UNITED STATES DEPARTMENT OF LABOR

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ADVISORY BOARD ON TOXIC SUBSTANCES
AND WORKER HEALTH

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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)

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MEETING

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TUESDAY,
JUNE 27, 2017

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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

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 VLIEGER

DESIGNATED FEDERAL OFFICIAL:

CARRIE RHOADS

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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?

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

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

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

MEMBER BODEN: I'm here.

MS. RHOADS: Ms. Faye Vlieger.

MEMBER VLIEGER: Present.

MS. RHOADS: Ms. Duronda Pope.

MEMBER POPE: Here.

MS. RHOADS: Dr. Ken Silver.

MEMBER SILVER: Here.

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

CO-CHAIR SOKAS: Here.

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

MEMBER DOMINA: Here.

MS. RHOADS: Mr. Garry Whitley.

MEMBER WHITLEY: Here.

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

MEMBER FRIEDMAN-JIMENEZ: Here.

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

(Simultaneous speaking.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Number one, we wanted to go over some

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

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

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

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

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

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

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

MS. RHOADS: Okay. I can --

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

department and now have my own consulting company.

MS. RHOADS: Okay. Dr. Boden?

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

MS. RHOADS: Ms. Vlieger?

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

MS. RHOADS: Thank you. Ms. Pope?

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

MS. RHOADS: Okay. Dr. Silver?

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

MS. RHOADS: Thank you. Dr. Sokas?

Okay. I'm not --

CO-CHAIR CASSANO: She's probably gone.

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

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

MS. RHOADS: Okay. Mr. Whitley?

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

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

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

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

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

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

MS. RHOADS: Hi, great. Every --

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

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

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

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

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

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

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

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

the claimants directly.

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

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

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

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

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

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

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

exposure.

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

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

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

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

evaluations in claim denials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

of.

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR CASSANO: Is she on mute?

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

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

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

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

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

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

the statutory criteria.

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

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

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

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

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

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

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

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

And I really am concerned that there's

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

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

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

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

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

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

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

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

The problem was, I don't think they got

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

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

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

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

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

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

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

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

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

CO-CHAIR SOKAS: This is Rosie.

CO-CHAIR CASSANO: Go ahead.

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

Because, as Faye just said, the idea

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

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

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

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

and the IH and CMC consultants that come onboard.

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

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

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

And I felt that was rather

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SOKAS: Yes.

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

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

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

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

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

CO-CHAIR SOKAS: Does any --

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

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

MEMBER VLIEGER: This is Faye. I don't

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

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

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

So, I think the usefulness of the

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

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

CO-CHAIR SOKAS: Any other discussion?

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

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

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

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

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

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

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

CO-CHAIR CASSANO: Yes.

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

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

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

CO-CHAIR CASSANO: Yes, I agree.

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

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

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

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

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

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

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

MEMBER SILVER: All right. On the radar.

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

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

let them know what you prefer.

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

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

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

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

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

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

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

at it but didn't really address the issue.

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

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

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

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

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

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

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

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

particular chemicals and certainly not with multiple chemicals.

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SOKAS: No, thanks for running

-- thank you.

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

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

CO-CHAIR SOKAS: Thanks, Carrie.

CO-CHAIR CASSANO: Thank you.

CO-CHAIR SOKAS: Thanks, everybody.

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

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