

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

THIRTY-SECOND MEETING

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

DAY THREE

MALLINCKRODT SEC PETITION

The verbatim transcript of the Meeting of the
Advisory Board on Radiation and Worker Health held
at the Westin Hotel, St. Louis, Missouri, on August
26, 2005.

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August 26, 2005

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-- "*" denotes a spelling based on phonetics, without reference available.

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(in order of appearance)

MR. STUART HINNEFELD, NIOSH
MS. DENISE BROCK, MALLINCKRODT
DR. DAN MCKEEL, VILLAGE IMAGE NEWS
DR. ARJUN MAKHIJANI, SC&A

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LASHAWN SHIELDS, Committee Management Specialist, NIOSH
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CASE, DIANE L., DEPT. OF LABOR
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ESPY, RICHARD, MALLINCKRODT CLAIMANT
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NUGENT, MARY, GAO
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SCHWENNESEN, CLARENCE, UNWW
SCHAEFFER, D. MICHAEL, SAIC
SCHNEIDER, MARILYN, UNWW
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ZIEMER, MARILYN

P R O C E E D I N G S

(8:40 a.m.)

WELCOME AND OPENING COMMENTS

1
2
3 **DR. ZIEMER:** We're going to reconvene our
4 session here this morning. A couple of the
5 normal housekeeping items. I remind you,
6 again, to please register your attendance in
7 the registration book if you've not already
8 done that.

9 We welcome this morning to the assembly Judith
10 Dungan. Did I pronounce that correctly,
11 Judith?

12 **MS. DUNGAN:** That is correct.

13 **DR. ZIEMER:** Good. And Judith is with Senator
14 Chris Bond's office and is with us here this
15 morning, so we're pleased to have Judith here
16 today.

17 Lew Wade has a couple of items to bring to us.
18 Lew?

19 **DR. WADE:** Thank you, Paul. Yeah, today is the
20 day that we -- we again take up the vote on the
21 Mallinckrodt SEC petition, the latter years.
22 And I just wanted to, as the Designated Federal
23 Official, make some comments about that
24 process.

25 I talked to you the last time about

1 understanding the fact that there will always
2 be tension between the passage of time, the
3 need to be timely and the need to be complete
4 in our scientific deliberations. That'll be a
5 tension this Board faces in everything it does.
6 We've certainly faced it as it relates to the
7 Mallinckrodt SEC petition.

8 I mean as the Designated Federal Official I
9 don't think we can leave St. Louis without a
10 decision on that petition this time. I
11 appreciate the process we've gone through. I
12 think it has certainly added value, but it also
13 has been a very difficult process for
14 petitioners and for claimants. And from my
15 perspective as the Designated Federal Official
16 I think we need to look at the material on hand
17 today and move to making a decision.

18 My agency values timeliness in what it does.
19 It also values the need to be complete, and we
20 understand that tension. We'll address it
21 differently in different situations. I think
22 the time has come now for us to -- this Board
23 to make a recommendation on the Mallinckrodt
24 SEC petition.

25 **DR. ZIEMER:** Thank you very much, Lew, for that

1 timely reminder.

2 We're going to move directly into the issue of
3 the Mallinckrodt SEC petition, and we have two,
4 I think, semi-brief presentations, one from
5 NIOSH and one from the petitioners.

6 In the absence of Larry Elliott, who we
7 indicated was facing some health problems this
8 week, Stu Hinnefeld from NIOSH is going to make
9 the presentation. And here's Stu approaching
10 the mike. Stu, you can use either one,
11 whatever is -- whatever you're com-- yeah, use
12 this one so you're facing everybody. That will
13 be fine.

14 **PRESENTATION FROM NIOSH**

15 **MR. HINNEFELD:** Good morning everyone. I'll be
16 -- I'll be brief today. The -- we have -- we
17 have not prepared an amendment -- an amended
18 petition evaluation report or revised petition
19 evaluation report, and so any presentation I
20 would present would just be the presentation
21 that's been presented to the Board in the past.
22 So I don't have a slide show presentation.
23 I would like to say that we have worked very
24 hard within the framework established by the
25 Board with our -- with the Board's contractor,

1 SC&A. A lot of people worked very hard on this
2 to get the best science we can to resolve the
3 questions that have been raised and that's been
4 the question at hand. And so we have done that
5 and that's what we expect to do, and I think
6 that's what should be expected of us is to work
7 hard to resolve the scientific questions in
8 front of us.

9 In this particular case, clearly it's made
10 things very difficult and we understand that,
11 and to engage in a process of SEC -- of
12 petition site profile, site profile evaluation
13 review while there is an SEC petition for that
14 affected site being considered by the Board is
15 clearly an extremely difficult circumstance and
16 we certainly recognize that. And we would like
17 to propose that for future actions I would like
18 the -- I would think that NIOSH and the Board
19 could perhaps work together for a set of
20 procedures or processes just to make sure that
21 we don't find ourselves in a similar situation
22 on other petitions at other times.

23 That concludes my comments.

24 **DR. ZIEMER:** Thank you, Stu. While you're at
25 the podium let me ask if any of the Board

1 members have specific questions for you at this
2 point. We may as we get into the debate
3 shortly, but any -- any immediate questions for
4 Stu Hinnefeld?

5 (No response.)

6 Okay. Thank you very much, Stu. Then let's
7 move to the petitioners and begin with Denise
8 Brock, and then any others. Denise, do you
9 have others also who will be making statements
10 for the petitioners or --

11 **MS. BROCK:** (Off microphone) (Unintelligible)

12 **DR. ZIEMER:** Okay. All right, fine.

13 **PRESENTATION FROM PETITIONERS**

14 **MS. BROCK:** Good morning everybody. Before I
15 begin today I would just like to point out that
16 subsequent to the issuance of the NIOSH
17 regulations and procedures in 2004, the FY '05
18 Labor HHS Appropriations Act restated the need
19 for both timely decisions and approval of SECs
20 when records documenting internal or external
21 dose were missing.

22 The committee strongly encourages NIOSH to
23 expedite decisions on petitions filed under the
24 procedures for designated classes of employees
25 as members of the Special Exposure Cohort, 42

1 CFR Part 83. It was Congress' intent in
2 passing the EEOICPA -- or, I'm sorry, the
3 Energy Employee's Compensation Act of 2000, to
4 provide for timely, uniform, and adequate
5 compensation for employees made ill from
6 exposure to radiation, beryllium, and silica
7 while employed at the Department of Energy
8 nuclear facilities or while employed at
9 beryllium vendors and atomic weapons employer
10 facilities.

11 The committee encourages the Department to
12 recognize that in situations where records
13 documenting internal or external radiation
14 doses received by workers at the specific
15 facility are of poor quality or do not exist,
16 that workers should promptly be placed in a
17 Special Exposure Cohort.

18 I would first like to thank the members of this
19 Advisory Board for their continued efforts in
20 this process. I want to thank you for
21 exercising such patience, diligence, and
22 integrity. I would also like to extend that
23 same thanks to SC&A, as well as to NIOSH. And,
24 again, before I begin with my statement, I
25 would also like to say that Senator Kit Bond

1 has been in touch with me and sends his regrets
2 that he is unable to attend this particular
3 meeting. He's also asked me to state that he
4 stands by his opinion that dose reconstruction
5 cannot be done, and that it further supports
6 the request to approve the Special Exposure
7 Cohort petition for the Mallinckrodt workers.
8 He wants it stated for the record that the
9 former Mallinckrodt workers are part of an
10 endless bureaucratic process.

11 Senator Bond has a staff member here today,
12 Judy Dungan. I believe that Dr. Ziemer or Dr.
13 Wade had mentioned Judy, and I want to thank
14 her personally as well for being here again,
15 and I would like to recognize all of the
16 Congressional delegation from Senator Talent's
17 office, Congressman Akin and their staff,
18 actually for their continued support in our
19 plight.

20 Most recently, or at least at the last Board
21 meeting, I've been able to listen to and/or
22 participate in workgroup meetings, conference
23 calls, et cetera, that were pertaining to
24 Mallinckrodt and this SEC petition. I have
25 seen and heard firsthand the amount of effort

1 and work that has been done by all entities and
2 I would like to commend each and every one of
3 you. There has been a tremendous amount of
4 work all the way around this thing. This is a
5 very difficult process.

6 I understand that Mallinckrodt is actually the
7 first SEC petition to actually been put in this
8 way, and so maybe this was just a big learning
9 process for all of us and I just appreciate all
10 the work that was put into it. I think the
11 work was -- was not for naught. I think that
12 this could help future cohort petitions, and I
13 greatly appreciate that. I think this was
14 long, but at the end of this I think would be
15 extremely helpful.

16 Several days ago I prepared a statement and as
17 you will see I've prepared something new, it's
18 actually a notebook, it's not typed. Today I
19 would like to start by giving some chronology.
20 In July of 2004 I filed this SEC petition. It
21 qualified on or about the 180-day mark. An SEC
22 evaluation report came in.

23 In February, 2005, we all met at the Adams Mark
24 Hotel here in St. Louis, and as I'm sure you
25 all remember, you voted to grant the SEC status

1 for my workers from 1942 to '48. I again want
2 to thank you for that. I greatly appreciate
3 that and I know the claimants do.

4 But at that same meeting NIOSH, at the last
5 minute, the 11th hour and without knowledge or
6 review of the petition -- petitioner, myself,
7 or the Board, stated that they had five or six
8 boxes of data which had not been gone through
9 and a 33-page memo which they claimed to have
10 had a couple of months, all of which needed to
11 be reviewed and all of which later failed to
12 support what they had contended.

13 NIOSH also stated that although the SC&A review
14 of Rev. 0 was complete, it was obsolete because
15 Rev. 1 had already been started. NIOSH also
16 stated that the TBD in place in February would
17 allow them to do dose reconstructions based on
18 uranium-driven models supplemented by radium
19 dose. The Board voted to table the vote.

20 Then in April we all went to Iowa, and due to
21 reprioritization or due to some unforeseen
22 things happening, the site profile review was
23 still not complete and, again, this was through
24 no fault of SC&A. This was just something that
25 happened, but again, it was tabled. NIOSH

1 still contended that this model that was in
2 place would allow them to do dose
3 reconstruction.

4 The next meeting moved to July, and I think you
5 all remember that. We were at the Chase Hotel,
6 again in St. Louis. Again, NIOSH claimed and
7 stood firm in their ability to do these dose
8 reconstructions with the present method. So
9 sure they were that they claimed to be able to
10 finish all of these Mallinckrodt cases within
11 four months. Stanford Cohen and Associates had
12 their review, and Dr. Makhijani asked how NIOSH
13 was going to implement this toolbox. NIOSH was
14 told to prove that they could do this.

15 And here we are again in St. Louis August,
16 2005. When the Board requested clarification
17 they got an entirely new method from NIOSH.
18 Now radionuclides which were once considered
19 trace, like thorium, protactinium, and
20 actinium, are now the dominant dose.

21 SC&A gave a report August 16th to the Board.
22 This outlined yet further improvements that
23 were needed. And between August 16th and the
24 23rd a vast amount of new data has been sprung
25 on the Board, data that I as a petitioner and

1 you as a Board again have not reviewed, data
2 that has not been analyzed. This is again and
3 another -- I'm sorry, this is again another
4 11th hour tactic, and whether intentional --
5 intentional or not, has become a pattern and
6 practice. It's a technique. None of this was
7 passed out to me, to the public, or to the
8 Board.

9 Some may call this real-time science. I call
10 it sandbagging. This is becoming an open-ended
11 process. This never has seemed like a level
12 playing field.

13 I, as well as the Board, are at a distinct
14 disadvantage. I've mentioned this for the
15 record before. These tactics of dumping new
16 data and information, new methods, new memos,
17 et cetera, all of which are never before seen
18 by the petitioner or the Board, or analyzed for
19 that matter, is very poor practice and
20 procedure. It's setting a poor precedent.

21 I'm not dealing with living documents. I'm
22 dealing with a moving target. We are now at
23 our fourth Board meeting regarding this
24 petition. We've had four audit reports, Rev. 0
25 and two or three supplements to Rev. 1, four

1 subgroup meetings and numerous teleconference.
2 Should we have a fifth audit report, a fifth
3 meeting? Should we expect that every time we
4 turn around, at the 11th hour we have new
5 discovery, new vast data, a new process; or
6 should an SEC petition be denied when we have
7 significant uncertainties, numbers that are
8 just turned in, missing data, unanalyzed data,
9 and a complete 180-degree turnaround from six
10 months ago.

11 The SEC evaluation is still on the table today,
12 or better or best yet, approve this SEC
13 petition because there are significant
14 uncertainties coupled with feasibility issues.
15 SC&A and the Board have spoke to the scientific
16 issues, I don't need to reiterate that, the
17 record's been laid. But I will speak to the
18 feasibility issues as I started this.

19 There are three areas of feasibility. Number
20 one would be technical, when relevant records
21 may be lacking or not exist altogether. NIOSH
22 does not have any dose on Plant 6 for
23 raffinates. Some datapoints are missing, some
24 data are not legible, et cetera.

25 Costs. When you may be able to construct dose

1 but would be cost prohibitive to do so. It is
2 costing \$80-\$100 per hour for contractors who
3 have spent untold hours to develop and revise
4 site profiles, and the auditor continues to
5 find problems, problems that need to be
6 corrected before this can be done. We now have
7 people or NIOSH has staff in Germantown
8 recapturing data. This list could go on and
9 on.

10 And, number three, the issue of time or
11 timeliness. This might take so long to
12 reconstruct dose for a group of workers that
13 they would all be dead before we have an answer
14 that could be used to determine eligibility.
15 Many Mallinckrodt claimants are already
16 survivors. The few living workers,
17 Mallinckrodt workers, deserve an answer before
18 they die.

19 And after almost four years to finalize
20 regulations for Special Exposure Cohorts and
21 another 13 months to assess my petition filed
22 in July of 2004, NIOSH has far exceeded time
23 contemplated by Congress for Special Exposure
24 Cohort petition processing. Any more time
25 expended on this or to extend this any longer

1 would be to reconstruct Congressional intent.
2 I think that Stu Hinnefeld had mentioned this,
3 but I understand this SEC evaluation report
4 that was given in February is what is on the
5 table today. I ask the Board to please vote to
6 approve my Special Exposure Cohort petition for
7 this group of brave workers, my workers of 1949
8 through 1957. Please give them the peace and
9 the justice that they so deserve. Thank you.

10 **DR. ZIEMER:** Thank you, Denise. And before you
11 leave the podium, let -- let me ask if any
12 Board members have immediate questions for
13 Denise?

14 (No response.)

15 Okay. Thank you. Then Dan McKeel is --

16 **MS. BROCK:** Dr. McKeel, I think, wanted to make
17 a quick statement.

18 **DR. MCKEEL:** I'll be very brief. Thank you for
19 letting me address you. Again, I'm Dan McKeel.
20 I'm a retired pathologist and a physician. And
21 today the Board has another opportunity to vote
22 the Mallinckrodt 1949 to '57 SEC up or down.
23 Wanda Munn's motion to deny the Brock petition
24 is on the table. I believe the credibility of
25 this Board will hinge on the vote. The

1 difficult decision is whether or not to accept
2 NIOSH's claim it can reconstruct doses under 42
3 CFR 83 guidance. For me, as a scientist who
4 has been awarded many competitive federal
5 grants, I do not believe the aggregated science
6 proposed by NIOSH passes the 42 CFR test of
7 being able to be accurate and to fairly
8 reconstruct or even to accurately bound
9 radiation doses for the Mallinckrodt '49-'57
10 class of workers.

11 This class of people have certainly had their
12 health harmed at MCW, at the St. Louis Airport
13 site and at the Latty Avenue work sites. Once
14 again I urge the Board to vote for the MCW
15 SEC0012.2.

16 My reasons for feeling the way I do have been
17 given in detail before, but here is a summary
18 of my reasoning. At least 107 Mallinckrodt
19 1949 to '57 EEOICPA claims still await dose
20 reconstructions. This is prima facie evidence
21 that NIOSH cannot do what it must do, perform
22 DRs in a timely manner. No best estimate MCR
23 (sic) DRs have been done to date.

24 The CER database is limited and biased and
25 encompasses only white male workers, who are

1 only about 70 percent of the total Mallinckrodt
2 workforce. Women and minorities are excluded.
3 The HASL database, which Mr. (sic) Neton
4 describes as the gold standard, is just being
5 reconstructed. Mark Griffon has found
6 discrepancies between the MCW raw data sheets
7 and the HASL database. Why is such late-
8 breaking news, why is this unfinished business
9 just being taken care of?

10 NIOSH largely abandoned daily weighted averages
11 to determine intakes and now relies on a 20
12 percent sample of breath radon. This is too
13 small a sample to provide valid bounding dose
14 data and thus fails to meet the prime 42 CFR 83
15 test. They have offered to the Board an
16 approach to DR, not completed actual
17 Mallinckrodt best-estimate dose
18 reconstructions.

19 The Weldon Spring 053 site profile was finally
20 approved between June 24th and 26th of this
21 year. It has not been presented to the Board
22 or reviewed by SC&A. Data therein is crucial
23 to performing Mallinckrodt dose reconstructions
24 in settling claims. Why? Because the majority
25 of Mallinckrodt workers were employed at both

1 the downtown and the St. Charles County sites.
2 Final point. SC&A and NIOSH have not fully
3 resolved their six points of issue between the
4 last meeting of this Board and this meeting.
5 Significant differences remain to be worked
6 out.

7 For all these reasons and many more, including
8 adherence to fairness and due process, the
9 Board should today recommend SEC status for the
10 1949-1957 class of Mallinckrodt Uranium
11 Division workers. Thank you very much.

12 **DR. ZIEMER:** Thank you, Dr. McKeel. And,
13 again, let me ask if any Board members have
14 immediate questions.

15 (No response.)

16 Denise, yes, a follow-up?

17 **MS. BROCK:** (Off microphone) (Unintelligible)

18 **DR. ZIEMER:** Sure, that's fine. Dr. Makhijani
19 has asked for an opportunity to address an
20 issue that was before us on the floor yesterday
21 and just one item, I think, either to correct
22 or clarify.

23 **PRESENTATION FROM SC&A**

24 **DR. MAKHIJANI:** Thank you, Dr. Ziemer.
25 Yesterday I -- and in my presentation I had

1 said that the calculated value for the AM-7
2 area of air concentrations which NIOSH proposes
3 to use as one of the bases for dose
4 calculations in the thorium areas, was the
5 average. And I misinterpreted the text that
6 was sent to us by NIOSH in the pressure cooker.
7 What NIOSH had said, on page 136 of your report
8 at the top, in the first paragraph there, first
9 full -- big paragraph, said, (reading) the area
10 air concentrations used in this analysis are
11 about a factor of 2 higher than the measured
12 air concentrations exposures in areas
13 associated with the AM-7 raffinate.
14 Now, I interpreted that phrase to -- to -- to
15 mean average, but Jim Neton told me yesterday
16 that it was the 95 percentile of the average
17 daily weighted numbers that they had gathered.
18 And he shared his spreadsheet with me last
19 night, which I looked at very briefly with his
20 assistance, and I agree that that's what
21 they've done. There's a page in the report
22 which will need to be corrected and we will
23 send you a corrected page.
24 My one observation from looking -- or two
25 observations to share with you from looking at

1 Dr. Neton's spreadsheet is that -- obviously
2 it's a very quick look that I took. I don't
3 believe it corresponds to the method that SC&A
4 had recommended for 95 percentile air
5 concentrations in our April report to you, and
6 I did note that there were some years for which
7 there was no data, which is why I think '50 to
8 '57 has been aggregated. Dr. Neton told me
9 that there are data for these years, it's --
10 there's just a methodological illustration that
11 -- which was the reason for the gaps, it's not
12 that the data may not exist. And obviously
13 this is an issue that we have -- we have not
14 reviewed because last night was the first time
15 that I saw this. But I did want most
16 importantly to put that correction into place
17 and we will send you the corrected page. Thank
18 you very much. Sorry about that.

19 **GENERAL DISCUSSION**

20 **DR. ZIEMER:** Thank you. Uh-huh. Now Board
21 members, we'll open the floor for general
22 discussion. You have two options before you.
23 One is to move immediately to the -- the
24 action. The other is to deal with any
25 questions or issues that you'd like to discuss

1 before we move to an action. And the action
2 possibilities are, one, to remove from the
3 table the previous motion. You also obviously
4 have the option of not removing it from the
5 table, which then would require a different
6 motion.

7 Any comments or questions in general? Jim?

8 **DR. MELIUS:** I would like to make a motion, and
9 I think this will also provide the basis for
10 discussion of -- of the issue. So it doesn't
11 necessarily expect quick resolution, but Mark
12 Griffon and I have worked on a motion and I
13 believe there are copies available.

14 **DR. WADE:** Would you like me --

15 **DR. MELIUS:** Yeah. And this would be a motion
16 for the Board to approve the SEC petition, and
17 it's in the same format that we've done with
18 our earlier letters. In fact, much of it is --
19 will be quite familiar to Board members since
20 it's there. And I think it's easiest if we
21 wait for the copies to be made available rather
22 than for me to try to read it here.

23 **DR. WADE:** The copies are being made.

24 **DR. ZIEMER:** We probably need to have it read
25 for the record in any event, so why don't you

1 for procedure read it, then we'll have -- by
2 then we'll have the copies.

3 **DR. MELIUS:** I move the following (reading):
4 The Board recommends that the following letter
5 be transmitted to the Secretary of Health and
6 Human Services within 21 days. Should the
7 Chair become aware of any issue that in his
8 judgment would preclude the transmittal of this
9 letter within that time period, the Board
10 requests that he promptly inform the Board of
11 the delay and the reasons for this delay, and
12 that he immediately works with NIOSH to
13 schedule an emergency meeting of the Board to
14 discuss this issue.

15 The letter reads as follows (reading): The
16 Advisory Board on Radiation and Worker Health
17 (the Board) has evaluated SEC Petition 00012-2
18 concerning workers at the Uranium Division of
19 the Mallinckrodt facility under the statutory
20 requirements established by EEOICPA and
21 incorporated into 42 CFR Sec. 83.13(c)(1) and
22 42 CFR Sec. 83.13(c)(3).

23 The Board respectfully recommends a Special
24 Exposure Cohort be accorded to all Department
25 of Energy employees or its contractor or

1 subcontractor employees who worked at the
2 Uranium Division of the Mallinckrodt Destrehan
3 facility from 1949 to 1957 and whom were
4 employed for a number of work days aggregating
5 at least 250 work days occurring under this
6 employment, in combination with work days of
7 employment occurring within the parameters
8 (excluding aggregate work day requirements)
9 established for other classes of employees
10 included in the SEC.

11 (Reading) This recommendation is based on the
12 following factors: Number one, these workers
13 were employed at a facility that processed
14 materials during the early time period for the
15 production of nuclear weapons. Radiation
16 monitoring methods for all isotopes were under
17 development at that time leading to significant
18 gaps in the monitoring of these workers in
19 comparison to current monitoring programs.
20 Number two, while there are ample monitor data
21 for some exposures, such as uranium and radium,
22 data on exposures critical for accurate
23 individual dose reconstruction are sparse. For
24 important exposures such as thorium, actinium,
25 and protactinium, there's relatively little

1 information available. The evaluation of these
2 exposures -- of these isotopes is critical in
3 reconstructing the organ doses for individual
4 workers due to their substantial contribution
5 to those doses. NIOSH has not yet demonstrated
6 that the sparse information currently available
7 are adequate to conduct individual dose
8 reconstructions with sufficient accuracy.
9 Number three, the available monitoring do not
10 adequately characterize high exposure areas in
11 the facility, leading NIOSH to attempt to
12 extrapolate exposures using data from other
13 areas. For example, there's not been an
14 adequate assessment of the use of the daily
15 weighted average -- excuse me, let me -- I'm
16 actually reading from the wrong version of
17 this. I apologize. Let me go back.

18 **MR. GRIFFON:** Are they copying the right
19 version?

20 **DR. WADE:** They are copying it right now.

21 **DR. MELIUS:** They are copying the right one,
22 yeah. I apologize to everybody.

23 **DR. WADE:** Just give me one minute and I'll get
24 the copies.

25 **DR. MELIUS:** Okay, point number two. Point

1 number three -- let me go through -- start with
2 the second point. Point number two, (reading)
3 There is relatively little information
4 available for estimating thorium, actinium, and
5 protactinium. NIOSH's approach to dose
6 reconstruction no longer relies on individual
7 monitoring, but rather plant-wide air
8 monitoring data, which is itself not even
9 isotope specific. These data have to be
10 converted into isotope-specific activity using
11 residue fraction points which have not been
12 validated. As such, NIOSH has not demonstrated
13 that it can conduct individual dose
14 reconstruction with sufficient accuracy.
15 Point number three, while there are many
16 internal exposure monitoring records for
17 uranium and some for radium, there are no
18 individual bioassay records for Plant 6 workers
19 for high consequence isotopes extracted from
20 the pitchblende ores and contained in the AM-7
21 and Sperry cake residues (thorium 230, actinium
22 231, and protactinium 227). There are only
23 bioassay data for two months in March and April
24 1955 for the Plant 7E workers (thorium recovery
25 operations) although operations continued in

1 1956 and 1957.

2 Next point, there are serious concerns about
3 the lack of a method to adjust for the angle of
4 incidents of external dose monitoring. This
5 adjustment has a significant impact on the
6 interpretation of the monitoring data and a
7 final method needed for individual dose
8 reconstruction is not yet available.

9 Next point. There are concerns about the
10 validity of the radon breath data being used
11 for dose reconstruction. Radium intakes based
12 on radon breath data were taken from a
13 secondary data source, and they have not been
14 validated against source data. In response to
15 questions about the validity of the data, NIOSH
16 has just started an effort to obtain the data
17 from the original records. This effort has not
18 been completed and the Board has not been able
19 to evaluate -- evaluate the results of this
20 effort.

21 Next point. The Board has reviewed data which
22 confirms that radiation exposures of the
23 Mallinckrodt facility during the time period in
24 question could have been endangered the health
25 of members of this class.

1 The Board has been deliberating for over six
2 months on the Mallinckrodt SEC petition for the
3 period 1949 to 1957. There have been four
4 separate audit reports, four board meetings,
5 four subcommittee or working group meetings,
6 and countless conference calls and memos.
7 NIOSH staff, the staff of their contractor, and
8 the contractor for the Advisory Board have
9 spent hundreds of hours working on this effort.
10 Despite many meetings and two years of work on
11 the site profile for the site, new data
12 continues to emerge on the site including some
13 first revealed to the Board during this most
14 recent meeting. Efforts to find new data on
15 the site could continue for years.
16 However, the Board also recognizes the need to
17 make timely decisions. EEIOCPA requires that
18 this program should produce a defensible
19 radiation dose reconstruction in a reasonable
20 period of time, and Congress has recently
21 reinforced this objective in the FY '05 Defense
22 Authorization Act and the Labor HHS
23 Appropriations Act.
24 Based on these considerations, the Board
25 recommends that this Special Exposure Cohort

1 petition be granted. It should be noted the
2 Board believes that the exposure information
3 available is adequate for the reconstruction of
4 external exposures, and where appropriate for
5 specific types of cancer, for example, skin,
6 these -- those individual doses can be
7 reconstructed.

8 And then final paragraph, enclosed is
9 supporting documentation from the Advisory
10 Board meeting held August 24-26, 2005 in St.
11 Louis. This documentation includes transcripts
12 of public comments on the petition, copies of
13 the petition, the NIOSH review thereof, and
14 related documents distributed by NIOSH and the
15 petitioners.

16 And that's it.

17 **DR. WADE:** Just a minute.

18 **DR. ZIEMER:** You've heard the motion. Let me
19 ask if -- before you get the printed copy, does
20 anyone wish to second the motion?

21 **MR. OWENS:** I'll second the motion, Dr. Ziemer.

22 **DR. ZIEMER:** Leon has seconded the motion. We
23 will pause just a minute till we --

24 **DR. WADE:** I also want to make sure Mike Gibson
25 is at the table, so let me...

1 (Pause)

2 **DR. ZIEMER:** Okay, are there copies -- there
3 are copies being run for the members of the
4 public as well?

5 **DR. WADE:** (Off microphone) (Unintelligible)

6 **DR. ZIEMER:** Okay, this motion is now open for
7 discussion. I'd like to -- just procedurally
8 like to -- whoever -- okay, Gen Roessler will
9 be first, and we will alternate. If someone
10 speaks for the petition, then I will ask if
11 there's any that wish to speak against and then
12 we'll alternate. Dr. Roessler, you want to --

13 **DR. ROESSLER:** I'm not going to speak either
14 for or against the motion at this -- at this
15 time. I would just like to make a few
16 comments.

17 **DR. ZIEMER:** Sure.

18 **DR. ROESSLER:** I think that Jim's motion is
19 very compassionate and very persuasive. The
20 thing I think we should keep in mind, though,
21 is that we've been definitely on a learning
22 curve. I think the Board has been at a
23 disadvantage in not really having a clear
24 definition on what we mean by "adequate
25 information to do sufficient dose

1 reconstruction." That's -- that's been my
2 problem is where do we draw the line, and I'm
3 not sure that it's clear in my mind yet. Maybe
4 it has to be done on an individual basis, but I
5 think we would -- in the future we really need
6 to address that.

7 The other thing that's on my mind right now,
8 and Denise mentioned this and I think this was
9 the Congressional intent, that as we go through
10 this process we have to remember that it's
11 uniformity. We have to be uniform in our
12 decisions. I think we need to think about
13 equity for the claimants, the claimants on the
14 SEC petitions and also the claimants who don't
15 go through that process. I think in fairness
16 to these claimants, that's what we really need
17 to think about right now is what we do here --
18 we have to think of equity.

19 **DR. ZIEMER:** Okay, thank you. Dr. Melius?

20 **DR. MELIUS:** Yeah, I'd like to respond, and I
21 would agree with Gen's comments, that we've
22 been approaching this without very tight
23 criteria because we've not been provided with
24 that, and I think NIOSH has also been
25 struggling with sort of what is the best

1 approach for evaluating SEC petitions, what
2 kind of information and how to, you know,
3 formulate and present that information to us in
4 order for us to make a recommendation. And I
5 would agree with you that I think we've been
6 doing sort of a case law approach where we deal
7 with each one as, you know, best we can. I
8 think we've handled them fairly so far, but the
9 delays in this one I think illustrate some of
10 the problems with that approach, for both of us
11 and for NIOSH in evaluating these.

12 And I would certainly think that we should -- I
13 think we need to deal with this petition and I
14 think we need to deal with it today; however, I
15 think we also -- it would be helpful if we have
16 time today, or if certainly not today at our
17 next meeting, that we discuss how to better
18 handle these in the future. We've talked about
19 that in the past. Stu mentioned in his talk.
20 I mean, we've made a recommendation to -- or I
21 shouldn't say "we." I made a recommendation in
22 discussion with Larry a long time ago how the
23 need for an SEC site profile and site profile
24 review was really necessary before we could
25 adequately handle these petitions.

1 I think there's issues we've raised, you know,
2 repeatedly about defining sufficient accuracy,
3 and this all comes back to this particular
4 instance we're dealing with today, but we
5 obviously don't have time today to sort of
6 reformulate the policy. We need to deal with
7 this petition first. But I would certainly
8 urge us to -- and NIOSH to consider sort of the
9 future and how we can better handle these
10 situations, what procedures we need to put in
11 place, do we need to develop better criteria,
12 et cetera, because what you said about equity I
13 think is also important. But when we're sort
14 of going along from case to case, we have to
15 sort of do as best we can.

16 **DR. ZIEMER:** Okay, other comments or does
17 anyone wish to speak for or against the
18 petition -- for the motion, rather? Wanda
19 Munn.

20 **MS. MUNN:** I just -- I also am not speaking
21 specifically to the petition. We've heard
22 already this morning many issues that have --
23 that we faced and some of the stumbling blocks
24 that we've had to try to crawl our way over.
25 Not very much has been said about those

1 stumbling blocks and how they have been
2 addressed. It might be wise for us to recall
3 that at our last meeting we specifically
4 outlined for NIOSH information that we wanted
5 from them, in effect proving that they could do
6 what we had asked to do; which is, give us
7 prove that you can do the reconstructions that
8 need to be done with the information that you
9 have at hand.

10 They did that, and to all appearances did that
11 very well. The fact that information can --
12 continues to develop does not change the fact
13 that they have in fact shown they can do that;
14 that is to say, they have shown that they can
15 do dose reconstructions on this group of
16 workers given the information that they have, a
17 fact I think we should bear in mind.

18 **DR. ZIEMER:** Okay, thank you. Let me give
19 others a chance to talk. Mark Griffon.

20 **MR. GRIFFON:** I guess I -- just going back to
21 Gen's comment about sufficient accuracy -- and
22 I've been grappling with this as I've gone
23 through this, too, but I mean part of where
24 I've seen this evolve is that it's really
25 apparent to me now that when it comes down to

1 being able to calculate dosage for individual
2 claimants, we're -- instead of having this
3 massive amount of data that we're relying upon,
4 we're down to smaller sets of data with very
5 limited information on how that's distributed
6 from an isotope standpoint. So we've got this
7 air data, together with the residue information
8 on the fractions from the residues, and that's
9 driving a lot of the dose. There's other
10 factors in here, obviously, but when you look
11 at some of the cases, a lot of these things are
12 now being driven by that.

13 So all of this information on uranium
14 urinalysis, to some extent the individual radon
15 breath data, we're not relying on that anymore.
16 So now we're -- and as we've gone through this,
17 at least my feeling, my sense has been that
18 each time we've asked for a refinement --
19 there's been a massive amount of work that's
20 gone into this, but where there's a -- where
21 there's a problem it's ended up that certain
22 critical information is not available so that
23 they're defaulting to -- it's not just a
24 claimant favorable approach, it's that there's
25 certain information critical to the first

1 method that wasn't available that limited them.
2 And I'm saying that that is my reason for
3 saying, you know, at some point you've got to
4 say there's just not sufficient data and it's
5 not -- you can't make an accurate estimate on -
6 - for all the claimants on their dose systems
7 in this site. You can't just come back with a
8 higher number and say, well, we're being
9 claimant favorable because critical information
10 was missing to support your first sort of
11 method.

12 I guess what I -- what I -- where that really
13 came true was, you know, we rolled around to
14 using this linchpin sort of -- of a method
15 became the radon breath data. So we all spent
16 a lot of time going into that and looking at
17 that and listening to the method description,
18 and then we had a discussion of the residues
19 and the fact that they weren't all K-65, but
20 there was this AM-7 and how would that -- you
21 know, that's got a different ratio of thorium
22 to uranium -- could potentially affect things.
23 The real answer is yes, you get higher numbers
24 when you use the thorium error combined with
25 this thorium residue fraction, but the reason

1 they went in that direction was they couldn't
2 tell which -- what people were dealing with AM-
3 7 or K-65 or a mixture of regular uranium. So
4 they had to default -- you know. So at some
5 point you've got to say that there's critical
6 elements that are missing that are making this
7 impossible for us to do an estimate with
8 sufficient accuracy.

9 I know that I'm grappling with how we define
10 that, too, but that's what I've kind of -- I've
11 felt like this has evolved with -- with these -
12 - with these patches to sort of -- okay, this
13 method didn't -- we're missing a critical
14 element in this method so let's go on to this
15 one, and we can argue that it's -- you know,
16 they're higher doses, so it's more claimant
17 favorable. But I think -- and now we're down
18 to -- the first presentation we saw we had
19 great amounts of information on urinalysis
20 data, we had air sampling data which could help
21 us as a reality check to bound these doses, all
22 this urinalysis data -- I mean, it might
23 contribute a little dose for the uranium, but
24 to much extent it's gone as far as the critical
25 dose consequence elements in this equation.

1 So you no longer have all this individual data
2 that you're going to reconstruct doses with.
3 You're back to gross air -- gross alpha air
4 sampling, multiplying by a fraction, and from
5 what I see from a spreadsheet I got yesterday,
6 you know, some of these -- I'm not -- we
7 haven't had a chance to review how these
8 fractions were developed, but I mean, there's
9 not a ton of data. Certainly these fractions
10 were not -- were not based on isotope analysis
11 done in the plant. They were -- they were sort
12 of after the fact from the residue material.
13 So, you know, you're down to a few. You know,
14 you've got gross air alpha sampling and
15 fractions which we've got a couple of values
16 for, that's hinging the whole -- that's driving
17 the whole -- at least a majority of the dose
18 consequence, I would say.

19 So I think that's what I'm saying that we've
20 lost our ability to be sufficient and accurate
21 on all the dose reconstructions for this
22 cohort.

23 **DR. ZIEMER:** Let me make an observation here
24 because there's been an implied criticism of
25 the change in methodology by NIOSH. But let me

1 point out that that change in methodology was
2 largely driven by the recommendations of our
3 contractor to consider some other issues. And
4 in fact had they been responsive to that, I
5 think we would be criticizing them for, for
6 example, digging in their heels and sticking
7 with the original data.

8 What we've seen emerge is almost a kind of new
9 methodology based on some considerations that
10 SC&A has asked be looked at, and obviously they
11 are considerations that have substantial
12 implications on dose. In fact, although the
13 estimations now that come out of that look like
14 they're relying less on original data, I think
15 the resultant doses, in most cases, maybe in
16 all cases, are substantially higher than would
17 come out of the original datasets. And in that
18 respect there is certainly a much more
19 claimant-favorable effect for the dose
20 reconstruction.

21 Okay, Jim, you have another comment?

22 **DR. MELIUS:** Again, I don't think there's any
23 attempt here to downplay the efforts that NIOSH
24 has made, and I think I, and I hope others
25 would, appreciate the great amount of effort

1 they've put into it and their integrity in
2 dealing with many of these issues. We -- in
3 one sense, you know, us getting a spreadsheet
4 last night, you know, finally to see some data
5 is -- this makes it difficult. At the same
6 time they have been honest enough to continue
7 to make efforts and to work on this and to
8 share that information the best we can.
9 But I still think the bottom line comes down --
10 it's where I disagree with Wanda. I don't
11 think that they've shown that they can do
12 individual dose reconstruction with sufficient
13 accuracy. They have addressed some of the
14 points that we asked them, but we've only -- as
15 Mark has just pointed out, we've only uncovered
16 more issues, more things that need to be
17 resolved. And I think we have to look at it at
18 this point in time and I'm certainly not
19 satisfied that they can, you know, do dose --
20 individual dose reconstruction with sufficient
21 accuracy. And I think on that basis we need
22 to, you know, pass and that -- this motion.

23 **DR. ZIEMER:** Anyone? Robert Presley.

24 **MR. PRESLEY:** I agree that, yes, the people
25 that work at Mallinckrodt were hurt, but some

1 of the things that have gone on about the
2 concern of the angle of the instrument, of the
3 badge. We have over 60 years of industrial
4 hygiene data that has gone on, and today the
5 best place to wear your badge is still upon the
6 upper portion of the torso of the body because
7 they feel like that that's where you get the
8 average dose. And so I question this thing
9 about the angle of the badge, but I feel like
10 that -- under the law, that NIOSH has stated
11 that they have enough information to do dose
12 reconstruction. And under our charge, that is
13 what the law says, that we -- if they say they
14 have it, then we go back and accept that.
15 Thank you.

16 **DR. ZIEMER:** Okay, Henry Anderson.

17 **DR. ANDERSON:** I mean I think there's been
18 tremendous advances made since the last
19 meeting, and I would just remind -- they told
20 us they could do it using the old data and they
21 could, and we raised -- I mean we were -- we
22 were very close at the last meeting to saying
23 they could do it using the methodology that's
24 still on the table, and now in response to our
25 concerns and our issues that weren't really

1 there in the first methodology, and we were
2 told that they would very promptly be able to
3 do all of these in a very short period of time,
4 and they would not just -- I mean, my feeling
5 is this probably would -- this issue would not
6 have been raised, we would not have the
7 modeling and the new methodologies that they
8 developed if we had not have held our ground
9 and said we want to -- you to show us that you
10 can do that.

11 And so I think we've had tremendous advances.
12 Again, it's moved to a recognition or an
13 appreciation that the thorium was more
14 important than it was previously realized, and
15 that is an advance and that will carry over
16 into their evaluation and understanding of
17 other circumstances elsewhere. So it's not as
18 though this time, effort and resource has been
19 needlessly expended. I think we've advanced
20 it. I think the difficulty, to me, is -- for
21 this particular one -- this has been a learning
22 exercise and when we started it there was a
23 great deal of information not available. It's
24 now become available and, again, the kind of
25 source that we saw in the cases appears in many

1 of these instances to be this thorium issue,
2 and I think that's still very new and new data
3 is coming and at some point I think it could --
4 given enough time and resource and effort, this
5 could become a very real robust model if there
6 was sufficient data available, but I think in
7 this particular instance there I think still
8 appears to be a paucity of what we need, and we
9 need to move on. We can't expend all our
10 resources. There's other issues that will come
11 up and this will be of benefit to us in
12 understanding what those exposures might be.

13 **DR. ZIEMER:** Okay, so you are speaking for the
14 motion, I think.

15 **DR. ANDERSON:** I think we need to draw to a
16 close --

17 **DR. ZIEMER:** Okay, okay.

18 **DR. ANDERSON:** -- don't have a revised --

19 **DR. ZIEMER:** Thank you. Is anyone speaking
20 against the motion?

21 (No response.)

22 Then the Chair will exercise his prerogative
23 and speak against the motion. The -- and there
24 are many things that are said here that I do
25 agree with. However, I believe that the Agency

1 and our contractor have both demonstrated that
2 dose reconstruction indeed can be done.
3 Our contractor has agreed, at least in
4 principle, that it can be done. They have
5 cautioned on a selection of a number of
6 parameters that go into this and how those are
7 selected, such as the -- the DR factors and
8 others. But nonetheless, the issue of can you
9 dose -- do dose reconstruction, in my mind you
10 can, based on what I've seen. The sufficient
11 accuracy issue, of course, is a hard target.
12 The accuracy that's required is an accuracy for
13 making a decision on compensation. In fact, in
14 most cases we do not claim that the numbers are
15 accurate. You could not do epidemiological
16 studies from the numbers that come out of this
17 program. I'm not just talking Mallinckrodt but
18 in general, because there are -- in many cases
19 are intentional overestimates because of
20 claimant-favorable considerations. So in my
21 mind we can do dose reconstruction with
22 sufficient accuracy to make a fair decision for
23 claimants in this case.
24 Also, I'd simply point out, and this often will
25 appear to be a discrepancy and we simply alert

1 you to the fact that -- and I think there's a
2 statement in here that in essence suggests that
3 those who -- if we go to Special Exposure
4 Cohort, those that are not successful in that
5 then move back to dose reconstruction, which we
6 say earlier we really can't do very well, if we
7 accept this. So there is a contradiction of
8 sorts in the document that I would certainly be
9 uncomfortable with.

10 But my bottom line here is -- and I agree with
11 everything on the timeliness. I think we have
12 to make a decision and, you know, the Chair is
13 -- I'm quite comfortable with moving ahead with
14 whatever this Board decides, you know that.
15 But I feel obligated to say that, in spite of
16 the limitations that we see, there's a vast
17 amount of data here and good dose
18 reconstructors can, in my mind, reconstruct
19 doses for purposes of making fair decisions for
20 workers. And I -- I would judge that in
21 probably almost every case, if we did have dose
22 reconstruction, because of the parameters that
23 have emerged out of this kind of new
24 methodology which makes use of and takes into
25 consideration particularly raffinates, that

1 these will be highly claimant favorable.
2 So I'm speaking against the motion, Dr. Melius.
3 Now, you get a chance -- who's next here?

4 **DR. MELIUS:** Mark or Leon, I'm not...

5 **DR. ZIEMER:** Mark -- Leon, yes, you're next.
6 Okay, Leon, please.

7 **MR. OWENS:** Dr. Ziemer, I speak in favor of the
8 motion, and not just because I seconded it.
9 But I think that Dr. McKeel spoke of a segment
10 of workers who have not been or who were not
11 monitored, who are not represented based on any
12 of the data that we are considering. And so in
13 order to perform dose reconstruction, whether
14 we rely on coworker data for this segment of
15 workers who would be claimants, I'm very
16 concerned -- troubled by that, for us to say
17 that we can accurately perform dose
18 reconstruction on this group of workers when in
19 fact we have a sizable segment of those workers
20 who were not even considered at all.
21 I think also when we look at the timeliness
22 issue that was brought up, the discrepancies in
23 some of the studies, it lends itself toward
24 granting a Special Exposure Cohort for these
25 workers.

1 **DR. ZIEMER:** Okay, thank you. Is Mark -- are
2 you next?

3 **DR. MELIUS:** I think Mark was next.

4 **DR. ZIEMER:** Mark and then Gen and then Jim.

5 **MR. GRIFFON:** Just a couple of points to follow
6 on what you said, Dr. Ziemer. I guess there is
7 this procedural question, too, that we have. I
8 don't think that we asked or that we could ask
9 SC&A their opinion on this SEC because they are
10 only doing a site profile review, and I think
11 this was one of the problems that we've
12 discussed on here and that's why we have a new
13 task forthcoming. So I don't think they
14 weighed in and actually kind of gave us --

15 **DR. ZIEMER:** And you're correct with respect to
16 the petition, they did not, yes.

17 **MR. GRIFFON:** Right, right.

18 **DR. ZIEMER:** I'm -- I'm characterizing their
19 characterization of what NIOSH said it could do
20 in terms of those items that we asked them to
21 address, right.

22 **MR. GRIFFON:** Okay. I guess -- I mean, I think
23 some things we heard from them was that a lot -
24 - a significant amount of work and things like
25 that, but --

1 **DR. ZIEMER:** Well, I'm basically quoting from
2 items in their report where they agreed with --
3 that in principle NIOSH could do what it said,
4 and then they cautioned on a number of these
5 things and -- I mean --

6 **MR. GRIFFON:** Anyway --

7 **DR. ZIEMER:** Yeah.

8 **MR. GRIFFON:** -- the other point you made
9 earlier, Paul, was that we had asked for --
10 actually, that the Board's questioning had
11 resulted in some of these newer models, and I
12 think I would disagree with that. I think, at
13 least my -- and it's been -- I don't know how
14 many meetings we've had on this so I might be a
15 little confused on the timeline, but my
16 remembering of this is that we asked for
17 clarification of the approach, and then we got
18 down to specifically saying, well, can we see a
19 couple of examples in how you're going to apply
20 this.

21 And my sense, having put a lot of hours into
22 this myself, is that when everybody went back
23 and dug into the weeds -- which is where, by
24 the way, from the beginning of this program
25 I've said we might want to look on certain

1 sites -- they realized that there were some
2 problems with their initial model. And I don't
3 think we asked them to come back with a radon
4 breath model, per se. We said consider people
5 who have radon breath data, because they had
6 talked about it as maybe a bounding condition,
7 or maybe -- in earlier discussions I remember
8 it being discussed as a way to identify who
9 were residue workers and who to apply different
10 fractions to than other people, non-equilibrium
11 versus equilibrium.

12 So I don't think we asked them for a new
13 method. I think --

14 **DR. ZIEMER:** Oh, no, we didn't ask them for
15 that, no.

16 **MR. GRIFFON:** -- after further examination we
17 realized --

18 **DR. ZIEMER:** I think it grew out of that, yes.

19 **MR. GRIFFON:** I guess my point is that after
20 further examination they realized that the data
21 wasn't sufficient to support their existing
22 method and they went to another proposal.

23 That's at least my feeling at this point.

24 And I also -- and I do -- I do appreciate all
25 the work. I've been doing a lot of work with

1 these guys and I appreciate the massive amount
2 of time that's gone into this. And I also
3 think at the end of the day here or in the next
4 meeting -- real soon we have to work out the
5 process stuff, the policy questions, and we
6 have to have an evaluation process, I believe,
7 for our Board so that NIOSH understands what
8 they're going against. And I think that's --
9 that is an important step I think we need to
10 take.

11 But at this point, you know, that's my feeling,
12 is that we didn't ask for a new model. I feel
13 like there wasn't sufficient information on
14 their initial evaluation report that was before
15 the Board, that they couldn't support that in
16 the depth that they first thought they could,
17 and then they came up with a variation on the
18 model.

19 **DR. ZIEMER:** Uh-huh.

20 **MR. GRIFFON:** And I don't know that -- I mean
21 it results in higher doses, and you could say
22 well, that's claimant favorable. I see it as
23 they didn't have sufficient data to support the
24 first model so they default to a sort of -- a
25 different approach in the higher -- and you

1 have higher -- higher doses at the end of the
2 day. I'm not sure that answers that question
3 of sufficient accuracy. That's my opinion.

4 **DR. ZIEMER:** Okay, Gen Roessler.

5 **DR. ROESSLER:** I know you're looking for an
6 indication of how we're going to come down on
7 this, so I will say that I'm going to vote
8 against the motion. On an emotional level I
9 don't want to do that. I think these
10 petitioners have been through a horrible
11 situation because of our learning curve, the
12 very first one. But I think on an actual
13 basis, the things that bother me are the
14 uniformity, how do we continue on in this
15 process -- and I brought that up before -- so
16 that every claimant is treated equally.
17 And I think about the claimants who maybe can't
18 go through the SEC process or the claimants who
19 don't have the support group and the amount of
20 effort that went into supporting them that
21 these claimants have had. And so keeping that
22 in mind, I just can't feel comfortable with
23 voting for the motion on this particular
24 petition.

25 **DR. ZIEMER:** Okay, thank you. Jim Melius.

1 **DR. MELIUS:** Yeah, I'd like to make three
2 points. One is, and I believe I said this at
3 the last meeting also, that I think one of the
4 things we need to be careful with if we try to
5 guess at what we think -- whether or not we
6 think NIOSH can meet the criteria and do
7 appropriate dose -- individual dose
8 reconstruction was that if we get to the point
9 where we then -- I mean, our next sort of
10 evaluation is when we would look at individual
11 dose reconstructions. And after putting people
12 through this process for over a year, if we got
13 to the point and it turns out that we weren't
14 satisfied with how NIOSH was doing those, I
15 mean it would make us look pretty foolish and
16 it would be, you know, grossly unfair to the
17 claimants. And I think we tried to pursue that
18 issue to some extent with the example cases and
19 I think to some extent that that was helpful;
20 though, given all the other changes that have
21 taken place and sort of how we've approached
22 this dose reconstruction, I'm not sure that we
23 ever really were able to take full advantage of
24 that.
25 The second point, you mentioned about the

1 utilization of these data for epidemiological
2 studies. Well, on one hand you're correct in
3 terms of claimant favorableness would not make
4 it appropriate for such use, but on the other
5 hand the test for use in an epidemiological
6 study is you're looking at group data. And our
7 -- you care about whether one group of workers
8 with a particular type of exposure and so forth
9 had increased risk. You don't focus as much on
10 the individual person; whereas, we are charged
11 with evaluating -- this data is sufficient for
12 individual dose reconstruction with sufficient
13 accuracy. And I think that's some ways a
14 different test. And so as the utility of this
15 data for epidemiological studies or I just -- I
16 don't think that's a relevant criteria.
17 Finally, the section on the ability to do dose
18 reconstruction with -- for external doses, I
19 think it was an issue that the petitioner
20 raised. I believe we've had some partial
21 discussions of this before. I think we were
22 actually scheduled to have a more complete
23 discussion last meeting and ran out of time,
24 'cause I think it's a -- it is a difficult
25 issue on non-SEC cancers and what's done with

1 them. I was trying to construct something here
2 that was narrow and that dealt with the
3 particulars of this case and was a statement,
4 not making -- not trying to make a broad
5 statement about what should be done with --
6 about individual dose reconstruction for non-
7 SEC cancers. I think that is something we need
8 to take up as a policy issue of this Board in a
9 more general sense, and that NIOSH and
10 Department of Labor need to wrestle with in the
11 context of the program and the law.

12 But to me, I think that this narrowly-defined
13 exception is appropriate and is helpful and it
14 is -- again, this letter is designed to convey
15 our understanding of the situation at this
16 particular point in time.

17 **DR. ZIEMER:** Okay, thank you. Other comments,
18 pro or con? Yes.

19 **DR. MELIUS:** I also need to make one friendly
20 amendment to my own motion --

21 **DR. ZIEMER:** Oh, all right.

22 **DR. MELIUS:** -- which is a correction in --
23 just for the record, in the second paragraph,
24 the third line from the bottom -- this is the
25 boilerplate language -- the -- after -- the

1 first two words on the third line from the
2 bottom are "this employment" and there should
3 be a --

4 **DR. ZIEMER:** Comma? Oh, or --

5 **DR. MELIUS:** -- "or in combination".

6 **DR. ZIEMER:** "Or in combination." Yes.

7 **MR. GRIFFON:** There's some other typos, too.

8 **DR. MELIUS:** I know there's some others. That
9 one was, I think, the most legally important or
10 whatever.

11 **DR. ZIEMER:** Other -- yes, Dr. Roessler.

12 **DR. ROESSLER:** While Jim is looking at the
13 wording -- I guess I'd better use the
14 microphone.

15 While Jim is looking at the wording, I have a
16 question that -- some of the wording seems like
17 a contradiction. In the second to last
18 paragraph you say, second sentence, "It should
19 be noted that the Board believes that the
20 exposure information available was adequate for
21 the reconstruction of external exposures."

22 That seems to be a contradiction to your bullet
23 on the first page, and that's the fourth bullet
24 where you talk about --

25 **MR. GRIFFON:** Yeah.

1 **DR. ROESSLER:** I think I'd like that clarified.
2 I don't know if anybody else --

3 **DR. ZIEMER:** Well, I referred to that
4 indirectly before, that there is a kind of
5 built-in contradiction here that on the one
6 hand we say you can't do them very well and on
7 the other hand we're saying that they should be
8 done in these cases. So it's a -- and I might
9 suggest, while you're -- while we're talking
10 about that -- again, I've indicated that I
11 oppose the motion, but nonetheless let me try
12 to help you improve it.

13 In fact, although the angular thing has been
14 brought up, it actually is not that difficult
15 of an issue to deal with. I -- I mean, you've
16 characterized it, but people have been dealing
17 with that angular issue for decades and it
18 actually is not hard to convert to organ dose,
19 even in cases where you really don't know what
20 the angles were a priori.

21 So you might say that there are concerns about
22 it; I don't know how serious they are at this
23 point. I honestly -- certainly within --
24 within monitoring -- you know, personnel
25 monitoring is not like measuring doses for

1 therapy where you have to know that dose within
2 one percent. Most health physicists are happy
3 if you're within, what, plus or minus 20
4 percent, Mark, would you say? I mean, for
5 field work.

6 **MR. GRIFFON:** Definitely, yes.

7 **DR. ZIEMER:** Right. And within the
8 uncertainties of what is present in many of the
9 dose reconstructions anyway, I would offer that
10 the angular incidence issue, if one were doing
11 dose reconstruction, is much more readily
12 handled than implied here. I'm not even sure
13 that that particular bullet adds to the
14 argument, the main argument, and it certainly
15 contradicts or weakens the suggestion that you
16 have later in the document. I simply offer
17 that up as a friendly --

18 **MR. GRIFFON:** Yeah.

19 **DR. MELIUS:** I think Mark...

20 **MR. GRIFFON:** I tend to think that -- you know,
21 we -- we felt -- I mean, the reason we have
22 that -- I see it as -- how you could read it as
23 contradictory, I guess --

24 **DR. ZIEMER:** I just don't think it's a
25 showstopper.

1 **MR. GRIFFON:** Right, it was a point that's not
2 -- it was a point that's not resolved, but the
3 reason we have that final paragraph in is, I
4 felt, basically that it's pretty readily
5 resolved and they're going to do it because
6 it's a program-wide effect.

7 **DR. ZIEMER:** It's not a showstopper and I think
8 for those who support this motion, you are
9 doing yourself a disservice to have both of
10 those in there, I'll simply tell you that.

11 **DR. MELIUS:** I would point out that what
12 disturbed me was -- you know, when this issue
13 was raised, NIOSH's defense -- and not that
14 this is inappropriate but it made it more
15 difficult for us -- was well, it wasn't one of
16 the six points so they weren't going to deal
17 with it.

18 **DR. ZIEMER:** No, let me say that Jim indicated
19 they would deal with it, but it was not one of
20 the six things they asked us to come back with
21 information on.

22 **DR. MELIUS:** Let me clarify, then. Jim's
23 response was he wasn't going to deal with it in
24 this meeting.

25 **DR. ZIEMER:** Oh, yeah.

1 **DR. MELIUS:** And so we're sort of left hanging
2 with that, and then we hear that they haven't -
3 - they may or may not -- there's a technical
4 bulletin of some sort that's still under review
5 someplace or still being written. I have no --

6 **DR. ZIEMER:** Maybe we would like to hear either
7 from NIOSH or ORAU, but Dick Toohey or Jim
8 Neton, do you agree that the angular incidence
9 thing is not a showstopper for dose
10 reconstruction or --

11 **DR. NETON:** Yes, yes, I agree with that
12 position. It's a matter of degree of what the
13 collection factor is, but it's -- I think it
14 can certainly be bracketed.

15 **DR. ZIEMER:** But it's certainly much smaller
16 than other uncertainties in this proposed dose
17 reconstruction methodology.

18 **DR. NETON:** Yes, I agree with that.

19 **DR. ANDERSON:** I mean, basically it's an
20 uncertainty --

21 **DR. ZIEMER:** But there's a lot of uncertainties
22 that are much -- if you're going to start
23 mentioning them, this is not one that should be
24 highlighted. I'd simply offer that up. I mean
25 you're welc-- the Board can do what it wishes

1 on this, but I believe that the contradiction
2 is still built into the motion if...

3 Any other comments? Yes, Michael.

4 **MR. GIBSON:** I tend to disagree with that
5 opinion only because on the few times that
6 we've -- people were monitored, right, at least
7 at the Mound facility, when they knew that
8 there was going to be radiation built from
9 different angles. They would strap a dosimeter
10 on our forehead, they would strap dosimeter
11 rings on our fingers, or our thighs and every
12 part of our body. So if the angle of the
13 dosimeter isn't important, why would they go
14 the extra steps at times to add all these other
15 dosimeters?

16 **DR. ZIEMER:** Okay, thank you. Other comments?

17 **DR. MELIUS:** I would just -- in response I
18 think I would accept as a friendly amendment
19 from an unfriendly source --

20 **DR. ZIEMER:** Hey, I'm always friendly.

21 **DR. MELIUS:** -- the -- let's take out "serious"
22 and leave that. I would prefer to leave that
23 in as an uncertainty, recognizing --

24 **DR. ZIEMER:** "There are concerns"?

25 **DR. MELIUS:** "There are concerns."

1 **DR. ZIEMER:** Is that -- the seconder agree to
2 that change?

3 **MR. OWENS:** Yes, sir.

4 **DR. ZIEMER:** Then without objection the motion
5 is changed to take that into account. Any
6 other comments, pro or con?

7 **DR. MELIUS:** And I would also offer -- in
8 response to your comments, whether friendly or
9 unfriendly here -- in the second to last
10 paragraph I think it would be a little bit more
11 clear, in the third sentence, it would be the
12 third line, "information available to
13 adequately (unintelligible) reconstruction of
14 individual external exposures."

15 **DR. ZIEMER:** For the --

16 **DR. MELIUS:** And where appropriate for --

17 **DR. ZIEMER:** Well, yes. Of course, I think the
18 "individual" actually is implied, but there's
19 no reason not to add it, and without objection
20 add the word "individual."

21 Okay. Any -- it's second to last paragraph,
22 third line would now read "adequate for the
23 reconstruction of individual external
24 exposures."

25 Any other comments, pro, con, or otherwise?

1 Friendly, unfriendly, nasty, really friendly?

2 (No responses)

3 Then can I assume that the Board is ready to
4 vote on this motion?

5 **UNIDENTIFIED:** (Off microphone) I call for the
6 question.

7 **DR. ZIEMER:** Okay, the question is being called
8 for. I'm going to ask for a show of hands.
9 Those who favor the motion, please raise your
10 right hand. Okay, we've got Owens, Melius,
11 Espinosa, Griffon, Anderson, and Gibson.
12 And those who oppose the motion, Roessler,
13 Munn, Presley, Ziemer.

14 The motion carries and the recommendation will
15 be made to the Secretary to support the -- or
16 to support the petitioners. I believe -- and
17 let me -- and we will follow the regular
18 procedure and generate the letter.

19 And let me point out again to those here
20 assembled that this is a recommendation that
21 accompanies the NIOSH recommendation, the NIOSH
22 recommendation is that dose reconstruction be
23 done. So both recommendations now will go to
24 the Secretary, and then the Secretary will take
25 both into consideration. The Secretary of

1 Health and Human Services makes the decision.
2 The Board does not make the decision, we make a
3 recommendation. The recommendation of this
4 Board then is to support the petitioners. It
5 is so ordered. Standing ovation of one.

6 **MR. GRIFFON:** Paul, could I --

7 **DR. ZIEMER:** Comment, Mark.

8 **MR. GRIFFON:** I just wanted to say I have a few
9 typos which I'll just provide. They're not
10 substantive.

11 **DR. ZIEMER:** We will take care of the typos.
12 We will take a break now and then reconvene in
13 about 15 minutes.

14

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C E R T I F I C A T E O F C O U R T R E P O R T E R**STATE OF GEORGIA****COUNTY OF FULTON**

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of August 26, 2005; and it is a true and accurate transcript of the testimony captioned herein.

I further certify that I am neither kin nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 7th day of September, 2005.

STEVEN RAY GREEN, CCR**CERTIFIED MERIT COURT REPORTER****CERTIFICATE NUMBER: A-2102**