

UNITED STATES DEPARTMENT OF LABOR

+ + + + +

ADVISORY BOARD ON TOXIC SUBSTANCES
AND WORKER HEALTH

+ + + + +

COMBINED MEETING OF THE SUBCOMMITTEE ON
MEDICAL ADVICE RE: WEIGHING MEDICAL EVIDENCE
(AREA #2) AND THE SUBCOMMITTEE ON IH &
CMC AND THEIR REPORTS (AREA #4)

+ + + + +

MEETING

+ + + + +

TUESDAY,
JUNE 27, 2017

+ + + + +

The Subcommittees met telephonically
at 11:00 a.m. Eastern Time, Victoria A. Cassano and
Rosemary K. Sokas, Co-Chairs, presiding.

MEMBERS

SCIENTIFIC COMMUNITY:

- MARK GRIFFON
- KENNETH Z. SILVER
- GEORGE FRIEDMAN-JIMENEZ
- LESLIE I. BODEN

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

MEDICAL COMMUNITY:

STEVEN MARKOWITZ
VICTORIA A. CASSANO, Co-Chair
ROSEMARY K. SOKAS, Co-Chair

CLAIMANT COMMUNITY:

DURONDA M. POPE
KIRK D. DOMINA
GARRY M. WHITLEY
FAYE VLIENER

DESIGNATED FEDERAL OFFICIAL:

CARRIE RHOADS

CONTENTS

Introductions - Purpose of the Meeting 4
Update on Board Recommendations from DOL 13
Report from Seattle Visit 20
Potential Merger of Working Groups 45
Other Items 56
Adjourn 63

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

P R O C E E D I N G S

11:10 a.m.

MS. RHOADS: Good morning, everybody.
My name is Carrie Rhoads, and I'd like to welcome you to today's teleconference meeting of the Department of Labor Advisory Board on Toxic Substances and Worker Health.

This is a combined meeting of the Subcommittee on Medical Advice for Claims Examiners Regarding Weighing Medical Evidence and the Subcommittee on IH and CMC and Their Reports. I am the Board's Designated Federal Officer, or DFO, for today's meeting.

First, we do appreciate the time and the work of our Board Members for all of their prep for this meeting and for this meeting and for everything they'll do afterwards. I'll introduce the Board Members on the Subcommittees and do a quick roll call.

Dr. Tori Cassano is the Chair of the Weighing Medical Evidence Subcommittee. Dr. Cassano?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CO-CHAIR CASSANO: I'm here. There's a
2 lot of background noise.

3 MS. RHOADS: Okay. Could everybody
4 mute their lines if they're not speaking? I hope
5 that gets better.

6 And the members of the, that Committee
7 are Dr. Leslie Boden.

8 MEMBER BODEN: I'm here.

9 MS. RHOADS: Ms. Faye Vlieger.

10 MEMBER VLIEGER: Present.

11 MS. RHOADS: Ms. Duronda Pope.

12 MEMBER POPE: Here.

13 MS. RHOADS: Dr. Ken Silver.

14 MEMBER SILVER: Here.

15 MS. RHOADS: And Dr. Rosemary Sokas is
16 the Chair of the IH and CMC Subcommittee.

17 CO-CHAIR SOKAS: Here.

18 MS. RHOADS: And the members are, Ms.
19 Vlieger, again. Mr. Kirk Domina.

20 MEMBER DOMINA: Here.

21 MS. RHOADS: Mr. Garry Whitley.

22 MEMBER WHITLEY: Here.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. RHOADS: Mr. Mark Griffon. I'm
2 not sure he's on. Dr. George Friedman-Jimenez.

3 MEMBER FRIEDMAN-JIMENEZ: Here.

4 MS. RHOADS: And Dr. Steven Markowitz.
5 And again, I'm not sure if Dr. Markowitz is on.

6 (Simultaneous speaking.)

7 MS. RHOADS: Okay. We're scheduled to
8 meet today from 11:00 a.m. to 12:30 p.m. Eastern
9 Time. In the room with me is Kevin Bird from SIDEM,
10 our contractor, and John Vance, the Policy Branch
11 Chief for DEEOIC. Today's meeting is I don't think
12 long enough to take a break, but we'll defer to Dr.
13 Cassano on that.

14 Copies of the meeting materials and any
15 written public comments are or will be available
16 on the Board's website under the heading Meetings
17 and the listing there for this Subcommittee
18 meeting. The documents will also be up on the
19 WebEx meeting so everyone can follow along with
20 this discussion.

21 The Board's website can be found at
22 dol.gov/owpc/energy/regs/compliance/AdvisoryBoa

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 rd.htm. After clicking on today's meeting date,
2 you'll see a page dedicated entirely to today's
3 meeting. We'll publish any materials that are
4 provided to the Subcommittee.

5 There you should also find today's
6 agenda, as well as instructions to participate
7 remotely. If you are participating remotely and
8 you're having a problem, please email us at
9 energyadvisoryboard@dol.gov.

10 If you're joining by WebEx, please note
11 that this session is for viewing only and will not
12 be interactive. The phones will also be muted for
13 non-Advisory Board Members. Please note that we
14 do not have a scheduled public comment session
15 today.

16 The call-in information has been posted
17 on the Board's website so the public can listen in,
18 but not participate, in the Subcommittee
19 discussion today. The Advisory Board voted at its
20 April 2016 meeting that Subcommittee meetings
21 should be open to the public. And so a transcript
22 and minutes will be prepared from today's meeting.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 During the Board discussion, as we're
2 on a teleconference line, please speak clearly
3 enough for the transcriber to understand. When
4 you begin speaking, especially at the start of the
5 meeting, please state your name so we can get an
6 accurate record of the discussion. Also, I'd like
7 to ask our transcriber to please let us know if
8 you're having an issue with hearing anyone or with
9 the recording.

10 As DFO, I see that the minutes are
11 prepared and ensure they are certified by the
12 Chair. The minutes of today's meeting will be
13 available on the Board's website no later than 90
14 calendar days from today, but if it's available
15 sooner, we will publish them sooner.

16 Although full minutes will be prepared,
17 we will also be publishing verbatim transcripts,
18 which are obviously more detailed in nature.
19 Those transcripts will be available on the Board's
20 website within 30 days.

21 I'd like to remind the Advisory Board
22 Members that there are some materials that have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 been provided to you in your capacity as special
2 government employees and members of the Board,
3 which are not for public disclosure and cannot be
4 shared or discussed publicly, including in this
5 meeting. Please be aware of this as we continue
6 with the meeting today.

7 These materials can be discussed in a
8 general way that does not include using any
9 personally identifiable information such as names,
10 addresses, specific facilities if a case is being
11 discussed, or a doctor's name.

12 And with that, I convene this meeting
13 of the Advisory Board on Toxic Substances and
14 Worker Health, the combined Subcommittee meeting
15 on Medical Advice for Claims Examiners and IH and
16 CMC. I'll now turn it over to Dr. Cassano.

17 CO-CHAIR CASSANO: Good morning,
18 everybody, and welcome to this combined
19 Subcommittee meeting. I'm very glad that you
20 could join us. The purpose of this meeting is sort
21 of three-fold.

22 Number one, we wanted to go over some

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of the Board recommendations that we made to the
2 Department of Labor and what their status is,
3 because a lot the work of both of these
4 Subcommittees going forward is dependent upon what
5 DOL has accepted as far as the recommendations go.
6 And that will become, I think, more apparent as we
7 get further on in the meeting.

8 The second reason for this meeting is
9 to go over our site visit to the Seattle District
10 Office and what we learned from that meeting and
11 some of our takeaways from that meeting. And I
12 will discuss that a little bit later.

13 And finally, I think that both the
14 members of Dr. Sokas's Subcommittee and my
15 Subcommittee realize that it's very difficult to
16 define a problem, so we're only -- or see what
17 problems are apparent, if you're only looking at
18 part of the issue.

19 The other two subcommittees and the
20 working group on presumptions have a very defined
21 task, whereas we're sort of looking at a
22 combination of process and decision-making. And

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 we think that it's sort of like the blind man and
2 the elephant, if all you see is the trunk, then you
3 think the problem is this, and if all you see is
4 the tail, you think the problem is something else.

5 And we really feel that we would be much
6 more efficient and be able to give much better
7 advice to the Agency if we were to combine these
8 two Subcommittees. And we will have an open
9 discussion about that for all people to -- all the
10 Members to participate in.

11 So, for right now, I'd just like to very
12 quickly, with one-liners please, just go around.
13 Is the moderator still on or not? No? Okay.
14 Carrie, can you just call names, and people can
15 introduce themselves?

16 MS. RHOADS: Okay. I can --

17 CO-CHAIR CASSANO: Starting with me.
18 I'm Dr. Victoria Cassano. I am an occupational and
19 environmental medicine physician, retired from the
20 Navy as such, and then worked at the Department of
21 Veterans Affairs, primarily writing policy on
22 environmental and occupational exposures for that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 department and now have my own consulting company.

2 MS. RHOADS: Okay. Dr. Boden?

3 MEMBER BODEN: Hi. I'm Les Boden. I'm
4 a professor in the Boston University School of
5 Public Health. I've done a fair amount of research
6 on coal mining health and safety.

7 MS. RHOADS: Ms. Vlieger?

8 MEMBER VLIEGER: Faye Vlieger, a former
9 Hanford worker and worker advocate under the Energy
10 Employees Program.

11 MS. RHOADS: Thank you. Ms. Pope?

12 MEMBER POPE: Duronda Pope, United Steel
13 Workers, a former worker at Rocky Flats.

14 MS. RHOADS: Okay. Dr. Silver?

15 MEMBER SILVER: Ken Silver, associate
16 professor of environmental health at East
17 Tennessee State University. Involved early on
18 with Los Alamos workers and families and getting
19 the attention of Congressional leaders. And I've
20 done some scholarship, mostly advocacy for nuclear
21 workers.

22 MS. RHOADS: Thank you. Dr. Sokas?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Okay. I'm not --

2 CO-CHAIR CASSANO: She's probably gone.

3 MS. RHOADS: Yes, she had to drop off for
4 a minute, she'll be back in a few minutes. Mr.
5 Domina?

6 MEMBER DOMINA: Kirk Domina, I'm the
7 Employee Health Advocate for the Hanford Atomic
8 Metal Trades Council in Richland, Washington. We
9 represent about 2,600 active workers. I guess
10 that's good.

11 MS. RHOADS: Okay. Mr. Whitley?

12 MEMBER WHITLEY: Garry Whitley, former
13 worker at the Y-12 National Security Complex,
14 former president of Atomic Trades and Labor
15 Council, and I work with the Worker Health
16 Protection Program at Oak Ridge.

17 MS. RHOADS: Okay. Dr.
18 Friedman-Jimenez?

19 MEMBER FRIEDMAN-JIMENEZ: Hi. I'm
20 George Friedman-Jimenez. I'm an occupational
21 medicine physician and epidemiologist at New York
22 University School of Medicine and Bellevue

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Hospital. And my research interests are on
2 work-related asthma, radiation and cancer, and
3 epidemiologic methods.

4 MS. RHOADS: Thanks. Thank you very
5 much. If Mr. Griffon and Dr. Markowitz have joined
6 us, please let us know.

7 MEMBER GRIFFON: Yes, Carrie, this is
8 Mark Griffon.

9 MS. RHOADS: Hi, great. Every --

10 MEMBER GRIFFON: Mark Griffon, I'm a
11 health physics and occupational safety and health
12 consultant.

13 MS. RHOADS: Thank you. Okay, I think
14 that's everybody.

15 CO-CHAIR CASSANO: Okay, great. Thank
16 you, Carrie. I'm actually going to now, I believe
17 you're going to give us the update on the
18 recommendations that we had so far sent to the
19 Department of Labor and what their status is.

20 MS. RHOADS: Yes, that's right. I'll
21 just go briefly over each recommendation, and the
22 status is that they're being reviewed by the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Secretary for the first set of recommendations, and
2 for the second set, the program is working on their
3 responses. And we've had one interim response
4 that's been issued in March, I believe.

5 So, from the October recommendations,
6 the first one was for the program to rescind
7 Circular 15-06, which was post-95 occupational
8 toxic exposure guidance. And this was done on
9 February 2nd by Circular 17-04. So, that
10 recommendation was taken.

11 The second one was to ensure that the
12 disease exposure links from the IOM report were
13 included in the SEM. And from the interim response
14 in March, OWCP agreed that these are useful and
15 requested that the Board narrow the list to those
16 more relevant, with recommendations as to how they
17 could be used in the SEM.

18 The third recommendation was that
19 former DOE workers be hired to administer the
20 Occupational History Questionnaire. The fourth
21 recommendation was to establish a process to allow
22 the CMCs and the industrial hygienists to interview

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the claimants directly.

2 The fifth recommendation was to post
3 redacted teleconference notes online. And the
4 sixth was to explore the feasibility of having new
5 case files made accessible to the claimant
6 electronically.

7 The seventh was that the Department of
8 Labor reorganize its occupational physicians into
9 an office comparable in structure to the
10 Solicitor's Office for attorneys to support
11 multiple agencies. The eighth recommendation was
12 that the program make the entire case file
13 available to the industrial hygienists and the
14 contract medical consultants, with the claims
15 examiners mapping the files for them.

16 That was the first set of
17 recommendations from the Oak Ridge meeting. And
18 the second set of recommendations was from the
19 Richland meeting. And I'll just give a quick
20 overview of those as well.

21 The first recommendation was a new set
22 of presumptions for asbestos-related diseases, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 there were four parts. And they're complex, so I'm
2 just going to do an overview. The second
3 recommendation was a presumption for work-related
4 asthma, which also has four parts.

5 The third recommendation was a
6 presumption for chronic obstructive pulmonary
7 disease, and it replaced Bulletin 16-02 with an
8 alternative that has a bunch of subparts, which are
9 that if someone has been diagnosed with COPD and
10 has covered employment, that any labor category in
11 Attachment 1, and for Attachment 1 to be expanded,
12 and exposure to vapors, gas, dust, and fumes for
13 five years be presumed the causation. Also,
14 people who have less than five years of exposure,
15 for their cases to be sent to a CMC or an industrial
16 hygienist.

17 A fourth recommendation was revisions
18 to the Occupational History Questionnaire that,
19 for each exposure, that the claimant be asked to
20 describe how they were exposed by describing their
21 tasks and rating frequency and checking a box
22 whether they were directly exposed or had bystander

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 exposure.

2 And also, that the list of hazards
3 should include several specific things that have
4 been shown to be related to occupational diseases.
5 Also, this is to add the BTMed's list of tasks to
6 the Occupational History Questionnaire.

7 And that specific questions about
8 vapors, gas, dust, and fumes be added to the
9 Occupational History Questionnaire as well about
10 exposure frequency and description of tasks.
11 Also, this recommendation is that the new
12 Occupational History Questionnaire be tested
13 multiple times.

14 The fifth recommendation was that the
15 program enhance its scientific and technical
16 capabilities. The sixth was that two borderline
17 beryllium lymphocyte proliferation tests should be
18 considered the equivalent of one positive test for
19 adjudication purposes under Part B and Part E.

20 And the seventh and last one is that the
21 Department of Labor provide the Board with
22 resources to conduct a quality assessment of 50 CMC

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 evaluations in claim denials.

2 And like I said, the status of the April
3 recommendations is that the program is working on
4 responses. And then, once they have responses,
5 they will be submitted to the Secretary. So back
6 to you, Dr. Cassano.

7 CO-CHAIR CASSANO: Okay. Thank you
8 very much to Carrie. I do have one question on the
9 recommendation number two on the received exposure
10 lengths. And they wanted us to whittle that down
11 to those which were most -- but has the Board acted
12 on that at all? Or not?

13 MS. RHOADS: I think it was discussed a
14 bit at the April meeting, but I'm not sure where
15 Dr. Markowitz is with that.

16 CO-CHAIR CASSANO: Yes, I can't remember
17 either. So, I don't remember discussing that at
18 the Board. Okay. This meeting probably will go
19 relatively quickly, given that we're a half hour
20 into it.

21 I wanted to talk next about our trip --
22 does anybody else have, before I start, does

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 anybody else have any other comments or questions
2 about the status of any of the recommendations that
3 we have adopted and sent to the Agency? Hearing
4 none, I will move forward. Okay.

5 As most people that are listening know,
6 after our full Board meeting in Richland, there
7 were four of us who journeyed on to the Seattle
8 District Office to review cases with
9 representatives of the claims examining community.

10 There were four of us there. It was
11 myself, Dr. Les Boden, Faye Vlieger, and Duronda
12 Pope. Unfortunately, she was ill in the morning,
13 but she did manage to drag herself in in the
14 afternoon, and I'm very grateful that she was able
15 to do that, because she was really, really sick,
16 and she needs some kudos. She should get some
17 kudos for coming out when she was that sick.

18 Anyway, I am not going to go through
19 each and every case that we discussed, because it
20 would be a little perilous in that we might
21 unwittingly disclose identifiable information,
22 and we certainly don't want to do that.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 There were 12 cases which we had
2 previously reviewed that we had questions about
3 that we asked the Agency to review with us and answer
4 our questions. And then, there were eight
5 additional cases, two of each chosen by each
6 district office. And some of them were
7 acceptances; some of them were denials. And so we
8 had a total of 20 cases to go through in a period
9 of maybe about four or five hours.

10 I want to note that these cases were not
11 random selection, so one of the issues I think we
12 also have is the fact that we're not sure how
13 representative they are of the general practice
14 throughout the Agency. And that's not -- I don't
15 mean to say that as a criticism. It's just the way
16 it is.

17 I do want to say that the LIS imaging
18 system that they use was so much better than trying
19 to leaf through a flat pile of the cases. It was
20 very easy to get from one section to another
21 section. They were much better organized than I
22 thought they were from looking at a downloaded file.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And I think we discussed this a little
2 bit I think at the full Board meeting or at the
3 Presumptions Working Group, I can't remember which,
4 that we are going to formally request that at least
5 a couple of members of this combined Subcommittee
6 be able to access, get access to that system in some
7 read-only capacity, some limited capacity, so that
8 we can look at things a little bit, number one, more
9 usably, and look at things that we -- in a more
10 random way.

11 And I think we'll present that, probably
12 when we get to the next full Board meeting, we'll
13 present that as a request. And in general, and
14 other Members can weigh in on this, people were very
15 responsive to the, and very receptive to the asks
16 that we had about coming out and looking at these
17 cases.

18 And I don't -- it should be expected,
19 that when some outsiders that are quote/unquote
20 listed as experts come on in and try to look at your
21 -- look at how you do things, we felt there was a
22 little bit of defensiveness on a part of a couple

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of the reps, but I think we got past that as the
2 meeting went on.

3 There was some confusion about exactly
4 what we were looking at, because our assigned
5 Subcommittee name is Weighing Medical Evidence and
6 so, when we wanted to look at information about
7 exposure or about work groups, et cetera, there was,
8 of course, some confusion about why we wanted to go
9 there.

10 And I think we were able to explain that
11 when occupational physicians look at medical
12 evidence, they look at it in the context of exposure
13 and work environment. And that's a little bit
14 different, I think, than what most physicians -- as
15 to how most physicians approach patients or
16 approach medical records in general. So we got
17 that sorted out after a while, and I think it worked
18 very, very well.

19 As I said, I'm not going to go into
20 detail on each case, but just to give a bit of a
21 synopsis of what in general we found. And I know
22 Faye had some notes as well, and she is -- anybody

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 actually is perfectly welcome to chime in on some
2 of these and give your opinions about what happened.

3 There was at least one case that we would
4 either, CMC -- there was at least one case, maybe
5 part of at least one or two cases, in which we felt
6 that, after looking at what the CE had done and
7 looking at what was in the case file, that really
8 needed a CMC or an IH review. Either because --
9 especially in the one case where the person was not
10 a member of a special exposure cohort.

11 And so, we denied, without anybody who
12 understood the risks of exposure and causal
13 relationships, simply because they were not -- they
14 claimed that they were exposed to radiation, but
15 were not part of a special exposure cohort. A CBD
16 case was denied because -- on the presence of a
17 calcified granuloma. And I'll go through later on
18 what the sum total of all of this was.

19 There were a couple of cases that were
20 not developed at all, either because there was no
21 SEM information, and it was actually two types: one
22 was a meningioma case; the other was an autoimmune

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 disorder. There's nothing in the SEM about either
2 of these.

3 The meningioma should have been -- maybe
4 should have been sent to NIOSH. But because it's
5 a tumor and not a malignant cancer, there was some
6 questions about whether that met the requirements
7 for cancer.

8 And the biggest problem I think we found
9 was actually not a CE issue, but an IH and a CMC
10 issue. And that is the arbitrary use of the word
11 significant. And what we thought -- we found this
12 word tossed around rather a lot without any
13 particular definition of what significant meant.

14 In one case, the IH said the exposure was
15 significant, but the CMC said -- and so, it became
16 very confusing even to us, as to why these seemingly
17 contradictory statements were being made. And
18 this related primarily to a case of symptoms of
19 mineral oil and/or arsenic exposure.

20 And then, another CMC issue, and this is
21 why we need to combine these two Committees, a case
22 of CBD was denied by the CMC because the claimant

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 smoked and said they found less than at least as
2 likely as not that it was caused by the -- the CBD
3 was caused by beryllium because the claimant
4 smoked.

5 Not only does that not make sense, but
6 it's sort of -- as I understand, the Agency does not
7 view smoking as a way to offset -- there's not a
8 relative risk discussion between the relative risk
9 of smoking versus the relative risk of any other
10 exposure for energy employees. And so that was
11 sort of an issue for us.

12 Now, as I think -- and the reason we
13 wanted to go through the Board recommendations to
14 the Department of Labor is that a lot of these
15 issues, in some way, especially those that were
16 related to policy or were related to the SEM or
17 related to the industrial hygienist or the contract
18 medical consultant, can be solved when those
19 recommendations get put into effect.

20 We had a whole discussion on the
21 presumption, and not a whole discussion, but in
22 reworking the whole, not policy, but the whole

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 procedures and training documents on beryllium, the
2 fact that they singled out the calcified granuloma
3 needs to go away because it is not medically
4 correct.

5 Those kinds of things, once that is
6 removed, then that won't be an issue for the CE
7 anymore. And, again, from recommendations, many
8 of the presumptions will also help in that we have
9 added some exposure risk presumptions that may be
10 very helpful, especially on the COPD and on the
11 asthma, because those are the ones that create the
12 most confusion, I think, for CEs.

13 And the other recommendation about the
14 quality assurance of the CMC, I really would like
15 to -- I think we need to expand that. There needs
16 to be an audit by, an independent audit by some group
17 of randomly-selected claims, and not just of the CMC
18 and of the IH, but of the entire claims profession,
19 because we find -- there's some issues in the
20 complaints.

21 For instance, sometimes the medical
22 consultant and the IH decision were sort of funneled

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 inadvertently into an incorrect direction because
2 of limited information provided by the CE, which
3 goes back to the recommendation about the entire
4 claims file or because of the limited questions
5 asked by the CEs.

6 And that's a more difficult problem to
7 solve. There are ways to solve it that I think we
8 need to chew on a little bit, but sometimes the CE
9 is looking for specific answers and then, the
10 assumption that leads to that question may not be
11 correct.

12 So, therefore, the answer one gets from
13 the IH or the CMC are incorrect. And because of
14 that, we still believe that maybe that IH and CMC
15 shouldn't be sent the whole claims file, but, again,
16 I think, somehow, they need to have access, so if
17 something doesn't seem correct to them, they can go
18 back into the file and figure out, gee, maybe
19 there's something else going on here. Maybe the
20 person has the wrong contention, has listed the
21 wrong contention, and there's another more feasible
22 exposure association that this person is unaware

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of.

2 And while the SEM does some of that, it
3 doesn't do it completely, because it is not up to
4 date as far as the medical literature goes. And so
5 that goes both -- the IH must have information on
6 jobs and tasks and exposures so that they can do what
7 would be considered a somewhat quantifiable risk
8 assessment, rather than just saying, well, they
9 were significantly exposed to a nonsignificant
10 level over a long period of time. And we actually
11 read almost verbatim those words.

12 And to me, it makes no sense to me. I'm
13 sure it made no sense to the CE. And also, the CMC
14 must have access to exposures mentioned in medical
15 reports to determine the causal aggravation or
16 contributory effect of the exposure.

17 That's my piece of it. If Faye or Les
18 or Duronda and Ken, if you have anything to add,
19 please go ahead and do so as far as your
20 understanding or your impressions of the meeting.
21 I know, Ken, you weren't there, but you had some very
22 good insights when you reviewed the files. So, I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 will open it to other members of the Subcommittee.
2 And actually, anybody else who wants to chime in on
3 this topic.

4 MEMBER BODEN: This is Les. I thought
5 that was a pretty good summary of the meeting. I
6 think that idea of trying to figure out a way of
7 reviewing a random sample, at least --

8 MS. RHOADS: Hi, this is Carrie, I'm
9 sorry to interrupt you. The transcriber is having
10 a little bit of trouble hearing. If you're on a
11 speaker phone, can you --

12 MEMBER BODEN: Okay. I'll speak into
13 the phone better.

14 MS. RHOADS: Thank you. That's much
15 better.

16 MEMBER BODEN: I think that this was a
17 pretty good summary of the meeting. I think the
18 idea of trying to review kind of a random sample of
19 maybe specific kinds of cases that we're concerned
20 about might be worth pursuing. But I think that
21 should wait maybe until we have a discussion with
22 more of the folks on a larger Committee.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CO-CHAIR CASSANO: Yes. I wasn't saying
2 that I wanted to do that tomorrow, for sure. But
3 I think it's a recommendation that we need to float
4 to the whole Committee. I know we had a little bit
5 of discussion on this last Thursday, when we talked
6 about presumptions, about new presumptions, and
7 looking at things like Parkinson's Disease and some
8 other issues.

9 So, but that's just a thought to keep in
10 the back of our minds. Thanks, Les. Anything
11 else, anybody? Faye, you had some insight into the
12 nature of the meeting. I don't know whether I
13 adequately represented those or not. Oh, I'm on
14 mute, aren't I?

15 MS. RHOADS: No, you're not. Dr.
16 Cassano, you're not on mute. Ms. Vlieger, are you
17 still there? I'm looking to see if you're having
18 a problem.

19 CO-CHAIR CASSANO: Is she on mute?

20 MS. RHOADS: I don't see a distress email
21 from Ms. Vlieger, but Ms. Vlieger, if you're on, we
22 can't hear you.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CO-CHAIR CASSANO: Okay. Well, does
2 anybody else have any comments? And I'll open this
3 up to both Subcommittee Members. Any comments from
4 anybody about what we discussed, what some of the
5 issues are, and how we move forward?

6 MS. RHOADS: Ms. Vlieger said she lost
7 connection, and she's redialing. So she will be
8 with us in a few minutes, sorry.

9 CO-CHAIR SOKAS: And this is Rosie, I
10 just wanted to thank you. It was really helpful to
11 get that picture of what your visit was about. So
12 thank you.

13 MEMBER SILVER: This is Ken Silver. I
14 realized after raising that issue about the
15 contradictory use of the word significant in an
16 opinion letter that Dr. Markowitz presented quite
17 a brilliant parsing of the causation standard at our
18 Oak Ridge meeting in October.

19 And we should probably take a look at the
20 claims examiners or the final adjudication branch
21 or those records' abuse of the word significant in
22 light of Dr. Markowitz's brilliant understanding of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the statutory criteria.

2 But as Dr. Cassano said, the third to
3 last sentence of the letter said the exposure was
4 significant, and the last sentence of the paragraph
5 said the disease was not significantly caused or
6 aggravated by the exposure. So we should probably
7 come up with a consistent, coherent application and
8 have clear criticisms to DOL in those terms.

9 And one other thing Dr. Cassano just
10 mentioned was the possibility of the CMCs and IHs
11 doing almost a quantitative risk assessment. I've
12 long been afraid that this program would spawn a
13 cottage industry of risk assessors and modelers who
14 would go off the deep end to create a chemical dose
15 reconstruction cottage industry.

16 So we don't want them to go in that
17 direction, but I think we really do want a few more
18 data points to back up their determinations in their
19 final opinion letters.

20 CO-CHAIR CASSANO: I mean, I don't want
21 every IH to do some kind of epidemiological
22 discussion on attributable risk or anything like

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 that, but I think we need something more than
2 undefined use of the word significant.

3 That means something very specific -- as
4 we all know on the Subcommittee, that means
5 something very specific when you're talking about
6 statistics or epidemiology. But those are
7 population-based. When you're talking about an
8 individual, the word significant becomes a little
9 bit more ambiguous.

10 And so, we need to help the IH and the
11 CMC get from this level of ambiguity to something
12 that can be used to say that there is greater than
13 -- there is a reasonable potential for causation,
14 aggravation, or contribution to the outcome. So
15 anyone else? Rosie, anybody on Rosie's Committee?
16 Okay.

17 MEMBER VLIEGER: This is Faye, Dr.
18 Cassano. In my comments, and everybody read them,
19 there seems to be, well, it's so because the process
20 says so, even though it's a crazy outcome on many
21 of these claims.

22 And I really am concerned that there's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 been no auditing of the CMC vetting, that they even
2 should be making these opinions. The vetting
3 that's done in order that a CMC can perform under
4 the contract is very thin.

5 No one actually checks their
6 credentials. They sign a form and an affidavit,
7 and then they're vetted. That's how it's done.
8 DOL does the same thing for anybody that's vetted
9 to do work under the program.

10 And I was approached by one of the
11 physicians here locally that does the impairment
12 ratings, and he reads these letters and files that
13 get to the point where he's doing an impairment
14 rating, and he's just baffled that the people that
15 are doing the work are so unknowing or uncaring of
16 what the medical standard is or current medical
17 science.

18 And he said, you know, the vetting for
19 me was very veiled and very thin. There was no
20 checking of my credentials. So I'm concerned about
21 that, that no one is actually auditing the vetting
22 process.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And the other thing is that, and I think
2 you touched on this lightly, is that there's no
3 auditing of the CMC reports themselves, and if the
4 Department is doing it, I don't think they're doing
5 it with any rigor, to sort out those CMCs that are
6 using boilerplate, those CMCs that are not using
7 current science.

8 So, that was one of the things that I
9 think was most compelling about our trip to Seattle,
10 those issues of no audit and no really confidence
11 in the people that are making these decisions that
12 they're actually using current science.

13 And then, when we looked at the IH
14 reports, as you had commented, it made no sense when
15 they would say, oh, this person was only passingly
16 exposed; it wasn't significant. And significant
17 was used so many wrong ways.

18 CO-CHAIR CASSANO: Yes. And I think
19 there was one, I remember there was some radiation
20 exposure, and it was actually sent to NIOSH, I
21 believe, and put through IREP.

22 The problem was, I don't think they got

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the information on the two incidents that the
2 gentleman mentioned that he was exposed to, and they
3 were only looking at exposure -- and I know we're
4 not supposed to be talking radiation here, but
5 anyway -- they were only looking at exposure that
6 was documented on TLDs or film badges, depending on
7 how long ago the person worked. So, there are some
8 of those process issues that we need to deal with.
9 Anything else, Faye?

10 MEMBER VLIEGER: My concern, and we
11 talked about this before, is when an IH or a
12 toxicologist is looking at the exposures, that
13 they're looking at chemicals in the pure state.
14 And that's just not the case at these sites. You
15 have a toxic soup of chemicals.

16 And so, the synergistic effect of the
17 chemicals is not looked at. So, okay, we can
18 understand that they wouldn't know what the
19 different combinations are. So, then to say that
20 they weren't exposed to a pure chemical, of course
21 they weren't, because they weren't working in a
22 laboratory setting with a pure chemical.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So it's easy for them to say they weren't
2 exposed, but the problem is, they were exposed to
3 a bunch of toxic substances that aren't even being
4 considered, because they're not in the SEM or
5 they're not considered part of their labor
6 category.

7 CO-CHAIR CASSANO: But I think that they
8 are. They still look at the risk for each
9 separately, rather than looking at synergistic
10 effects. And unfortunately, there's a couple of
11 things now, like, they act as if it's nothing,
12 certain solvents. It's really, to determine it, if
13 neither one meets criteria for causation, it really
14 is, there's no scientific way of judging what the
15 synergistic effect might lead to.

16 So, that has to be up to the judgment of
17 the CMC, if they understand what those issues are.
18 And that --

19 MEMBER VLIEGER: Correct. And then, I
20 go back to my previous statement that I don't think
21 they're adequately vetted. One thing that I found
22 recently, within the past two weeks, from a claims

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 examiner, that I don't think we were aware of when
2 we were looking at the cases and it was news to me,
3 that the CMC only -- the IH, toxicologist, CMC only
4 gets seven chemicals to consider, no more, no less.
5 If there are less, one or two, yes. And that's
6 decided by the claims examiner.

7 And so I said, well, on what basis do you
8 do that? Well, we look at the ones that have the
9 strongest disease links. Well, compared to what
10 literature? And they couldn't answer that. So,
11 there's a weeding out process. Again, it's a
12 process, and I don't think it's benefitting the
13 claimant.

14 CO-CHAIR SOKAS: This is Rosie.

15 CO-CHAIR CASSANO: Go ahead.

16 CO-CHAIR SOKAS: Okay. I apologize,
17 I've been off and on the call. But I had two
18 comments. One is, I think it's critical that the
19 recommendation that the CMC and the IH have access
20 to the entire file, which I believe has already been
21 made, it's a priority.

22 Because, as Faye just said, the idea

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 that you would pick and choose which questions to
2 go forward when you're missing whole -- you may be
3 missing quite a bit is kind of silly.

4 And the second point, that I would
5 disagree, just a little bit, in the sense that, the
6 CMCs that I've seen, I've been impressed with their
7 credentials. The problem has been that this
8 definition of contribution is really much different
9 than it is for many of the other things that they
10 do.

11 And so there really needs to be kind of
12 a specific training program or some sort of
13 clarification each time, because they -- there are
14 other problems, but qualifications have not been
15 problematic in the people that I've seen. They're
16 very well qualified, but they just don't get some
17 of the aspects of the program, which is
18 understandable.

19 And I think that kind of gets us to our
20 third agenda item, which is that the problem has
21 overwhelmingly been, since the beginning, this kind
22 of communication failure between the program itself

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and the IH and CMC consultants that come onboard.

2 And any approach that we can figure out
3 to help bridge some of these communication gaps, I
4 think would be really helpful in general and
5 specifically when it comes to having these opinions
6 given.

7 CO-CHAIR CASSANO: Yes. I agree. I
8 think it depends on the type of contract that is used
9 as to how well the credentials are vetted. If it's
10 a personnel services contract, I think they're
11 vetted much better than if it's a contract that goes
12 out to QTC or LHI or something like that where you're
13 sort of at the mercy of the contracted entity to
14 determine the qualifications.

15 What I have seen in some cases were
16 people, well, in at least one case that I know of,
17 the person had marvelous credentials but had
18 probably been retired for about 25 or 30 years and
19 really wasn't clinically up-to-date and was using
20 30 year old references to make a -- to come up with
21 a determination.

22 And I felt that was rather

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 inappropriate, which doesn't bode well for me or
2 anybody else of my age who's moving towards
3 retirement here and want to do some stuff like
4 there.

5 And I will take what you said one step
6 further in that I think -- it seems to me IHs should
7 be able to communicate with each other. If the CMC,
8 if they have the record, and they see that this
9 person might have been exposed to this, they should
10 be able to communicate with the IH and say, hey, can
11 you tell me what type of exposure this person may
12 have had?

13 It's not in the SEM. It's not -- so that
14 there can be this robust discussion. And I'm not
15 saying on every case. Many cases are
16 straightforward. But I think in cases that are not
17 so straightforward, I think we need that kind of
18 discussion.

19 And I also think that we need -- and I'm
20 not sure, it's not a blanket statement -- but if
21 there's a truly good reason to believe somebody was
22 exposed and their disease may have been caused or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 contributed to by that exposure, regardless of what
2 -- that a claims examiner should not deny a case in
3 those instances for a medical question or an
4 exposure question without the benefit of it going
5 to the IH and the CMC.

6 But obviously, it can't happen for all
7 denials, or it's going to be backed up until next
8 century. So again, start thinking about ways that
9 we can try to pull those down, and maybe this is some
10 kind of discussion we can have with the Agency
11 Medical Director and the Agency IH at some point.

12 I failed to mention earlier that Dr.
13 Sokas and I will be having a discussion with them,
14 so that we can sort of straighten some of this out.
15 Okay.

16 Well, on to the next topic, because it's
17 12:00, and we've spent a half hour on each segment
18 so far. And I'm going to turn this over to Rosie
19 here -- she's going to hate me, but anyway -- for
20 this discussion about should we combine these two
21 Committees.

22 CO-CHAIR SOKAS: So, this is Rosie, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 I'm just going to remind everybody of what the
2 mission for each one of the Committees was. The
3 Medical Guidance for Claims Examiners was to focus
4 on medical evidence, the weighing of the medical
5 evidence.

6 And the Committee, Working Group that
7 I've been on, is the work of industrial hygienists
8 and staff physicians and consulting physicians, and
9 the reports, kind of doing a quality assurance of
10 what goes on and maybe identifying ways in which
11 that could be approved.

12 And it may be that the entire four
13 Working Group construct is due for a change anyway,
14 because I think the evidentiary requirements for
15 claims under Schedule B, related to lung disease,
16 has kind of been done already. And the
17 presumptions have sort of taken over as an
18 alternative way to have a working group.

19 But then these two pieces, the claims
20 examiner, weighing the medical evidence and the
21 reports of the CMCs and the IHs really ought to be
22 together. And just in terms of focusing on the IH

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 for a minute, I know Mark may or may not be on, but
2 Ken is on. I mean, it would be useful to have a
3 working group that had more than one IH on it,
4 probably. That that would give a little bit of an
5 ability to kind of collaborate a little bit more
6 there.

7 I think the same may be true -- and I --
8 for the physicians to have, again, a chance to do
9 some more chart audits that the three of us now could
10 do, as opposed to one when Tori is by herself. So,
11 that's a thought. I mean, I'd like to hear pros and
12 cons and whether this makes sense or whether some
13 other configuration would make better sense.

14 The other thing I did want to mention,
15 actually, and this is a question for Carrie, is it
16 may well be useful -- so, Tori and I wanted to have
17 this conversation with the Agency Physician and
18 Industrial Hygienist, just to kind of explore
19 communication from their perspective, but it may be
20 useful to have an industrial hygienist participate
21 in that conversation as well from the Working
22 Groups. So thoughts, if anybody has any comments.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER BODEN: This is Les. I always had
2 this uncomfortable feeling that we were trying to
3 divide things up that couldn't really be divided up
4 so easily. So, I think it's a good idea to think
5 about it merging in some way so that these things
6 can be talked about by everybody who's interested
7 at the same time, rather than at separate times and
8 then coming together.

9 MEMBER MARKOWITZ: This is Steve
10 Markowitz, can you hear me?

11 CO-CHAIR SOKAS: Yes.

12 MEMBER MARKOWITZ: Yes, hi. I got on a
13 half hour ago, because I wrote down the wrong start
14 time for the call, so I apologize. But it was
15 always a little bit of a mystery to me what the task
16 assigned to the Board of weighing the medical
17 evidence actually meant, because clearly the claims
18 examiner examines more than just the medical
19 evidence. Examines the exposure information as
20 well and puts them together.

21 But it did seem useful for a while, and
22 maybe no longer, to separate out the tasks of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Board, because if we had sort of skipped over this
2 issue of the claims examiner as an actor and zeroed
3 in on the experts, the industrial hygienist and the
4 physician, then attention of the claims examiner's
5 role might have gotten short attention.

6 So, I think it's been useful so far, but
7 that's not an argument against combining them at
8 this point if the issue really is what information
9 is brought to bear on deciding the claim, where does
10 it come from, and how best to ensure that the input
11 is adequate and that good decisions are made.

12 So, in that sense, I mean, there's
13 clearly an overlap and there's clearly a continuum
14 between sort of these two charges to the Board
15 overall. So it sounds like a fine idea to me.

16 CO-CHAIR SOKAS: Does any --

17 CO-CHAIR CASSANO: I would agree -- oh,
18 go ahead.

19 CO-CHAIR SOKAS: Yes, I was just asking
20 if anybody had any kind of contrary opinion or saw
21 any problem.

22 MEMBER VLIEGER: This is Faye. I don't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 necessarily have a contrary opinion. I just wonder
2 with so many people and the time required if we're
3 all going to be able to find time to review
4 everything we need to with such a large group.

5 CO-CHAIR CASSANO: And I think that's
6 part of the process of how do we do this? Do we
7 reconstitute a different Subcommittee? And maybe
8 some Members that may be spread a little bit too thin
9 because they're on two other Subcommittees as well
10 drop off? Or do we divvy up the work a little bit
11 differently?

12 I agree with Dr. Markowitz that I think,
13 initially, we needed to sort of look at the specific
14 jobs of the IH and the CMC versus the claims
15 examiner, but I think in order to get to the point
16 where we can actually make recommendations
17 regarding how they weigh the medical evidence, we
18 have to be able to see what medical evidence they're
19 being given to make a determination from. And, as
20 Dr. Markowitz said, it's not just medical evidence.
21 It's the exposure evidence as well.

22 So, I think the usefulness of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 separate Committees has sort of been fulfilled, and
2 I think, especially from my Committee's
3 perspective, I think we need to have it a little bit
4 broader.

5 And I think from Rosie's it is too,
6 because if the IH, if they're looking at the
7 decision made by the CMC, they may not necessarily
8 understand exactly what information the CMC was
9 given or what information the IH was given. So it's
10 hard to do them separately at this point.

11 CO-CHAIR SOKAS: Any other discussion?

12 MEMBER SILVER: This is Ken. I know the
13 Committee would have a lot of people, but there's
14 another very labor-intensive task that is neither
15 here nor there for the two Committees but I think
16 is very important for the Board: the case resources
17 that this Committee, Medical Evidence, and probably
18 the Part B Committee assembled, might have a real
19 impact if we were to take the presumptions that have
20 been cobbled up from the science and kind of applied
21 them to that test, these cases -- if the
22 documentation could ever be arranged in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 chronological order -- and see how the presumptions
2 would have worked to lessen the burden on everybody.

3 It falls a little bit outside the scope
4 of these two Committees, but I would like to be a
5 part of such an effort. Maybe it requires a Board
6 decision to go in that direction, but I think it
7 would give real, particularized, almost a human
8 face to the need for DOL to take our recommended
9 presumptions seriously.

10 CO-CHAIR CASSANO: Yes, no, I hear you.
11 I think, and I probably shouldn't speak for the
12 Agency, but I feel shudders going down my spine just
13 as the Agency representative, because if we find out
14 that, gee, three-quarters of the cases that we
15 looked at should have been adjudicated differently,
16 that creates a major issue for the Agency.

17 Not to say that that's wrong, but I can
18 -- that would scare me, if I was in the Agency. But
19 anyway. Because I don't know if those presumptions
20 can be applied, even retroactively.

21 MEMBER SILVER: A couple of compelling
22 examples, I can't stop thinking about the 1,700 page

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 file with 23 doctors that resulted in a COPD
2 determination after three or four years.

3 CO-CHAIR CASSANO: Yes.

4 MEMBER SILVER: It would be interesting
5 to back-test our recommended COPD presumptions, but
6 maybe we need to hear from our Chair about how to
7 organize this or put it aside for another day.

8 CO-CHAIR CASSANO: I think that the
9 recommendation might be able to be made to the full
10 Board. I don't know.

11 MEMBER SILVER: All right. I'll hold it
12 for then, but some of the labor of these two
13 Committees might get spread in that direction.
14 That's all I'm saying.

15 CO-CHAIR CASSANO: Yes, I agree.

16 MEMBER MARKOWITZ: This is Steve. I
17 think some of the recommendations around
18 presumptions are tied into other recommendations,
19 like improving the Occupational Health
20 Questionnaire or allowing, arranging for the
21 industrial hygienist to speak directly to the
22 claimant and getting better exposure information,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 such that it would probably be difficult to take
2 those presumptions, if they were fully adopted, and
3 use them to rejudge, reexamine the claims.

4 Because we're recommending that new
5 information be collected, better information be
6 collected for decision making. So, it may not even
7 be all that practical.

8 I'm also hoping that our
9 recommendations, particularly around
10 presumptions, are, since they are science-based and
11 since they do facilitate the process of decision
12 making, because they're more specific and clear,
13 that they won't take the kind of evidence, Ken, that
14 you're suggesting we need to collect to be adopted.
15 But we'll see.

16 MEMBER SILVER: Very thoughtful
17 response, thank you. So I'll table my idea and --

18 MEMBER MARKOWITZ: Actually -- this is
19 Steve. I'm not actually speaking out against it,
20 because I thought it was really intriguing, but I
21 was also wondering whether it was even possible,
22 because we hope to rely on improved exposure

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 information that would allow the presumptions to go
2 forward. So, I wouldn't -- so we should keep it out
3 there on the radar as a possible avenue.

4 MEMBER SILVER: All right. On the
5 radar.

6 CO-CHAIR CASSANO: I think that even goes
7 for the auditing of what the CMCs and IHs do and the
8 CE, the general audit, is that maybe there is some
9 benefit in doing that before all of our presumptions
10 and other recommendations are accepted, but
11 definitely it should be set up to be a routine
12 process, not necessarily by us, after the procedure
13 manual is redone or these notifications are put out,
14 so that we can make sure that once the process and
15 the procedures are changed, that they are actually
16 being followed.

17 And that's all the comments I have.
18 Anybody else have any comments on this? Or on how
19 to restructure the Subcommittees? If we want
20 everybody involved, or do some people not want to
21 be involved in the combined Committee. I guess you
22 can email your respective Subcommittee Chairs and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 let them know what you prefer.

2 CO-CHAIR SOKAS: And this is Rosie. I
3 think we want to really as a group develop a proposal
4 for the full Board meeting, because obviously this
5 is a decision that I think would go before the Board.
6 So we should do that electronically between now and
7 the next Board meeting.

8 CO-CHAIR CASSANO: Okay. Are there any
9 other items that anybody wishes to bring up? To
10 either Subcommittee?

11 MEMBER MARKOWITZ: This is Steve.
12 There's -- I just want to comment on, if there's not
13 a lot of other items, on something that Faye raised
14 earlier that's really interesting.

15 This whole issue of synergistic
16 mixtures, the scientists on the Board always kind
17 of come up with a blank on this, because there's been
18 so little scientific study of synergism. And being
19 defined as when two agents are involved with
20 exposure, that the sum of the effect is greater than
21 -- the net effect is greater than the simple sum of
22 the individual effects.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And as Tori said, asbestos, uranium,
2 smoking, these are a few examples, but they're
3 relatively few. And it occurred to me, something
4 obvious, which is that, which Faye may have been
5 referring to, which is that mixtures can produce an
6 additive effect, which the scientists wouldn't
7 consider to be synergistic, because it's not
8 interaction. It's not above and beyond. It's not
9 the whole is greater than the sum of the parts.

10 But that mixtures provide, actually,
11 additive effects, which the industrial hygienists
12 and the physicians can probably come a lot closer,
13 given the current science, to incorporating into
14 their analysis.

15 If a person is exposed to a solvent and
16 a second solvent of a similar class, chances are
17 they have a similar effect, and you could almost
18 double the exposure, if both of them are involved.
19 And I know we need, as a Board, to come back to this
20 issue, because Faye raises it repeatedly and
21 because it is an important issue and because IOM,
22 in their report four years ago, kind of took a shot

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 at it but didn't really address the issue.

2 In any case, I hadn't quite thought of
3 it that way before, so I just wanted to kind of
4 inject it into the conversation.

5 CO-CHAIR CASSANO: Yes. I guess we
6 probably were using synergistic in an incorrect
7 way, because there are additive effects, and then
8 there are synergistic effects.

9 And it's been good. From what I see,
10 there's pretty good information out there on mixed
11 organic solvents, but not when you look at two
12 dichotomous chemicals that may have their same
13 effect through the same pathophysiologic pathway.

14 A lot of that is being elucidated now,
15 benzene and dioxin, for instance, both interact
16 with one particular receptor and, therefore,
17 obviously potentiate each other's effects. But
18 it's going to be hard to do that, and it's going to
19 be, for a long time coming, that idea of additive
20 and/or synergistic is going to be really a decision
21 that's left to sort of a gut feeling of the CMC or
22 the industrial hygienist.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER MARKOWITZ: And actually our
2 recommendation around COPD and using vapors, gas,
3 dust, and fumes in kind of a nonspecific way is in
4 a way adopting at least an additive approach. We
5 don't care, in a sense, which vapors, which dust,
6 but if you add them up over any number of years, then
7 you're going to have sufficient exposure. And
8 that's actually the way the science has been done.

9 So that kind of incorporates, at a
10 minimum, an additive approach, without worrying
11 much about synergism. So there may be some
12 examples like that that we can talk about in the
13 discussion and try to enhance it.

14 MEMBER FRIEDMAN-JIMENEZ: This is
15 George. There's sort of a continuum of different
16 models that you can use from additive to less than
17 additive, which is antagonistic, in other words,
18 one chemical reduces the effect of another
19 chemical, which has been observed.

20 And then superadditive and synergistic,
21 and it's -- we don't have enough data to separate
22 out which kind of effect is happening with two

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 particular chemicals and certainly not with
2 multiple chemicals.

3 There's not enough data on mixed --
4 total VOCs, for example, as an exposure and what the
5 health effects of those are. And so maybe we could
6 just define it as nonantagonistic, in other words,
7 make the assumption that it's at least additive,
8 unless there is data to the contrary.

9 That someone has done experiments
10 showing that there's a real antagonistic effect, in
11 other words, one exposure eliminates or reduces the
12 effect of the other exposure. Which is fairly
13 rare, as far as I can tell, in toxicology, but it
14 does occur.

15 But I think, Steve, your suggestion that
16 we start with a default assumption of additive
17 effects or greater is very reasonable, from what
18 I've seen in toxicology. I'm not a trained
19 toxicologist, but I have worked a lot with the
20 National Toxicology Program, and I think it's a very
21 reasonable approach to just essentially say the
22 effects will be presumed to be additive or greater

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 unless there are data to show that it's
2 antagonistic.

3 CO-CHAIR CASSANO: And I think what -- go
4 ahead.

5 MEMBER MARKOWITZ: Yes, this is Steve.
6 Just to follow-up, I mean, actually if there were
7 some specific instructions to the CMCs and the
8 industrial hygienists along that route, assume
9 additivity, if not greater, that actually might
10 help in the way they approach the cases.

11 CO-CHAIR CASSANO: I think that also
12 leads -- gives weight to the recommendation that a
13 case should not be denied without the benefit of
14 going to an IH and a CMC, when we have multiple,
15 especially when we have multiple exposures.
16 Because the CE is only looking at the sum and looking
17 at one exposure at a time.

18 CO-CHAIR SOKAS: And the other thing, I
19 think that both Steve and George were describing is,
20 again, some guidance for the CMCs and for the IH,
21 with consultants, basically, that there's a list of
22 things to keep in mind. One is the definition of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 what's covered under the Act, but another could be
2 the role of assuming additive or more. And other
3 items as well.

4 MEMBER MARKOWITZ: This is Steve. This
5 topic doesn't yet have a home by a Subcommittee and
6 the Board, so I'm not suggesting it necessarily
7 belongs here, but we should -- we'll probably come
8 back to the discussion at the fall Board meeting and
9 then try to park it somewhere.

10 CO-CHAIR SOKAS: And the specific
11 discussion, it could go wherever, but there is kind
12 of an overarching discussion about training
13 materials or guidance for some things, quality
14 assurance for sure, for the CMCs and the IHs.

15 CO-CHAIR CASSANO: I agree. We are
16 almost out of time. Is there anything else that
17 anybody wants to add to this discussion? Or if you
18 want, if you think about it later, just email me and
19 Rosie or email the whole group and we can -- I'll
20 add it to the minutes when we get them. Any other
21 comments? Rosie? Steve?

22 CO-CHAIR SOKAS: No, thanks for running

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 -- thank you.

2 CO-CHAIR CASSANO: You're welcome.
3 Anybody else? Okay. Carrie, do you have anything
4 to say before we disconnect?

5 MS. RHOADS: No, nothing else. Thanks,
6 everybody.

7 CO-CHAIR SOKAS: Thanks, Carrie.

8 CO-CHAIR CASSANO: Thank you.

9 CO-CHAIR SOKAS: Thanks, everybody.

10 (Whereupon, the above-entitled matter
11 went off the record at 12:25 p.m.)

12

13

14

15

16

17

18

19

20

21

22

1
2
3