbers were inflated because the CDC Warned not to use the 2016 Guidelines or set mg limit and they still sued and got Billions in lawsuits and Warren still wanted to go after the Families"

"in a dying patient, how are they going to become addicted?! Use some common sense! "

Response to Andrew Kolodny PROP founder "Suicides by chronic pain patients is totally bogus" response -
"So when a person commits suicide a year after being abandoned by their doctor. How does his comment apply ?"

"I am PLEADING as a professional health care provider and the spouse of a paid Fire Captain and Homeland Security employee who sustained a severe injury and lives daily with the resulting agony. “My life will not be tolerable without the small bit of medicine I’m allowed, I will be forced to permanently end my nonstop suffering!”He GAVE so MUCH to so manyand ABSOLUTELY does NOT deserve the terror he undergoes just to be able to get his
medication! PLEASE, PLEASEHELP CEASE THE INHUMANETREATMENT OF INNOCENT PATIENTS!! I Thank You Graciously!"

""I want stats on the parallel of suicides/suffering going UP alongside the decline in PRESCRIPTION MEDS vs ILLEGAL DRUGS. They are lumped together for the infamous "opioid crisis."

"I hope the Sacklers NEVER back down -- there are 1 million+ chronic pain patients that used OxyContin with enormous success and zero addiction issues --I ceased taking it when they reformulated and didn't realize what had been done - my life just ceased 99% and I didn't know why but I NEVER went thru withdrawals or others; just indescribable pain for >90 days - inhumane care & treatment & notification by the Pharmacist "Oh by the way, the medication you have successfully used for 10 years has been changed - let us know if you have any problems" was NEVER heard - didn't read about THAT in the newspaper or hear it on TV - - thought I was going to die as no one should ever be in that much for >90 days nor should the govt be telling Purdue/Saclers HOW to create their effective medication for legitimate pain. I'm here to support them 100% - - I'd fly wherever to testify on their behalf. The DEA and CDC knew what they were doing - they wanted a Cash Cow like the tobacco companies that paid dearly for 2-3 decades and they thought they had one........at OUR expense. Go Get Em Sacklers - WE are in your corner cheering you on."

"me too. I got tricked into switching to op. What a disaster that was. Thankfully I went back to reg meds at a huge reduction and haven't worked or had a normal day since. That was 2016. Then I lost more than half of those in 2019 and was abandoned in 2020. I rarely leave my home and now get help from family. This is no way to live as an American citizen. My 14th amendment rights are laughable at best by the CDC ,FDA and other agencies. Prop is nothing but an aspiring political entity that should be dissolved."

"I still do it but I pay a severe price for it. Working full time doing heavy labor is killing me but I refuse to let them win. 13 years I had pain control and lived a normal life, 3 years of this BS propaganda is taking its on all of us. We deserve better"

"Yup. Getting to my car is the equivalent of climbing the Hillary Step on Everest"

"The cops don't listen and neither do doctors anymore. I've been a chronic pain patient for over twenty years. They all assume you're an addict."

" HPPA laws.... out the window. My CPP doc of only 3 months had his office raided and ALL his patients' records taken. The gov't violates our privacy laws just by requiring "pain contracts."

"Today is another debilitating Chronic Pain Day "

"This is BARBARIC!!! MENGELE would be pleased."

"Your local and state & federal government. have already judged you too be wanting of being a addict.. There for any pain treatment will turn you in to a uncontrollable addict at once , 59 here and seen the one earlier about the guy that was 89 yr=ears old Crionic pain suffers 89 and i or anyone else is going to worry about him. Shit just keeping him alive is what matters right. and that's pain free as much as possible ."

"It’s been about the $$$ from day one. Even when people committed suicide because of unbearable pain the CDC and Prop with Attorney Generals and Senators sued companies for cash!! The CDC should be investigated along with Prop. Follow the money, the settlements and campaign contributions!"

"This is exactly what my doctor did! She asked how I was doing. My skin disease had been so bad that I hadn't slept in awhile because of the pain. She said I was probably depressed and needed antidepressants! I said you would be depressed too if you were in constant pain and couldn't sleep for months at a time. I said no thanks and left just shaking my head!"

"Often the drugs substituted for actual pain medication have worse side effects that opioids"

"Sadly, the pain community & the APDF Group lost another pain warrior & advocate yesterday, Kimberly Derewenko-Freitas. May she forever be pain free "

"We sadly lost another Chronic Pain Patient CPP - Erin Gilmer, An Attorney & Patient Advocate who was abandoned by her doctor. Erin took her own life due to living with excruciating pain"

"a lifetime of being invalidated one would expect to be somewhat desensitized...it didn't turn out that way but instead presented as PTSD...."

"My whole life was taken from me by the opioid paranoia.i am a senior citizen with alot of metal in my back because of a tumor in my spine I am not an addict although I have been treated like one.I am not a criminal though they treated me like that also.this law has made people become invisible and suicidal.i haven’t been out of my house for almost 2 years now not because of covid but because most days my pain is Soo we Xtreme I can’t get out of bed and on my feet .I have died twice this year from my heart stopping.my body starts shitting down after so many nights without sleep from the pain and most nights my prayers are not to wake up in the morning.i want to commit suicide but I can’t cuz my mom killed herself and it devastated me my brothers and sisters and I can’t do that to my kids.so I’m stuck now with no life just existing for more pain and more pain until my body gets tired can’t take anymore pain and shuts down.existing only for pain is not existing I have no life everything I love was taken away my grandbabies my softball riding my motorcycle with my hubby all gone now there is pain in the place of my former life only pain.and I am drowning in pain but no one will teach out their hand to pull me out keep my head above water and save me.please help there’s lots more of us out here and we need someone to be our voice PLEASE."

"My story is Millions of Veterans and non veterans being harmed forced off our prescription pain medicine, we had productive life’s now most are bedridden"

"One reason is people don’t know what to say. So it’s easier for them to either stay away or assume that since you put make up on or got dressed or did something yesterday, that you’re doing just fine. You can’t always see pain! We want to blend in with healthy people. We want to feel like we’re a part of something and forget what we push through constantly. For just a little while...we want to forget and live, because tomorrow is coming and we will have to recover from doing something, from being stronger than normal and for showing up.So yes, we hide our pain. We will smile and live in that moment and it will be a happy memory that we wouldn’t have otherwise had. "

"RIP My heart goes out to her and her Family and Friends. We must continue to make a stand for all the Chronic Pain Patients we have lost and all those who are suffering at the hands of some Prop members that use money to lobby the CDC, Certain Senators and Some AGs using hidden agendas to Profit leaving Chronic Pain Patients to suffer in unbearable 24/7 pain to the point of suicide! "

"or they come right out and tell you they dont care about the negative impact its going to have...
aware...
don't care....very niceThis is all to common these days, while I can understand why doctors worry, their decision not to help with prescribing pain medication is so wrong on so many levels."

"So sick of media intentionally lumping pain rx and illegal narcotics "

"Your group has caused severe pain and suffering to thousands of patients with your BS science. I hope that someday you will all know and feel the pain and suffering that you have caused to, not only the patients, but also their families."

"In response to a Alabama mom facing felony charges for taking pain meds in her last 6 weeks of pregnancy. She had limited functioning without her meds (that she stopped when first pregnant) & she had other small children to take care of. She also informed her OBGYN . Comment- " that headline fishing report tho! In all seriousness, this is insane, infuriating, and terrifying. I have several severe pain conditions that required me to be on round the clock pain meds during my pregnancy. All of my docs were aware and coordinated care, as well as having me consult with neonatal specialists. The delivery hospital was also aware-- my ob/gyn made sure every single nurse and doc on the floor knew what the deal was, that my condition was due to a drunk driver hitting me, and that every step of my pregnancy had been followed and approved by my docs so I wouldn't face any problems regarding my meds. Also, pregnancy makes it impossible to take the other meds used for pain, like gabapentin, and I had to stop getting the dystonia injections as well. Pain meds were my only option and the pain was worse with the elimination of the other meds and the hormone changes. Thankfully, I had the full support and awareness of my docs and hospital team, because the associated stigma is so insanely high. I still had to deal with some incredible ignorance-- I had a NICU nurse tell me I would have to join all sorts of support groups bc my kid was going to have all sorts of issues, which was completely inaccurate and unforgivable coming from a nurse caring for NICU infants-- but generally, the overall response was sympathetic, helpful, and supportive because my docs all coordinated their info and made absolutely certain the delivery hospital knew the story. My son is 8 now. He never had any of the issues the nurse mentioned. My pregnancy was uneventful and normal, as was delivery, even at age 37 and despite 2 prior miscarriages that happened before the pain conditions showed up. My kid is gifted. I cannot imagine having faced this kind of persecution over choosing to have a child while suffering from debilitating and disabling conditions. This kind of discrimination against pain patients, who are supposed to be protected by ADA, is unconscionable. And horrifying."

"As pain patients we are treated as scum, you can be an upstanding citizen, never in trouble and suffer from debilitating conditions and still have to fight to get treatment. I agree this would be a horrible situation to be in and I am so sorry you went through it also. Thank you for your response."

Concerning medical marijuana .....

"I’m worried about how I’m supposed to care for my 80 year old dad and kids on the MM… I might have to only take it at nighttime and just suffer more all day long. This whole prescribing limit thing is disgusting and inhumane! If my kids and my father didn’t need me? I’d be checking out of this world instead of endure this level of under treated pain 24/7.
Oh and btw this doctor had me leave his office yesterday in a neck brace, full back brace, 2 knee braces, 2 ankle braces and I have a brand spanking new TENS unit - I look like I just got into a car accident or something. I feel like I’m forced to do this simply because dr doesn’t want to go over the 90mme. I think I’ll try dispensary CBD but nothing else. The “legal” full spectrum hemp CBD oil I’ve tried is a total joke and waste of money."

"The problem with canabis is muscle control. I can take Norco and go about daily tasks just fine. Not so with cannabis. But Dr's are blind to the differences"

"My doc pushed medical marijuana, too. After he cut me off, I had no choice but to try it. It cost $600/month and made me deathly ill. A big nope for me. I hope you can work this out"

"I worked 35 years construction and only allowed less than 40 mme for I'm on SSI and they would not give me SSD I paid into."

"My pain meds got cut to over half of what I had been on for 20 yrs when these CDC guidelines started! My pm doctor hates these changes also but his hands are tied! Life has been unbearable since! I feel like our lives doesn't matter and descriminated against! Medical marijuana didn't do anything for me other than give me bad muscle spasms. I also didn't like feeling so high constantly. I can't function like that nor can I function without proper pain treatment!I'm so sorry yours were stopped all together! I was lucky to have a very compassionate pm doctor for over 20 yrs and he dropped me down to the 90 MME limit which has been hell on me! Not a day goes by that I think, what if I need surgery or break a bone. Nobody is going to give me any extra pain meds! I could understand new patients on the 90 MME limits but us long time Chronic pain patients that never broke the rules got thrown under the bus!"

"Even my pharmacist admits the conversions dont work like they are written on paper."

"I recently had a c-section and after the first day all they recommended was Tylenol and Motrin. I had to specifically ask for something stronger because I was in so much pain and it made me feel shameful and guilty because it wasn’t their norm. "

"Please do the right thing. My grandmother is 70 and she is very healthy, but her chronic pain is going to be the reason she quits getting out of bed. She has been to several doctors trying to find answers and she has been labeled as “drug seeking”. She is not “Drug Seeking”. She is Relief Seeking. All she wants to do is make it through a little league game for my kids. She can’t do it. She can’t finish her shopping. She has had 5 knee replacements and needs another. No doctor will touch her knees. They also won’t treat her pain. This is neglect."

Thank you for listening. Now we pray you take immediate action to STOP the pain patient crisis that's has been the result of the CDC Guidelines. HELP THE PEOPLE -STOP THE STIGMA & PATIENT DEATHS WHILE FIGHTING ILLEGAL STREET DRUGS. YOU CAN HELP THOSE WITH ADDICTION WITHOUT HARMING OTHERS BY REMOVING THEIR FUNCTIONING, QUALITY OF LIFE & HOPE.

Chronic Pain Voices

From: Amy Monahan-Curtis
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:40:58 PM

I have been a chronic pain patient since 1993 with cervical dystonia, a neurological disorder in the same family as Parkinson's that causes chronic pain and constant muscle spasms. I was disabled from this disorder in 2013. I was never prescribed opioid pain medication until 2008 as a patient under the care of a pain management physician (in conjunction with other therapies,) going against the myth that opioids were often and frequently prescribed as a first-line treatment.

I am one of the lucky chronic pain patients to still have pain medication treatment since the advent of the draconian 2016 CDC "guidelines." I still have been negatively affected. My pain management physician now only prescribes an extended release patch for me and a muscle relaxer. He cut an immediate release pain medication tablet that was used for extreme breakthrough pain, citing he could not write two opioid scripts for me. He explained the DEA would flag his prescribing rates per CDC "guidelines" and he needed to keep scripts as low as possible. The change in my medication had nothing to do with a change in my medical condition, diagnosis or prognosis. He even cut one muscle relaxer citing the same problem. This was two years after the CDC "guidelines." Due to the reductions in my medication, the increase in pain led me to the only solution I could think of to help alleviate pain and make up the gap for the medications my doctor discontinued, fearing the DEA following CDC "guidelines." I began to drink alcohol to help with physical pain. (Mind you I continued to also make use of botox injections for my muscles, PT exercises, massage, TENS unit, psychotherapy, meditation, heat, ice, etc. from a lengthy list of treatments attempted prior, during and after being prescribed opioids.) Drinking led to further health issues with my pancreas, and another option was taken away for pain control and more damage done to my health.

Also since the guidelines were implemented, a pharmacist, citing the MME "recommendation," and who knew nothing of my condition, medical history or medication history, refused to fill my valid pain medication script after holding it for 8 hours. She was simply "uncomfortable" with the dose. I went into withdrawal with no recourse.

I agonize before every appointment that this will be the time my doctor says he can no longer prescribe my remaining pain medication. It is a crucial part of my treatment and without it I will go from being 75 percent bedridden to 100 percent bedridden.

Going forward, it is necessary the guidelines are explicitly about the benefits and positive outcomes opioids can and do have for millions of chronic pain patients.

Opioid pain medication cannot just be advised for certain types of pain, (sickle cell, cancer, end of life,) which creates exclusionary care. An arbitrary 90 MME dosage fits no one, yet has now been legislated and made into policy that harms millions, forcing medication tapers for no therapeutic reason. Patients cannot be blamed for an addiction crisis through such guidelines when numbers do not bear out that chronic pain patients become addicts, nor are overdoses coming from prescription opioids.

Stakeholders in the chronic pain patient community, physicians and patients, need to be a strong part of the committee deciding these revisions, especially based on the direct harms from the 2016 guidelines - uncalled for medication tapers, removals, loss of physicians that will even offer pain care and patients dying by suicide. We are in a state of emergency and have been since the 2016 guidelines were enacted. Those guidelines have created another type of opioid crisis.

From: sheryl s
To: NCIPCBSC (CDC)
Subject: Comment on Updated Guideline
Date: Friday, July 23, 2021 4:40:54 PM
Attachments: CDC.docx

Good afternoon,

Please, include my comment with the Opioid Work Group’s report to the CDC on the recommendations for the updated guideline.

My name Is Sheryl Freed. I am a member of the RSDSA Advocacy Committee. I am a chronic pain patient. These words are my own.

I have been on and off opioids since I was diagnosed with Complex Regional Pain Syndrome (CRPS) in 1997. Some worked well for me for a while, and others have not. Currently, I am not taking any opioids. However, I am sharing my feelings today for the members of the chronic pain community who have no longer have a voice and for those, including myself, who have suffered as a result of these guidelines.

The pandemic brought to light just how important the treatment of chronic pain is. Suicides among Chronic Pain Patients have increased. Some of these suicides have been the direct result of the prescribing guidelines which named only a few medical conditions. CRPS was not a named disease. CRPS pain is excruciating and intractable. CRPS rates higher on the McGill Pain Scale, 42/50, than even cancer which was named. It is currently the most painful condition known to man. It is the nicknamed The Suicide Disease.

When access to life changing medications is limited, quotas initiated, and patients are forced to taper, some patients are so desperate they feel they are left with no other options. I open my Facebook feed everyday and pray that I do not see that another fellow pain warrior has taken their own life. The week prior to this meeting, I awoke to learn that three of my fellow CRPS friends had passed away at least two were suicides. It saddens me that I have actually lost count of how many we have lost, mostly to suicide, this year alone. Each of these people was someone’s child, sibling, parent, friend. Their lives ended because of a war on drugs where we are uncounted casualties. Their lives are no less important than the addicts who overdose. This is the other side of the opioid crisis.

Opioids, when used properly, can improve quality of life. They can mean a life in bed writhing in pain or being able to function. They can mean the difference between disability and the ability to work. They can give people hope and the ability to get up and face another day when they live with a rare, progressive, and incurable disease.

The Work Group touched on the fact that certain individuals have had their pain minimized or dismissed altogether based on gender, race, cognitive impairment, or whether a patient has ever experienced domestic violence or mental illness. I implore that care in wording be taken into account because some medical professionals are using this verbiage as a checklist to limit access to what could be life changing medications. The more boxes that are ticked off, the less likely a patient is to receive opioids or have their pain acknowledged. Does a woman of color with autism who has been abused by a spouse and is depressed because of it deserve to feel less relief from their physical pain than anyone else? I can check off some of those boxes, so just by being a chronic pain patient, I am, at times, treated as an addicted drug seeker when I arrive at the emergency room even if I am there for a reason other than pain and even if I have not asked for pain medication.

The current guidelines have caused blanket limits to prescribing. Many times discharge instructions recommend a follow-up appointment within one to three days. In real world conditions, upon post-operative and emergency department discharge, it can take weeks to get an appointment. Sometimes the wait is even longer if a patient is new to the practice. A patient is given only enough medication to get to that unreasonable and unattainable date. This can leave them in a situation where their pain is uncontrolled, requiring yet another visit to the hospital.

Doctors and pharmacist should not fear for their jobs when trying to provide safe and responsible care to their patients.

These guidelines have resulted in dehumanizing treatment of us all. I pray that you and your loved ones never have to experience the stigma of chronic pain.

Thank you for allowing me this opportunity to express my concerns.

Sheryl Freed
RSDSA Advocate
CRPS Patient

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Sheryl Freed
RSDSA Advocate
CRPS Patient

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July 22, 2021

Gwendolyn H. Cattledge, Ph.D., M.S.E.H.
Deputy Associate Director for Science, NCIPC, CDC
4770 Buford Highway NE, Mailstop S-1069
Atlanta, GA 30341-3717

Submitted electronically via email (ncipcbsc@cdc.gov)

Re: FR Doc. 2021–11771; Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)

Dear Ms. Cattledge,

We appreciate the opportunity to provide comments related to ongoing efforts around the draft Guideline for Prescribing Opioids and report from the Board of Scientific Counselors (BSC) Opioid workgroup, including the relationship between the opioid crisis and pain management.

Medtronic, the world's leading medical technology company, has been involved in the study and treatment of pain for more than 40 years. We have a broad portfolio of device-delivered pain therapies, including targeted (intrathecal) drug delivery (TDD) and spinal cord stimulation (SCS) which have benefited hundreds of thousands of patients worldwide. SCS is a technology implanted under the skin to deliver mild electrical pulses to the spine, modifying pain messages before they reach the brain, and has proven to provide long-term effective pain relief and improve quality of life.[1,2] TDD is an implanted pump and catheter, programmed by a physician, that releases prescribed amounts of pain medication directly into the intrathecal space, near pain receptors in the spine instead of the circulatory system (at a fraction of the oral medication dose).

These therapies, both approved by the U.S. Food and Drug Administration (FDA), enable healthcare providers to help their patients manage chronic pain and, in some cases, reduce or eliminate the overall use of systemic (oral and patch) opioids. We have attached a white paper entitled "Using Medical Technology to Relieve Pain and Disrupt the Opioid Epidemic" which provides further information and citations on these therapies. Medtronic also leads in the development of technologies used in minimally invasive surgery (MIS), which have been shown to reduce post-surgical (acute) pain and is associated with reduced need for prolonged post-surgical opioid use, as well as reduced readmissions, surgical site infection, and length of stay.[3-5]

As you know, in 2016 the CDC updated a prior Agency for Healthcare Research and Quality (AHRQ)-sponsored systematic literature review of the effectiveness and risks of long term opioid use in the management of chronic pain conditions.[6,7] This review provided the framework for the widely implemented CDC guidelines for systemic opioid prescribing.[6] While the guidelines are comprehensive, they fall short of extending recommendations for alternative interventional management options for patients with uncontrolled pain who have a history of chronic use of systemic opioids.[6] Subsequently, in 2018 the FDA released an updated opioid education Blueprint that includes statements around the use of approved/cleared medical devices, which are often classified as "interventional" therapies, for pain management.[8] The FDA cited medical devices as one category of non-pharmacologic treatment options healthcare providers should be knowledgeable about as part of a multidisciplinary approach to pain management.[8]

In addition, on May 9, 2019 the U.S. Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force (Task Force) published its Final Report on "Pain Management Best Practices: Updates, Gaps, Inconsistencies and Recommendations." The Task Force specifically outlined interventional procedures of spinal cord stimulation, intrathecal pain pumps, and vertebral augmentation along with several other procedures that can be considered singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions.[9]

While SCS and TDD do not treat opioid addiction, they are device-based alternatives to traditional pharmacologic management of chronic pain that may reduce the need for systemic opioid use. In addition to effective pain relief, TDD has been shown to reduce or eliminate use of oral pain medication and to reduce side effects compared to systemic pain medication.[10-15] Two large retrospective analyses of commercial insurance claims data found that 43-51 percent of chronic non-malignant pain patients eliminated systemic opioids within one year of initiating TDD therapy.[14,15] Among patients that eliminated systemic opioids, total per patient payer cost savings (both medical and pharmacy) in the year following start of TDD therapy were $11,115 relative to patients with TDD who remained on systemic therapy.[14]

With regard to SCS, multiple studies have provided clinical evidence to suggest some patients treated with SCS may be able to reduce oral opioid consumption.[16-19] One large study of more than 5,000 patients showed that 22 percent discontinued and 20 percent reduced opioid use after starting SCS, with payer costs significantly reduced in both years of follow-up vs. one year before start of therapy (excluding the up-front cost of the device).[19] A review of cost studies has also shown that SCS therapy is cost effective among patients with chronic low back pain when compared to conventional medical management or re-operation.[20]

We believe that sound patient education and preventative consultation earlier in the care continuum plays a meaningful role in preventing opioid misuse and addiction while ensuring patients have their pain addressed. As you work toward continuing to evaluate prescribing guidelines, we hope you will include discussion of medical technologies, including interventional medical therapies like TDD and SCS, in future CDC guidance as a critical step toward ensuring patients and providers are aware of the full spectrum of evidence-based treatment options for pain. Thank you for your consideration of these comments.

Sincerely,

Stephanie Wimmer

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Enclosure

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USING MEDICAL TECHNOLOGY TO RELIEVE PAIN AND DISRUPT THE OPIOID EPIDEMIC

LIFE EXPECTANCY in the United States increased modestly in 2018 by 0.1 years to 78.7 after falling for three years in a row, systemic opioid overdose was identified as a key driver of the decrease in previous years.[13-16]

Misuse Defined[4]
The use of prescription drugs without a prescription or in a manner other than as directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or for longer than told to take a drug; or use in any other way not directed by a doctor.

PERSPECTIVE SYNOPSIS

Millions of Americans are affected by pain and have been prescribed systemic opioids (typically oral) as part of their treatment plan by healthcare providers.[2] In the pain continuum, chronic pain can start with acute pain. Both pain types prompt an urgency of addressing patients' needs, often with systemic opioids. This is despite the limited evidence on the benefits of long-term systemic opioid therapy and evidence that long-term systemic opioid therapy is associated with increased risk for opioid misuse or addiction.[3] Here's what is known about the misuse of prescription opioids:

- An estimated 10.3 million Americans are misusing opioids with 63.6% doing so to relieve physical pain.[5]
- An estimated 25% of chronic pain patients are misusing prescription oral opioids.[6]

> ***"We cannot solve the opioid crisis, until we solve the nation's pain crisis.[1]"***
> -Admiral Brett P. Giroir, M.D.
> Assistant Secretary of Health, US Department of Health and Human Services

A CDC review of scientific evidence yielded many mitigation steps to reduce the risks associated with long-term systemic opioid use, including misuse, addiction and overdose.[7] In its guidelines, the CDC recommends patients with acute pain ask their doctors for treatment options that do not involve prescription opioids.[8] In addition, for chronic pain, CDC recommends nonpharmacologic therapy and nonopioid pharmacologic therapy as preferred treatments.[9] The FDA's updated opioid education Blueprint includes the use of approved/cleared medical devices for pain management as one of several nonpharmacologic treatment options healthcare providers should be knowledgeable about as part of a multidisciplinary approach to pain management.[10] Enacted into law on October 24, 2018, the federal SUPPORT for Patients and Communities Act includes provisions to raise provider and patient awareness of alternative, non-oral opioid pain treatments, including medical device-delivered therapies.[11]

As part of the comprehensive efforts in the United States to address the opioid epidemic, device-delivered therapies are being considered as an alternative or adjunct to systemic opioids in the management of acute and chronic pain. Device-delivered therapies of spinal cord stimulation, intrathecal pain pumps, and vertebral augmentation along with several other procedures have been identified by the U.S. Department of Health and Human Services in The Pain Management Best Practices Inter-Agency Task Force Report as interventional procedures that can be considered

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MICHELSON
TECHNOLOGY
AT WORK

singularly or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions.[12] Through greater awareness and use of device-delivered therapies, healthcare providers can reduce pain for many patients, potentially reducing their exposure to high dose opioid and/or long-term systemic opioid use that could lead to opioid misuse and addiction. As more patients effectively take control of their pain, these patients may no longer need to turn to misusing opioids to attempt to control their pain. This could help disrupt the opioid epidemic.

Burden of mortality is highest among adults aged 25 to 34 years; in this age group, **1 in 5 deaths in the United States is opioid related.**[23]

Medtronic Pain Therapies do not treat opioid addiction, but rather offer patients a way of managing their pain as an alternative or adjunct to systemic opioids. Medtronic has already published clinical evidence that shows reduction in the use of systemic opioids in managing and treating chronic pain with Targeted Drug Delivery (i.e. intrathecal pain pumps) and acute pain associated to vertebral compression fractures (VCF) using Balloon Kyphoplasty[17,18] as a technology for vertebral augmentation. It is important to understand that not every patient experience is the same. We continue to invest in clinical trials designed to generate new evidence to help physicians make more informed pain treatment decisions.

Medtronic supports ongoing efforts by stakeholders across the U.S. – patients, providers, payers, regulators, elected officials, patient advocacy groups, and employers – as they pursue approaches for preventing and treating prescription opioid misuse, addiction, and overdose. Medtronic is playing an important role alongside other stakeholders in helping patients take control of their pain by:

- Informing patients with acute and chronic pain of their options for device-delivered pain relief as an alternative or adjunct to systemic opioids so that patients may have an informed discussion with their doctors.
- Partnering with providers to consider non-systemic opioid pain relief in treatment plans for patients with acute and chronic pain.
- Educating payers, policymakers, and regulators to enable greater patient access to medical devices shown to alleviate pain as an alternative or adjunct to systemic opioids.

$170 BILLION

The economic impact of the opioid crisis in the United States was at least $631 billion from 2015 through 2018 and was estimated to exceed $170 billion annually in 2017 and 2018.[24]

Amongst 500 Human Resource professionals surveyed in America, **67 percent** said their organizations "are impacted by opioid use today or will be in the future," and **65 percent** reported that opioid addiction is having a financial impact on their company.[25]

SYSTEMIC OPIOIDS AND PAIN MANAGEMENT CRISES

There are two interrelated healthcare crises occurring in this area in the United States: the opioid epidemic, and the ongoing public health problem of inadequate pain management.

The Opioid Epidemic

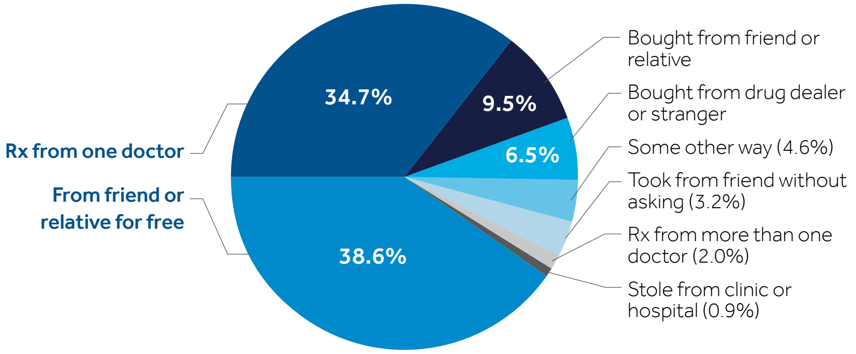
The alarming opioid epidemic has had a devastating impact across the United States with 128 Americans dying every day from an opioid overdose in 2017.[19] In 2018 , opioids were involved in 46,802 overdose deaths and represented 69% of all fatal drug overdoses (67,367).[13,20,21] As a result, public officials declared the opioid epidemic "the worst drug crisis in American history."[22]

Urgency of this epidemic has drawn the attention of all American elected officials and regulators. One area that regulators were quick to look at was prescription opioid use for pain relief and how they were then sourced among people whom misused them. In 2018 , roughly 38% of people whom misused prescription pain relievers obtained them from one or more doctors.[5] In addition to recommendations on prescribing opioids for pain relief, the CDC recommends nonpharmacological therapy and non-opioid pharmacologic therapy as the preferred treatments of chronic pain.[9] If used, prescription opioids should be combined with other therapies, as appropriate.

An estimated **21% to 29%** of patients prescribed opioids for chronic pain misuse them. And, between **8% to 12%** of these patients develop an opioid use disorder.[6]

Source of Pain Relievers obtained by people who had misused prescription Pain Relievers[5]

(Year 2018, 9.9 million people age 12 or older)



Pain Management Problem

The ongoing public health problem of pain management constitutes a crisis of its own.[2] More than 100 million Americans experience chronic pain lasting greater than 3 months, costing the nation approximately $560-635 billion annually in direct medical treatment costs and lost productivity.[2] Millions more experience pain caused by a specific event (e.g. surgery, broken bones, dental work, or childbirth) that may last for 6 months.[26,27]

Although research suggests systemic opioids are effective at reducing pain and improving function in the short term, evidence on long-term systemic opioid therapy for relieving pain is limited.[3,7] Comparisons of opioids with nonopioid alternatives suggested that the benefit for pain and functioning may be similar.[31] CDC has identified long-term prescription opioid use and high daily opioid doses as risk factors that could lead to abuse or overdose.[32] An estimated 10.3 million Americans are misusing opioids with 63.6% doing so to relieve physical pain.[5] Furthermore, risks of prescription systemic opioids are high: prescription systemic opioids contributed to ~32 percent of all U.S. opioid overdose deaths in 2018.[33]

Up to **80 percent** of Americans will experience low back pain at some point in their lifetime.[30]

Patients with chronic pain have voiced their frustration with the inability to access effective pain relief and the devastating sociological impacts this has had on their lives.[34,35] These people are victims of chronic pain and the effects of the opioid epidemic on our society. Patients deserve other options for pain management through access to effective alternate and adjunct pain therapies.

An estimated **19.6 million Americans** in 2016 had high impact chronic pain (pain that limited their life or work activities on most days or every day for 6 months).[29]

INSPIRED TO PROVIDE BETTER PAIN MANAGEMENT

Medtronic has more than a 40-year history of developing innovative medical devices that have been shown to alleviate pain in different disease states.[36] Moreover, we have established expertise to demonstrate clinical outcomes and health economics of these products.

Given the current opioid epidemic and pain management crisis, our work to alleviate pain has never been more critical. That is why we leverage our capabilities and product portfolio in partnership with stakeholders — patients, providers, payers, regulators, elected officials, patient advocacy groups, and employers — to address the unmet needs of pain patients.

We are aware no single entity can solve America's opioid and pain crises alone. It is when we work in partnership that we expand patient access to non-systemic opioid pain management therapies. Therefore, we are pursuing collaboration with others in pain management to:

PAIN
affects more Americans and is costlier than diabetes, heart disease, and cancer.[28]

Broaden Therapy Awareness and Advocacy

- Increase stakeholder **awareness** of the clinical and economic evidence of device-delivered therapies along with the risks of long-term systemic opioid use to treat pain.
- Leverage social media networks, pain advocacy groups, and local treatment clinics to heighten **patient awareness** to device-delivered options that have been shown to treat pain or painful conditions. Only a physician can decide if these therapies are right for a patient.

Deliver Innovation

- Develop **novel payment models** for private and public payers that will help healthcare providers deploy evidence-based clinical workflows, guidelines, and policies for device-delivered therapies to manage pain or painful conditions.
- Explore with industry partners the **use of medical technology** to track objective patient metrics, coupled with clinical workflows, to deliver and monitor non-systemic opioid pain relief.

Advance Clinical and Economic Evidence

- Expand the body of existing **clinical and economic evidence** (independently and through partnerships with providers and payers) on the ability of Medtronic Pain Therapies — coupled with clinical workflows — to reduce or eliminate systemic opioid usage.
- Educate state and federal government officials about the need for **policies to ensure patient access** to the clinical and economic benefits of device-delivered therapies for pain or painful conditions.

MISSION-DRIVEN TECHNOLOGY TO IMPROVE OUTCOMES

With our company mission to alleviate pain, restore health, and extend life, Medtronic strives to be at the forefront of medical device innovation, challenging ourselves to develop high-quality therapies for pain or painful conditions. Our view is that medical technology should not be only for reducing pain, but also for improving quality of life. And at every stage of the process — from technology advancements to physician training — we strive to understand the patient experience through the principles of human-centered design.[37]

The Medtronic Pain Therapies portfolio includes implantable medical devices for Targeted Drug Delivery (TDD) and Spinal Cord Stimulation (SCS) for chronic pain. Our portfolio also includes products indicated for: vertebral augmentation therapies such as Balloon Kyphoplasty (BKP) for vertebral compression fractures (VCF) due to osteoporosis, cancer or benign lesion; OsteocoolTM radiofrequency ablation of painful bone tumors; and Sacroplasty for the treatment of pathological sacral fractures. These minimally invasive technologies treat these conditions, which are associated with acute pain. To date, over a million patients have received treatment from Medtronic Pain Therapies.[38] In addition to the risks of surgery, the medical devices discussed in this paper carry significant risks. Please refer to the important safety information at the end of document.

While these therapies do not treat addiction, they can help patients manage their pain. Medtronic is committed to providing clinical evidence and in studying the use of systemic opioids in managing and treating chronic pain with TDD and acute pain associated to VCF with BKP.[17,18] Through our medical education and ongoing clinical support programs, we continuously strive to educate about device therapies as an option in pain management with the goal that fewer patients will need to rely on long-term systemic opioid use.

Along with clinical evidence demonstrating pain relief, we have strong coverage and reimbursement in the United States for clinical indications recognized and covered by government and non-government payers. For example:

Two retrospective claims analyses found that **43 and 51 percent**, respectively, of chronic non-malignant pain patients eliminated systemic opioids within one year of TDD therapy.[17,47] In the second study which evaluated patients starting TDD therapy between 2012-2015, overall (regardless of discontinuation), **82% reduced** their average daily morphine milligram equivalents (MME) in the year following start of TDD therapy relative to one-year baseline MME values.[47] Among patients that eliminated systemic opioid use, the mean annual per-patient medical and pharmacy **cost savings to the payer in the first year of therapy were $11,115** relative to patients who continued, a **29% reduction**.[47]

A smaller, single-center, retrospective chart review (n=99) of patients with chronic non-malignant pain who agreed to transition from systemic opioids to TDD with the goal of eliminating systemic opioids, demonstrated that **84 percent of patients were able to eliminate systemic opioids after 12 months** when using TDD to relieve their chronic pain.[53]

- TDD and SCS are covered by Medicare under national and local coverage determinations.
- BKP has coverage from all Medicare MAC's via Local Coverage Determinations.
- Most commercial payers have published coverage determinations for all our Medtronic Pain Therapies.

Knowing how and when to use alternative and adjunctive therapies to systemic opioids is more important than ever. That is why, before committing to long-term treatment, physicians will have their patients undergo a trial for some therapies (i.e. TDD and SCS) to experience the therapy.

MEDTRONIC PAIN THERAPIES

Targeted Drug Delivery

Targeted Drug Delivery (TDD) with SynchroMed™II, also known as a pain pump or intrathecal drug delivery system (IDDS), for the treatment of chronic intractable pain, including intractable cancer pain, provides pain relief at a fraction of the oral medication dose.[39-42] An implanted, programmable pump and catheter releases prescribed amounts of pain medication directly into the intrathecal space, near pain receptors in the spine instead of the circulatory system. The CONTROL Workflow℠ in combination with SynchroMed ™II encourages systemic opioid elimination and is an alternative to long-term systemic opioids.

Intrathecal drug delivery has been shown to improve patients' ability to function, return to work, and participate in activities of daily living.[39,41,43,44] In addition to effective pain relief, TDD has been shown to reduce or eliminate use of oral pain medication and to reduce side effects compared to systemic pain medication.[17,39-42,45-47]

TDD is often viewed as a "salvage therapy" when high dose systemic opioid therapy has not worked. This is despite success of the therapy as demonstrated in randomized controlled trials, and the demonstrated cost effectiveness of the therapy.[17,40,48-52]

The implanted pump stores and dispenses medication inside the body, reducing the opportunity for diversion of the drug, for misuse by individuals who are not prescribed the opioids. Additionally, the physician programs the pump to deliver a certain amount of medication, allowing more physician control compared to systemic opioid therapy, reducing the opportunity for misuse of prescribed opioids.

Systemic opioid dose levels prior to initiation of TDD have shown significant correlation with ultimate patient success with TDD. In a retrospective study of 631 patients, those whose MME was < 50 mg/day had two times the odds of discontinuing systemic opioids following initiation of TDD (OR = 2.08, 95% confidence interval 1.42-3.02, p = 0.001).[47] Knowing that systemic dosing levels and intrathecal dose levels matter, Medtronic developed The Control Workflow℠ for TDD providing a pain relief option utilizing a low-dose protocol with the SynchroMed™ II intrathecal drug delivery system and as guidance for eliminating systemic opioids. This workflow assists physicians with patient selection and includes oral opioid weaning and treatment protocols that can be tailored to individual patients. By having an outlined workflow for physicians, we are working to simplify the therapy and expand patient access to TDD therapy.

Medtronic is currently sponsoring the Embrace TDD Post Market Clinical Study that will evaluate the use of the SynchroMed™ II intrathecal drug delivery system as an alternative to oral opioids for patients with chronic intractable non-malignant primary back pain with or without leg pain.[54] The study will follow patients who wean completely from all oral opioids and have a positive response to an intrathecal drug trial. The study will assess pain control and opioid-related side effects at six months following a route of delivery change to intrathecal preservative-free morphine sulfate.

Spinal Cord Stimulation

Medtronic's Intellis™ implantable neurostimulator for Spinal Cord Stimulation (SCS) is the smallest spinal cord stimulator implanted under the skin to deliver mild electrical pulses to the spine. SCS modifies pain messages before they reach the brain and has proven to provide long-term effective pain relief and improve quality of life.[55-57] In addition to pain relief, spinal cord stimulation is more cost-effective than conventional medical management and reoperation.[58,59] Multiple studies have provided clinical evidence to suggest some patients treated with Spinal Cord Stimulation (SCS) may be able to reduce oral opioid consumption.[60-62] Spinal cord stimulation is more effective than repeat surgery for persistent radicular pain after lumbosacral spine surgery.[63]

As a platform technology, Medtronic is providing more than just pain relief with the Intellis neurostimulator. This is the only platform that has embedded measurable activity data through Snapshot™ reporting, which tracks and shares activity, body positions and therapy usage continuously. Snapshot complements patient self-reporting with an objective look at their mobility. By reporting objective activity data, Intellis offers physicians insights into patient treatment beyond patient-reported pain scores. This may enable better treatment personalization to support improvement in function.

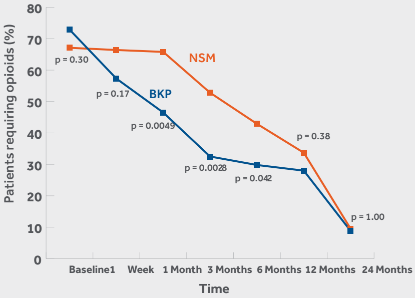
Interventional Pain Therapies

Vertebral compression fractures (VCF) are associated with a downward spiral of complications, including decreased mobility, pain, and function.[18,64-66] While vertebral augmentation (VA) is not for everyone, Balloon Kyphoplasty (BKP) and vertebroplasty (VP) are important treatment options to consider for patients with vertebral compression fractures (VCF) due to osteoporosis, cancer or benign lesion.

Early diagnosis and interventional treatment are important steps to avoiding complications associated with VCFs.[67-69] To help physicians navigate this complex condition, Medtronic is proud to support a VCF multispecialty panel of experts in recommending a clinical care pathway to guide physicians in treating the common condition of vertebral fragility fractures.[70]

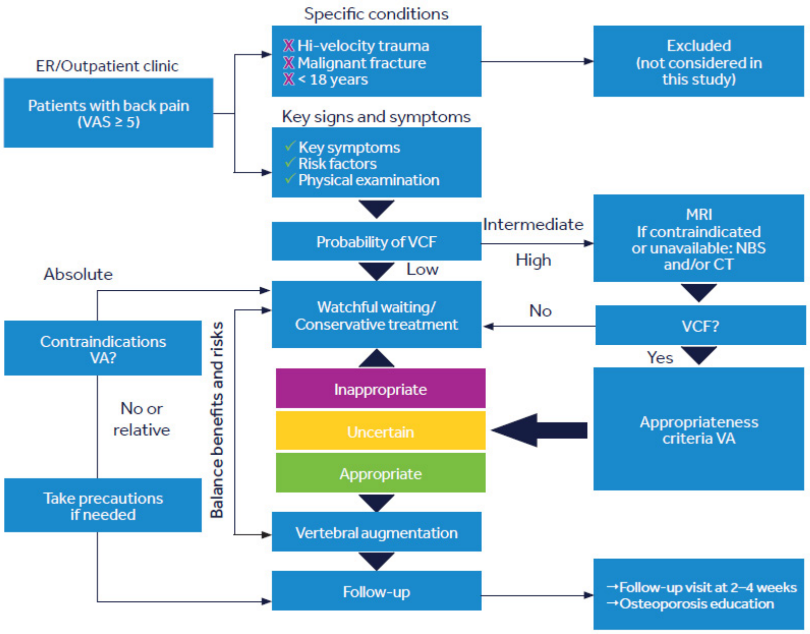
"VCF Clinical Care Pathway" was recently developed by a multi-specialty panel of physicians and published in August 2018. The study – which included a systematic literature review of 83 randomized controlled trials, systematic reviews, and observational studies – aims to support greater consistency in the early diagnosis and treatment of VCFs with a goal to establish a clinical care pathway for patients with VCF to include : Key signs and symptoms of suspected VCF, Diagnostic evaluation of patients with suspected VCF, Appropriateness criteria for vertebral augmentation (VA) or nonsurgical management (NSM) Contraindications for VA and Follow-up after treatment.[70]

A prospective, randomized controlled trial (N = 300), **FREE** study, reported Kyphon™ BKP (n=149) demonstrated **31%** less prescription opioid use at 6 months* compared to non-surgical management (n=151) (29.8% BKP vs. 42.9% NSM, p=0.042)[18]



Kyphon™ BKP demonstrated less opioid use[18]

** Differences between groups were similar in opioid usage at 12 months (28.0% BKP vs. 33.7% NSM, p = 0.38) and 24 months (8.8% BKP vs. 9.5% NSM, p = 1.0).*



VCF Clinical Care Pathway

Kyphon™ Balloon Kyphoplasty (BKP) is a minimally invasive vertebral augmentation technology that uses orthopedic balloons to restore vertebral height and correct angular deformity due to vertebral compression fractures (VCF) from osteoporosis, cancer or benign lesion. After reduction, the balloons are deflated and removed. The resulting cavity (void) allows for a controlled deposition of Kyphon bone cement forming an internal cast and stabilizing the fracture. Risks of the procedure include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events.[18,64-66]

A prospective, randomized controlled trial (Free Study, 2011 N = 300) reported that Kyphon™ Balloon Kyphoplasty offers important clinical benefits compared to non-surgical management, including pain relief, reduced opioid use, and improved quality of life.[18]

TOGETHER TO FIND LASTING SOLUTIONS

Millions of Americans are affected by the opioid epidemic, and their best hope is partners in healthcare coming together to create lasting solutions.[2] Healthcare providers, payers, elected officials, regulators and patient advocacy groups all hold important pieces to the puzzle and must work together. It starts with novel care pathways and personalized treatment options to help these patients break their cycle of misuse or dependency. Solutions must also help the approximately 6.9 million patients who misuse opioids to alleviate pain, and these patients need effective policies and programs that will expand access to medical devices shown to relieve pain as an alternative or adjunct to systemic opioids.[71]

Partnership is the path forward in addressing the systemic opioid and pain management crises. All stakeholders must work together, pursuing effective policies and programs that will expand patient access to medical technologies shown to relieve pain as an alternative or adjunct to systemic opioids.

SynchroMed® II Drug Infusion System Brief Statement:

Review product technical manuals, including information about EMI, and the appropriate drug labeling prior to use for detailed disclosure.

Indications: US: Chronic intrathecal infusion of Infumorph® preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, Prialt® chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Drug Information: Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration, screening procedures, and under-/overdose symptoms and methods of management. Patients should be informed of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions, and signs and symptoms that require medical attention.

Contraindications: System implant is contraindicated in the presence of an infection; implant depth greater than 2.5 cm below skin; insufficient body size; and spinal anomalies. Use of the system with drugs with preservatives and drug formulations with pH ≤3. Use of CAP kit for refills or of refill kit for catheter access and use of PTM to administer opioid to opioid-naïve patients.

Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose.

An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Monitor patients appropriately after refill if a pocket fill is suspected. Failure to recognize signs and symptoms of pocket fill and seek appropriate medical intervention can result in serious injury or death. Overinfusion may lead to underdose or overdose symptoms. Strong sources of electromagnetic interference (EMI) can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. The SynchroMed II system is MR Conditional; consult the labeling for MRI information.

Precautions: Monitor patients after pump or catheter replacement for signs of underdose/overdose. Infuse preservative-free saline at minimum flow rate if therapy is discontinued for an extended period to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions.

Adverse Events: In addition to procedure-related risks, the following may occur: pocket seroma; hematoma; erosion; infection; pump inversion; post-lumbar puncture risks (spinal headache); CSF leak and rare central nervous system pressure-related problems; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; allergic response to implant materials; surgical replacement due to end of service life or component failure; loss of therapy, drug overdose, or inability to program the pump due to component failure; catheter complications resulting in tissue damage or loss of or change in therapy; potential serious adverse effects from catheter fragments in intrathecal space.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com

Infumorph® is a registered trademark of West-Ward Pharmaceutical. Prialt® is a registered trademark of TerSera Therapeutics LLC. Lioresal® is a registered trademark of Saol.

USA Rx Only

Rev 1118

Neurostimulation Systems for Pain Therapy

INDICATIONS Spinal cord stimulation (SCS) is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain.

CONTRAINDICATIONS Diathermy - Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death.

WARNINGS Sources of electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device.

PRECAUTIONS Safety and effectiveness has not been established for pediatric use, pregnancy, unborn fetus, or delivery. Avoid activities that put stress on the implanted neurostimulation system components. Recharging a rechargeable neurostimulator may result in skin irritation or redness near the implant site.

ADVERSE EVENTS May include: undesirable change in stimulation (uncomfortable, jolting or shocking); hematoma, epidural hemorrhage, paralysis, seroma, infection, erosion, device malfunction or migration, pain at implant site, loss of pain relief, and other surgical risks.

Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events.

USA Rx Only

Rev 0119

Kyphon Balloon Kyphoplasty and Sacroplasty Important Safety Information

Kyphon Xpede™ Bone Cement and Kyphon HV-R™ Bone Cement are indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism.

Osteocool Important Safety Information

The OsteoCool™ RF Ablation System is intended for the palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body and of benign bone tumors such as osteoid osteoma. It is also intended for coagulation and ablation of tissue in bone during surgical procedures, including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

Risks of the system include damage to surrounding tissue through iatrogenic injury as a consequence of electrosurgery; pulmonary embolism; nerve injury including thermal injury, puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis, and paralysis.

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