

U.S. DEPARTMENT OF LABOR

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ADVISORY BOARD ON TOXIC SUBSTANCES
AND WORKER HEALTH

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MEETING

+ + + + +

TUESDAY
JUNE 16, 2020

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The Board met via telephone at 12:00 p.m. Eastern Standard Time, Steven Markowitz, Chair, presiding.

MEMBERS

SCIENTIFIC COMMUNITY

JOHN M. DEMENT
GEORGE FRIEDMAN-JIMENEZ
MAREK MIKULSKI
KENNETH Z. SILVER

MEDICAL COMMUNITY

MANIJEH BERENJI
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CALIN TEBAY

DESIGNATED FEDERAL OFFICIAL

MICHAEL CHANCE

C-O-N-T-E-N-T-S

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P-R-O-C-E-E-D-I-N-G-S

12:12 p.m.

MR. CHANCE: All right. Thank you very much. Good morning, everyone. Actually good afternoon for many on the East Coast. My name is Michael Chance. Today is June 16th, 2020. I'd like to welcome you to today's teleconference meeting, the Department of Labor's Advisory Board on Toxic Substances and Worker Health. I'm the Board's Designated Federal Officer or the DFO.

We appreciate the work of our Board members in preparing for today's meeting and their forthcoming deliberations. We are scheduled to meet today from noon, we had a little bit of a late start, until 5:00 Eastern Time. There will not be a public comment period for this particular meeting.

Today, as you are aware, like our April meeting, this meeting will be completely virtual as a precaution against the COVID-19 pandemic. We of course hope everyone is staying

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safe out there and taking proper precautions as this format is designed to ensure. I'm joined virtually by Carrie Rhoads from DOL and Kevin Bird from SIDEM who is our contractor. I appreciate Kevin's work in helping to pull all of this together.

For the timing, we shall take a break. The agenda is up on the WebEx at the moment. For those of you who are signed into the WebEx, we will have a break. Please consult the agenda as break times are listed. Copies of all 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 the subcommittee meetings.

The documents will also be up on the WebEx screen so that everyone can follow along with the discussion. Please visit the Board web page for additional information where after today's meeting, you'll see a page dedicated entirely to the meeting. Web page contains publically available materials submitted to us in

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advance of the meeting. We publish any materials that are provided to the subcommittee.

There you will also find today's agenda. If you are having a problem, please email us at energyadvisoryboard, that's all one word, @dol.gov. If you're joining by WebEx, please note that the session is for viewing only.

It will not be interactive. The phones will also be muted for non-Advisory Board members.

Please note that this is a new way of conducting meetings. We ask that you be patient as we work out all of the technological issues. But I think we had a pretty good meeting in April, and this format worked out well.

About meetings, minutes, and transcripts, there is a court reporter. There will be a transcript, and minutes will be prepared from today's meeting. During the Board discussions today, as we are on a teleconference line, please speak clearly enough for the transcriber to understand.

When you begin speaking, especially at

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the start of the meeting, please state your name so we can get an accurate record of the discussions. Also, I'd like to ask our transcriber to please let us know if you're having issues hearing anyone or with the recording. I think we've already had a few problems with phones this morning, so let's make sure that everybody is properly heard and recorded.

As the DFO, I see that the minutes are prepared and ensure they're certified by the Chair, Dr. Markowitz. And today's meeting will be available on the Board's website no later than 90 calendar days from today per FACA regulations.

If it's available sooner, they will be published before that 90-day period.

Also, although formal minutes will be prepared, we'll also be publishing verbatim transcripts as I mentioned which are obviously more detailed in nature. Those transcripts should be available on the Board's website within 30 days.

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I'd like to remind Advisory Board members that there are some materials that have been provided to you in your special -- in your capacity as special government employees and members of the Board which are not for public disclosure and cannot be shared or discussed publically included in this meeting. Please be aware of this as you continue on with the meeting. These materials can be discussed in a general way which does not include using any personally identifiable information such as names, addresses, and facilities that the case is being discussed or doctors.

And another extra word of caution today for everybody is regarding the nondisclosure agreements. Recently Board members have been granted access to redacted contract information that the energy program has with contractors to provide expert opinions from industrial hygienists. Board members will soon have access to a contract with the contract medical consultants as well.

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Please be mindful that the Board members signed the nondisclosure agreements or NDAs to get access to these contracts so the terms of these contracts cannot be disclosed or discussed in a public meeting. These are better discussed in working groups, so please keep that in mind as we proceed with the meeting today. So thank you for bearing with me and getting through my opening script. With that, I now convene the meeting of the Advisory Board on Toxic Substances and Worker Health, and I will now turn over the meeting to Dr. Markowitz.

CHAIR MARKOWITZ: Thank you, Mr. Chance. And I want to -- the Advisory Board. Welcome to the members of the Board. Welcome -- and also welcome to the members of the public. Whether we have members of the public online --

MEMBER GOLDMAN: There's a tapping sound.

CHAIR MARKOWITZ: I'm sorry?

MEMBER GOLDMAN: There was a tapping sound when you were talking, Steve.

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MR. BIRD: Yes, Dr. Markowitz, it sounds like you might have a bad audio connection kind of cutting out.

CHAIR MARKOWITZ: That's not good. Is it still cutting out?

MR. BIRD: Yeah, there's like kind of a strange like tapping or repeating sound that's kind of in the background. It makes it hard to hear you.

CHAIR MARKOWITZ: Yeah. Well I'm going to -- you want me to just call back in and see if I get a better connection?

MR. BIRD: Yeah, I think -- I don't know. I'll let Carrie make that call and Michael. Excuse me. But I think, excuse me, it's going to be very hard to hear you.

MS. RHOADS: Yeah, you're cutting in and out in the middle of your sentences. So maybe try another line.

CHAIR MARKOWITZ: If I speak like this, or is this the same?

MS. RHOADS: I can hear you that time.

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I still hear the tapping sound.

CHAIR MARKOWITZ: You still -- okay.
Well -- okay. So just give me a moment.

MS. RHOADS: Okay.

(Pause.)

MR. BIRD: And Carrie, if this doesn't fix his issue, I can try to call him and then conference him in or something like that.

MS. RHOADS: Okay. Hopefully we'll get a better line this time.

CHAIR MARKOWITZ: Am I in now?

MS. RHOADS: Yes, and I don't hear a tapping sound yet.

CHAIR MARKOWITZ: Okay. Well that's good.

MS. RHOADS: Good.

CHAIR MARKOWITZ: Okay. So let me know if there's a problem. So I was just asking Calin whether -- do we know whether we have members of the Board on the call -- oh, excuse me, the public?

MR. BIRD: We can ask the operator.

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We do have members of the public tuned into the WebEx though. So --

CHAIR MARKOWITZ: Okay, okay. Well that's good. That's all I wanted to know. So just to point out particularly for members of the public. For some of the materials -- for the agenda but also for some of the materials that we're going to review today, all of which will be shown on the WebEx.

But if you want to access them otherwise, they're on our meeting website. You just have to go to the Advisory Board's website to today's meeting. And at the bottom, you'll see briefing book materials and the various materials will be listed. The minutes from the last meeting are not yet available but will be available shortly.

So let's do introductions from Board members and then we'll review the agenda. So I'm Steven Markowitz. I'm an occupational medicine physician, an epidemiologist at the City University of New York.

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MS. RHOADS: Do you want me to go down the list?

CHAIR MARKOWITZ: Yeah, if you could, Carrie. That'd be great.

MS. RHOADS: Sure. Okay. Dr. Dement?

MEMBER DEMENT: I'm John Dement, professor emeritus in the Duke University School of Medicine, industrial hygiene and epidemiology.

MS. RHOADS: Thank you. Mr. Domina?

MEMBER DOMINA: Kirk Domina, I'm the employee health advocate for the Hanford Atomic Metal Trades Council in Richland, Washington.

MS. RHOADS: Thank you. Dr. Goldman?

MEMBER GOLDMAN: I'm an occupational environmental medicine physician at Cambridge Health Alliance and also associate professor at Harvard Medical School and Harvard School of Public Health.

MS. RHOADS: Thank you. Mr. Mahs?

MEMBER MAHS: I'm Ron Mahs. I'm a former employee at all three plants at Oak Ridge representing the building trades at AFL-CIO.

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MS. RHOADS: Thank you. Dr. Mikulski?

MEMBER MIKULSKI: Marek Mikulski, University of Iowa College of Public Health, occupational epidemiology.

MS. RHOADS: Okay. Ms. Pope?

MEMBER POPE: Duronda Pope, a former worker of Rocky Flats and currently with the United Steelworkers Union.

MS. RHOADS: And Dr. Redlich?

MEMBER REDLICH: I'm an occupational environmental medicine and pulmonary physician on the faculty at Yale School of Medicine and the School of Public Health. And I'm director of the Yale Occupational Environmental Medicine Program.

MS. RHOADS: Thank you. Dr. Silver?

MEMBER SILVER: Ken Silver, associate professor of environmental health in the College of Public Health at East Tennessee State University, about 100 miles east of Oak Ridge. Before coming to ETSU, I worked very closely with families, congressional offices, and organizations to campaign for EEOICPA and the

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Part E amendments.

MS. RHOADS: Thank you. Mr. Tebay?

MEMBER TEBAY: Calin Tebay, Hanford Workforce Engagement Center representative and site-wide beryllium health advocate at Hanford.

MS. RHOADS: Okay. And Dr. Berenji, are you on the call yet?

(No response.)

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

(No response.)

MS. RHOADS: Okay. That's everybody.

CHAIR MARKOWITZ: Okay. Thank you. So let's just review the agenda. Let me say this is the final full Board meeting of the Board's term which ends end of July. Our hope this meeting is to vote on certain recommendations that we can vote on but also to discuss if there's other issues, make additional progress. And I expect over the next four weeks, we'll be able to do some additional work so that we can hand off various issues to the next Board in a

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suitable fashion.

First we'll hear some updates from the program, and then we will discuss the report and recommendation on Parkinson's-related disorders led by Dr. Mikulski. If Dr. Berenji joins us, we'll hear a report on the IARC Group 2A carcinogens in relation to the Site Exposure Matrices. If not, we'll discuss that regardless but probably in less detail. And then I'll lead a discussion on job titles related to asbestos and a recommendation.

We'll take a break. Let me add that all our time frames here are entirely approximate. It's really just guessing how much time each topic would take. We certainly will finish by 5:00 p.m. So I don't expect a problem.

We'll take a break, and then we'll discuss the very preliminary language on resource request that the Board has discussed in the past. And then we'll discuss again just some draft language relating to the assessment of the contract medical consultants and the industrial

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hygienists.

We'll discuss and review claims that we received, some 20 or so lung cancer claims. And I don't recall the number of post-1995 claims, but about 10 of those actually. We will discuss the Department of Labor's request for us to look at the development letters that they send to providers to see if we can help them improve the response from providers, and then any additional issues that would arise. And we'll finish with the work plan for the last month of the Board's term. Are there any additional items anybody would like to add?

(No response.)

CHAIR MARKOWITZ: Okay. So let us begin with the report from the program. I think, Ms. Pond, are you on the phone or Mr. --

(Simultaneous speaking.)

MS. POND: I am.

CHAIR MARKOWITZ: Great.

MS. POND: This is Rachel Pond. Thank you for the opportunity to provide some brief

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updates about the program and address a couple of Board issues this morning. I'm just going to go ahead. I'm going to probably just start with just some general updates about what we've been up to and then address some Board activities.

First, I just wanted to mention -- and I may have mentioned this last time but I'm not sure. But we did undergo -- at the end of March, we underwent a new case assignment process for the way that we assign cases to our district offices. We actually instituted this similar process in our FAB offices a couple of years ago, and it has worked fairly well.

Historically we used to assign cases according to where the latest state of employment was. So if they were in Paducah, it went to Jacksonville. If they were in Denver or Rocky Flats, for example, their cases went to our Denver offices. And that was pretty appropriate and necessary early in the program only because we had -- we wanted to make sure that people could develop specialties in those particular

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facilities, and we were doing a lot of traveling, a lot of outreach. And we could send targeted people to places close to those district offices.

However, as the years have progressed and the program has expanded a little bit, we determined that those jurisdictional lines aren't necessary. And this will allow for a wider variety of examiners reviewing cases. It also allows for hiring flexibility so that we -- we were starting to decrease in certain areas like in our Cleveland office. We weren't getting as many claims.

And in our Denver office, this way we can even that out. We were not overworked in one office and underworked in another, or basically we can evenly distribute those claims all the way across the country. It seems to be working fairly well so far.

We did have a series of trainings for all of our district office staff who are working on these claims, meaning that we have specialists who knew a lot about certain plants and certain

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facilities. And they would go and give presentations to the district offices about those particular sites so that when they're developing claims, they have a better understanding of the unique particulars of those sites and those areas.

So that's been going well. And we also continue to have specialists who are POCs, for example, points of contact for those sites if claim managers around the country have questions.

I just wanted to mention that because it's something I think that authorized reps around the country are noticing. And it's just because you may not -- people always expect that they'll go to Jacksonville if they've worked at a particular site in that area. So that has changed.

I also just wanted to acknowledge some of the things that we have done related to the current COVID-19 emergency. We have gone to complete telework for all of our district office staff. Luckily, we have digitized all of our case files, at least most of them in terms of

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active cases files have been digitized for years and so they're paperless. And people can review case files online.

We do have some historical cases and a lot of them actually. We've had a project going for the last year or two to turn all of our old case files into paper. So a lot of that's been done. And those that have not been done, we've been able -- we have contractors that are still working on turning those into -- the paper into digitized case files. And so whenever a case file is needed, we've been able to do that. So honestly, it's going to safe to remain at home and still do their job.

We also have an interactive voice response system for our phone calls which means that any phone calls that come in can be transferred to -- it'll go into the claims examiners' phone lines and then transferred into whatever number they want to forward it to without revealing phone numbers -- personal phone numbers.

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So that's been working very well. I've been happy to be able to report that our quality remains constant. Our timeliness has been fairly constant as well. We still do rely on other records from Department of Energy. And there's been some record centers that aren't able to provide records. So we are allowing for that.

Some physicians that aren't able to provide support because they can't see a patient were also allowing some leeway in terms of deadlines for those activities.

That being said, we also did publish a couple of bulletins that will allow for temporary use of telemedicine during this time, which means that for face-to-face examinations in order to authorize payment, we normally -- I'm sorry, for home healthcare, we normally require face-to-face examinations in the last 60 days. And we, during this time, are waiving that and under certain circumstances, if a physician wants to do telemedicine, as long as that physician has the state licensing requirement for telemedicine and

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other specifics are met, they can provide it with those reports based on a telemedical examination. We also are allowing for that to occur with routine physician appointments in certain circumstances where the physician feels like it would be unsafe to see the patient in the office.

We have also had some changes to our resource center hours in terms of what's open. We had to close all of our resource centers, but our resource center staff are still working. They have also been able to telework. They've been answering phones from a remote location. Just as I explained, that we were able to do that with our district office staff. They are able to do that through our interactive voice response system, and that has been working well.

As well they've been able to talk through claims information, intake claims. They've been going into the office around the country one day a week to gather any document that claimants want to submit. They've been dropping them outside the door. And we've been

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able to pick them up and process those. Effective next week, our resource centers will still be closed. But we will have staff going in every day, at least one person in the office per day, to be able to talk to claimants, answer phones, and those sorts of things.

So that's -- we've also changed from -- well we're not having any in-person hearings for our hearing reps and people who want to have hearings. So those have been revised to only WebEx or telephone hearings during this time period. So I'm happy to report we've been able to continue to work and things have been going fairly well during this time.

I also just wanted to mention that we have not been doing so much outreach. So we are going to try to do a webinar, a stakeholder update June 25th. That information has gone out to our provider -- our email blast group for claimants and whoever signed up for those. We will be getting more information about that out on our website hopefully this week as well.

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So that's basically kind of a very brief update of some of the things going on with us. In terms of Board activities, we did receive some recommendations based on the last meeting that were related to the OHQ. We have reviewed those recommendations. They are currently in clearance within the Department. I hope to have that out very shortly. But we are making some changes to our OHQ that we hope to start piloting soon.

With regard to the March 5th letter from the Board, recommendation to change the language in Exhibit 15-4 related to asthma, we did make some changes and provided a May 1st response. I've got a reference to mechanism of disease but kept some of the other language. I've also gotten a lot of data requests from the Board.

We've provided -- as Dr. Markowitz alluded to, we've provided some cases regarding lung cancer and cases with post-1995 IH reports. We've also sent in a lot of development letters

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to try to give the Board an idea of what we're sending out with regard to asking physicians for documentation.

And we've sent out -- we've received a request for the contract which we just very recently have been able to get out to you. And then there was some information that had been requested on the Site Exposure Matrices, which we have -- we've provided a response and we're working on gathering more information related to that data request. Those are the updates I have.

I'm happy to take any questions from the Board regarding any of those things and anything else.

CHAIR MARKOWITZ: Thank you. And thanks also for the timely response to our various requests. I just have a quick question.

If I understand it correctly, the district offices around the country will be handling cases from other geographic areas around the country. And I assume that each district office develops some degree of experience and expertise at the particular sites which fall within their

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geographic area, that the claims examiners get to know those particular DOE sites and et cetera.

So my question is, I understand the advantage of flexibility of being able to handle claims at other district offices. But is there any chance that there's some loss of expertise or experience at the particular DOE sites? And if so, how do you address that?

MS. POND: So as I mentioned, we didn't actually consider that when we made this change. And that's why we did some expensive training before the change occurred. We had specialists, people who are particular knowledgeable in each of the district offices related to specific sites. And they gave presentations to the other district offices with regard to what to look for related to those sites.

We've maintained those points of contact so that if claims examiners around the country had questions, they can go to this person and obtain more information. We also maintained

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some books full of information in each district office that has specific information related to what to look for at these sites so that those have all been shared nationwide. And people can reference those to look up, well in this particular location, you need to look out for certain types of records. I mean they get pretty detailed in terms of what claims examiners should be looking for.

So yes, while I see that some expertise having known certain sites for a long time, it may be lost in this transition. I think that we've put mechanisms in place to be able to address that and work with each other to make sure that the knowledge is being shared.

CHAIR MARKOWITZ: Okay. Thanks. Any other questions from the Board members? Okay. Thank you very much.

MS. POND: All right. Thank you.

CHAIR MARKOWITZ: Let's move on. Kevin, if you could put up the PowerPoint that I sent you yesterday. Dr. Mikulski -- also Kevin,

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if you could have handy the Word file that is the complete recommendation and rationale of Dr. Mikulski's group, although I think if we just show initially the PowerPoint, that would be the best way to start. So Dr. Mikulski?

MEMBER MIKULSKI: Thank you. This is Marek Mikulski. Kevin, can you go to the next slide please? I will briefly go over the revised test of the recommendations. And afterwards, we can open the floor to comments and edits and hopefully vote on the final text of the recommendations to submit to the Board.

So the first set of questions that the Board was asked to advise on was related to the diagnosis and the terminology of Parkinsonian-type disorders. And we were asked specifically about differentiation between manganism and Parkinson's disease. Can you move to the next slide please?

We recommend that for the purposes of claim adjudication or the clinical diagnosis of Parkinsonism as established by a clinician be

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treated the same as a diagnosis of Parkinson's disease. This combining of diagnosis and the following recommendation is based on the lack of biomarkers or valid clinical diagnostic tests that would allow a clear differentiation between these disorders. As part of our recommendation, we had also provided the commonly used aliases for both disorders, and we recommend that these are used when updating the SEM information. We have also provided ICD 9 and ICD codes to help with the adjudication process. Next slide please.

So the next set of questions was related to exposures associated with the diagnosis of Parkinsonism. And we were specifically asked about causation presumptions including duration of exposure. Next slide. After reviewing the literature, we recommend that exposures to solvents, carbon disulfide and trichloroethylene, be presumed, in addition to carbon monoxide and manganese products that cause, contribute, or aggravate Parkinsonism.

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There is ample evidence, both from DOE's own studies and former worker program reports, that these exposures were common historically throughout the DOE weapons complex.

And in human studies including case reports and epidemiologic studies have found their association with increased risk of Parkinsonism.

In addition, based on the epidemiologic studies, we recommend eight years as a minimum exposure duration in adjudicating the claims with these newly identified exposures. Next slide please.

At this moment, we do not feel that the evidence is strong enough to issue a recommendation for other solvents, including methanol, n-hexane, toluene as well as polychlorinated biphenyls and pesticides. However, as this is an emerging research coming up in claims, we do recommend that DOL performs a periodic review of human studies to update the list of toxicants that may be associated with these diagnoses. Next slide please.

Finally we also included in our

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recommendation this statement, and we hope that this will help clarify the Board's recommended use of causation presumptions throughout the claim adjudication process. These presumptions are based on the current state of knowledge and are intended to streamline the adjudication process, and those individuals with straightforward presentation of the disease by removing the need for detailed review by IH and CMCs. The claim does not need the presumption. It does not imply lack of sufficient evidence.

It just means that their claim would need to be more thoroughly taking into consideration the work history by both IH and ME to make adjustment on whether the exposure contributed and related to the claimed disease. And let me stop at this point. Are there any questions to these recommendations?

CHAIR MARKOWITZ: This is Steven. So if we could -- what we need is a move to accept the recommendation. And if you could, Kevin, just go up to a couple of these slides. If you

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go up to the top, so what we're voting on is -- go to the third slide. So this is the first part of the recommendation that Dr. Mikulski outlined.

And if you go to the next slide. I'm sorry, the next slide.

MR. BIRD: Sorry. Do you want Slide 4 or 5?

MEMBER MIKULSKI: Page 5.

CHAIR MARKOWITZ: Yeah, the following one.

MR. BIRD: Okay, great.

CHAIR MARKOWITZ: So this is the second part of a recommendation. And then this really centers on carbon disulfide and trichloroethylene, eight years of exposure. Then the next slide is the final part of the recommendation. Now is there a move to accept this recommendation?

MEMBER GOLDMAN: This is Rose Goldman. I move to accept them.

CHAIR MARKOWITZ: Thank you. Is there a second?

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MEMBER DEMENT: It's John Dement. I second.

CHAIR MARKOWITZ: Okay. So now we're open for discussion. Well, I read the longer write-up that Dr. Mikulski and the group did, which has been provided for a couple weeks now to the entire Board. And if need be, Kevin can bring that up if anybody wants to look at any part of it.

But I thought it was an excellent review, very balanced, very insightful about the current state of evidence. It weighed things appropriately. And I was convinced that this is the appropriate recommendation based on current knowledge. Are there other comments, other discussion?

(No response.)

CHAIR MARKOWITZ: While you're thinking for a moment, let me just ask about Dr. Berenji and Dr. Friedman-Jimenez. Do you know whether they're on the line?

MS. RHOADS: I just had an email from

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Dr. Berenji. She's trying to join now.

CHAIR MARKOWITZ: Okay.

MS. RHOADS: She should be on in a minute.

CHAIR MARKOWITZ: Okay. We haven't heard from Dr. Friedman-Jimenez, right?

MS. RHOADS: I have not.

CHAIR MARKOWITZ: Okay. Yeah, I texted him, but haven't heard --

MS. RHOADS: Okay.

CHAIR MARKOWITZ: -- back. Okay. So --

MS. RHOADS: I emailed him as well.

CHAIR MARKOWITZ: Yeah. So any further discussion on this recommendation?

MEMBER REDLICH: This is Carrie Redlich. Just in terms of how it would be implemented to those who are more familiar with the literature in terms of trying to assess the amount of exposure, and we have this seven-year period of time. Then do we have a sense of amount or generally potentially the types of

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jobs? I'm just thinking of trying to help someone decide whether there was sufficient exposure.

MEMBER MIKULSKI: So there is, of course, no quantification of exposure included in the studies. But most of these exposures were low chronic exposures, which in my mind would've been typical of most of the DOE operations as symptoms for the most frequent of the uses in degreasing and also in the production processes.

MEMBER GOLDMAN: This is Rose Goldman. To add to it, this literature is a bit difficult. That eight years came mostly from one study that was one of the better studies done with a lot of IH that looked at workers with long-term exposure. And the only ones -- they had a minimum of eight years. So that's where that came from.

That would not necessarily apply to something like manganese where we don't have that kind of data. And what we know about manganese is more from overdoses and the same is true for carbon monoxide. Those two have the development

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of Parkinson's after recovering usually from a high exposure. So this was more based on chronic exposures months before the solvent.

MEMBER REDLICH: This is I think largely my relative ignorance on this area. But in terms of skin exposure, is that something that you think is another contributing factor?

MEMBER MIKULSKI: Absolutely. I think that the two main routes of the exposure would have been inhalational and dermal in this case. But again, to quantify that, it would've been far more difficult. We can add that in the recommendation. However, I think that the text itself implies that these are occupational exposures and as such would have included those routes.

MEMBER REDLICH: Yeah, because I think the importance of the skin is I think you mentioned was there. So low levels, airborne levels do not rule out the opportunity for lots of skin exposure.

MEMBER MIKULSKI: Well the eight years

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is coming from the epidemiologic observations of the workers working in the degreasing parts for a small industrial plant making gauges. And definitely there was a potential for dermal exposure in that study.

MEMBER GOLDMAN: Can we go to the recommendation? Did it say specifically -- I have to see that slide again -- that it had to be inhalation or was it just general exposure which would have included both respiratory as well as skin?

MEMBER MIKULSKI: Kevin, can you go up two slides?

MEMBER GOLDMAN: Okay. So here's --
(Simultaneous speaking.)

MEMBER GOLDMAN: -- TCE. These exposures associated with -- so at that point -- all right. So we were just -- this was mostly addressing trichloroethylene. And I don't think we specified that it had to be chronic inhalation exposure. It was just more on the order of minimum exposure. So that could be skin or air.

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We didn't really specify.

MEMBER REDLICH: Yeah, so I was just wondering the assumption tends to be that it's inhalational. Maybe we should just somewhere in this -- I don't know exactly where the best place would be -- would be to just mention that it includes skin exposure.

MEMBER GOLDMAN: I'm wondering on the background, do we mention that TCE can be -- and carbon disulfide are both inhalation and skin in the background?

MEMBER MIKULSKI: Yes, we did. Yes, we did mention it in the description, in the background text for all the solvent exposures pretty much.

CHAIR MARKOWITZ: This is Steven. If you go to the next part of the recommendation. The next slide, yeah. So if we wanted to include this, if you look at the third line from the bottom, it says, a minimum exposure duration of eight years. We could add either through inhalation or through skin absorption, that

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phrase there to include this concern if we want to or just leave it as a rationale.

MEMBER GOLDMAN: Yeah, I guess one of the questions would be we'd have to go back. I mean, this is based, believe or not, to try to come up with a minimum of eight years, this one study. And I'm not sure if those workers had skin and air exposure.

So I think Carrie's point is well taken. One good thing about just leaving it as exposure, you can make an assumption of what it is. If we really wanted to tie it back to that study, I think we'd -- with the eight years, we'd have to check and see if they had both skin and air exposure. I don't remember offhand. Do you?

MEMBER MIKULSKI: I believe that those were both exposures. I don't remember specifically. But the process itself would have implicated both dermal and inhalation. They were working right next to the solvents containers and soaking those parts in the solvents. So one way or the other, I'm sure there was some potential

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for even the minimal skin exposure.

(Simultaneous speaking.)

MEMBER REDLICH: There are others that know more about this than I do, but it's much harder to prevent skin exposure. So my experience, it's rare that there's a setting with something like solvents. It's much easier to prevent inhalation exposure. So if there's inhalation, there's almost --

(Simultaneous speaking.)

MEMBER GOLDMAN: -- skin exposure. Yeah, you had more efficient absorption through air, though. But I don't think there would be a problem with putting that in probably. Just put it in parenthesis, skin or air.

MEMBER MIKULSKI: I agree, yes.

CHAIR MARKOWITZ: So Kevin, if you could bring up the Word version of this so we can make a change. It would be in the Parkinson's disease file.

MR. BIRD: Do you all see the Word document now?

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MEMBER MIKULSKI: Yes.

MR. BIRD: Okay. Am I in the right spot here, or should I --

CHAIR MARKOWITZ: Yes, you are. Up to eight years, should we just say either through inhalation or through skin absorption?

MEMBER MIKULSKI: And/or skin absorption maybe.

CHAIR MARKOWITZ: Okay.

MR. BIRD: Like that?

CHAIR MARKOWITZ: Yes.

MEMBER MIKULSKI: And if we go after, the first sentence ends with Parkinsonism claims. As I re-read it right now, I think we can cross out claims.

CHAIR MARKOWITZ: Okay. Is there any further discussion?

(No response.)

CHAIR MARKOWITZ: Okay. So in that case, we can take a vote. Does anyone want us to read out loud again the recommendation, or can we leave it as is and just vote on it? Anybody in

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favor having it read aloud?

MEMBER BERENJI: Yes, this is Mani Berenji. I apologize. I came in a little late. So if you could restate the recommendation, that would be very helpful.

CHAIR MARKOWITZ: Sure. Okay, great. Well, welcome. Glad you could join us. Dr. Mikulski, do you want to read it?

MEMBER MIKULSKI: Sure.

CHAIR MARKOWITZ: But just let me interrupt for a second. We're not -- I don't think -- we're not looking at the first part of the recommendation. There's another part to it, right?

MEMBER MIKULSKI: Yes, I'm only going to read the one about causation presumptions. The Board recommends that in addition to carbon monoxide and steel manganese products already included in the EEOICPA Procedure Manual and DOL Site Exposure Matrix, exposures to carbon disulfide and trichloroethylene be presumed to cause, contribute, or aggravate Parkinsonism.

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These exposures were present in the DOE weapons complex and have been shown to be associated with increased risk of Parkinsonism in human studies.

The Board also recommends, based on the epidemiologic studies, a minimum exposure duration of eight years, either through inhalation and/or skin absorption, for Part E causation in adjudicating Parkinsonism claims with exposures to carbon disulfide and trichloroethylene.

At present, the Board issues no recommendations for methanol, toluene, n-hexane, and polychlorinated biphenyls, or other work-related exposures common throughout the DOE weapons complex. The Board also issues no recommendation for pesticides or specific pesticide products that may have been used on DOE installations. Current evidence is not sufficient to support a presumption of these additional agents with regard to Parkinsonism. As new research is emerging, the Board recommends the periodic review of human studies literature

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on the risk factors for Parkinsonism for DOL to provide updates in this field.

Presumption of causation implies the judgment that the literature at the current time is sufficient to support the statement that the exposure can contribute to causation of the disease or aggravate the course of the disease in exposed populations, and the judgment that the degree exposure in the individual is sufficient to have produced this contribution to causation in that individual. The use of presumptions is intended to identify the subset of people with the straightforward presentations to streamline the compensation process by eliminating the need for detailed causal evaluation by the physician and industrial hygienist.

It must be emphasized that, if an individual does not meet the criteria for the presumption of causation, this does not imply there is not sufficient evidence of causation. It simply means that individuals who do not meet these presumptive criteria and would need to be

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evaluated through a fact-based process entailing industrial hygiene and medical review to make the judgment whether the exposure contributed to causation of the disease. So a couple more -- yes, thank you.

CHAIR MARKOWITZ: Okay. So I think we need a roll call to do a vote actually.

MS. RHOADS: I can do that. Okay.
Dr. Dement?

MEMBER DEMENT: Yes.

MS. RHOADS: Mr. Domina?

MEMBER DOMINA: Yes.

MS. RHOADS: Dr. Goldman?

MEMBER GOLDMAN: Yes.

MS. RHOADS: Mr. Mahs?

MEMBER MAHS: Yes.

MS. RHOADS: Dr. Markowitz?

CHAIR MARKOWITZ: Yes.

MS. RHOADS: Dr. Mikulski?

MEMBER MIKULSKI: Yes.

MS. RHOADS: Ms. Pope?

MEMBER POPE: Yes.

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MS. RHOADS: Dr. Redlich?

MEMBER REDLICH: Yes.

MS. RHOADS: Dr. Silver?

MEMBER SILVER: Yes.

MS. RHOADS: Mr. Tebay?

MEMBER TEBAY: Yes.

MS. RHOADS: Dr. Berenji?

MEMBER BERENJI: Yes.

MS. RHOADS: Dr. Friedman-Jimenez,
have you joined us?

MEMBER FRIEDMAN-JIMENEZ: Yes, I have
joined you. And yes, I vote yes.

MS. RHOADS: Okay. Thank you. That's
everybody. It's unanimous.

CHAIR MARKOWITZ: Okay. Welcome, Dr.
Friedman-Jimenez. And I want to thank Dr.
Mikulski and the work group for a thorough review
and recommendation. I would point out this was
developed in response to a question from the
Department of Labor for assistance, and I think
that this is an example of a very useful
interaction. So let's move on.

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MEMBER REDLICH: Yeah, I was just going to say thank you for doing such a thorough job on this.

MS. BRISTOL: Yeah.

MEMBER MIKULSKI: Thank you to all for your support.

CHAIR MARKOWITZ: Dr. Berenji, do you want to go next, or do you want to wait for a bit while I talk about asbestos? Or do you want to give your report on the Group 2A carcinogens?

MEMBER BERENJI: Oh, apologies. You can go ahead and present. I'm just trying to get everything together. So I'll be a few minutes.

CHAIR MARKOWITZ: Okay. That's fine. No problem. So we're going to skip ahead and talk about the recommendation around asbestos job titles. So Kevin, if you could go back to the PowerPoint to the next slide. Okay. So --

MR. BIRD: Sorry, Dr. Markowitz. Would you rather me pull it up as a PowerPoint, or would you rather me pull it up as a Word file?

CHAIR MARKOWITZ: PowerPoint

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initially. Okay. Let me read the recommendation and then discuss what the group has worked on. We recommend that the Department of Labor evaluate the job categories and associated aliases for all Department of Energy sites in the Site Exposure Matrices and revise its list of occupations with presumed pre-1995 asbestos exposure, Exhibit 15-4, to reflect current knowledge as summarized in the rationale provided below and associated data and references. Supervisors of the listed job categories should also be considered for inclusion. A committee of the Board should work with the Department to conduct this exercise and achieve a consensus on a revised list of occupations with presumed pre-1995 asbestos exposure. So if you'd go to the next slide.

This is the current list of job titles in the Procedure Manual that are presumed to have significant exposure to asbestos. And we've looked at this list many times, mostly construction trades with a few other people

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involved, added auto mechanic, maintenance mechanic, and a couple of others, heavy equipment operator. So, some time ago, the Board suggested that this list was not quite full enough.

And we actually had looked at what we thought to be a subgroup, relevant job titles at a number of different sites. And we made some specific recommendations around those job titles to be added. We kind of realized that the complex -- the DOE complex has many job titles that have evolved over time, both within and across the DOE site.

And we're not going to be able to come up with a complete list of all the specific job titles that we thought should be added. So we kind of took a different approach, if you could go to the next slide. So we started to look at the literature on job titles in relation to malignant mesothelioma.

We used that disease outcome because it's highly specific for a history of exposure to asbestos, much more so than lung cancer and not

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as -- maybe not quite as specific as asbestosis. But asbestosis presents different challenges. So we used job titles in relation to mesothelioma as a window into what job titles should be considered as having significant exposure on a presumption basis prior to 1995.

So here, I'll show a publication from 15 years ago. It's in the U.S. It relies on U.S. data compiled by NIOSH in one year, 1999. They looked at death certificates, and they looked at what the death certificates by industry and occupation. And you can see they provide the proportionate mortality ratio. Let me take a moment and explain what that is.

That's a measure of risk. And if it's above, in this slide, 1.0 -- if you look at that column, it's above 1.0 and it's elevated. More commonly, PMR is expressed as above 100. But in this slide, you see it as 1.0. And what it is, is the proportion of people in a given trade.

Let's see. You can see plumber there.

The proportion of deaths among plumbers that's

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caused by mesothelioma and then you compare that. You divide that by the total proportion of all deaths caused by mesothelioma among all occupations. So if on average one percent of deaths across all occupations is caused by mesothelioma and they find among plumbers' deaths that it's five percent, then we would take that five percent divided by one percent and come up with a PMR, in this case 4.76. So it's a measure of the increased risk.

It's not the best measure, and it's vulnerable to certain issues which we probably don't need to go into here. But it is a recognized measure that's used. And in fact, so we see from this study 20 years ago, very few occupations were identified as having excess risk of mesothelioma.

Now let me say that there are other occupations that were at increased risk. But in part because they were looking at very limited data, one year from 19 states, and again, only death certificates that included information

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about industry and occupation. They really were constrained in how many occupations they could actually look at. If you go to the next slide.

So NIOSH continued this work and in 2016 published a longer list and using a very similar approach with PMR. And here they're looking at deaths from 23 states for malignant mesothelioma from 1999, 2003, 2004, 2007. So they had multiple years. And these are just the occupations with elevated rates or risks of mesothelioma, and it's gone from 4 to about 16 or 17.

And we see, if you just look at a bunch of them are actually drawn directly from or identical to the list on Exhibit 15-4 as part of the Procedure Manual. So this was published in 2016. And I would point out the title of the table is based on 1,830 malignant mesothelioma deaths.

So John Dement had the brilliant idea of looking at the same data -- same type of data only what is currently available. And if you go

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to the next slide. And John, if I get any of this wrong, just feel free to correct me. But there is something called the National Occupational Mortality System which is a compilation really of deaths that NIOSH has put together, the National Institute, for a number of different outcomes. We're just focusing on malignant mesothelioma.

And what they've done is for a large number of death certificates coded what a death certificate says about the person's occupation and what industry they were in and then related those listings to the cause of death. And they published a few years ago. Cynthia Robinson is the leader of NOMS who published the analysis in 2016 in a great journal, the American Journal of Industrial Medicine, actually on leukemia and heart disease, not only mesothelioma. But this system NIOSH has been operating for almost three decades and from 26 states. So it's a large data set. Next slide.

So what John did was go in and look at

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malignant mesothelioma. Kevin, if you could move it ahead. Yeah. See, here I just defined what the proportionate mortality ratio is, which I've already gone over. So we don't need to go over it again.

And we found when we looked at the current NOMS data that instead of the 17 job titles that were found and published in 2016, there were now 64 individual job titles with increased mesothelioma risk. And these are deaths from 1999 to 2014. Not every year, but a good number of years actually. Ten years out of that time period.

So in the next three slides, we provide the individual job categories by the standard Census coding system. And if you look at the fourth column from the right, you see the PMR. And now it's in the hundreds, not in the ones. So for instance, architects has a PMR of 337. That means almost three and a half times the risk of the general risk for mesothelioma based on 19 deaths.

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And if you look on the two columns on the right, these are confidence intervals. That's what the CI stands for. And as long as we see the lower confidence level above 100, we're confident that this was not a statistical fluke.

And so this slide and the next two slides, they only provide the job titles. No, you can go back. That's okay.

But we only provide the job titles. The previous slide, Kevin? Yeah, thanks. The job titles which have elevated PMRs which are statistically significant. So you can see here architects. You see various types of engineers, marine engineers for obvious reasons. A lot of asbestos on ships. But we also see chemical engineers and mechanical engineers, electrical engineers.

What's interesting is I think it's a reasonable interpretation that there was sufficient exposure to asbestos in enough of each of these occupations such that a broad look at mesothelioma rates in these occupations is

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showing a significant elevation. If you go down, we see chemical technicians. We see fire fighters. Law enforcement workers, I have no explanation for that.

It's not surprising that we see a job category that's hard to explain. What's remarkable about this list and as we go through the next two slides is how many of these job categories are readily explained by the likely history of exposure to asbestos. And here's the construction and extraction trades, and you see for insulation workers a PMR which is sky high, 3,539 worked heavily in asbestos and various other familiar job categories.

And if you go to the next slide. So we've moved from construction now to the Census codes of installation, maintenance, and repair occupations. And this is of interest because I think there are a lot of job titles in DOE that haven't quite been captured by the list in Exhibit 15-4 that would be encompassed by the job categories.

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And the other thing of interest here is that whereas in construction we expected to see a lot of categories, it wasn't clear within this overall group, installation, maintenance, repair, that we would see quite this number. Although when you look at them, actually most of them are readily explained. Now I think there's one more slide with additional elevated risks.

Yeah, so this is on the production side. And production can be tricky with respect to asbestos exposure because some production workers have exposure, some don't. We're interested in presumptions, and you see here that people who work with metals, because they frequently work with heat, have exposure to asbestos on a routine basis. They did in the relevant time period, and there's some other production occupations as well listed down below.

I think that's the last slide of the occupations. If you could go to the next one, yeah.

So how does this fit into the overall

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knowledge about mesothelioma? So we looked at a number of the large studies. It's mostly the study design called case control because of occupations and risks by occupations. And these are a number of the major studies over the last 20 years.

In the U.S., I already showed you the Mazurek study of 2016. The Tomasallo study is shifted to Wisconsin. It's really just one state and then the others are various countries. You wouldn't really expect their experience with mesothelioma in terms of risk to be that different from ours. So it did provide a useful diagram.

There are also some registry-type studies which I haven't included here. Australia has an excellent registry. They published occupations in relation to that, and Italy has an excellent registry too. Next slide. It may be the end of the slides.

Yeah, so this is just a repeat of the -- so in a full report on this which was

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distributed to the Board members a couple weeks ago, there's several pages of text describing what I really just reviewed and also including that attachment with a listing of other relevant studies. Actually, we took the important tables from all of those relevant studies and included those tables in the report, in the rationale with a list of the references. Actually, if you could put up the Word version of this, Kevin, just for a moment. Okay. So if you could just scroll down here.

So here's the rationale which we describe what we did. And then keep going down. This is available on the website, by the way. Keep going, yeah. We briefly attached some of the other U.S. studies and then referred to the international studies and then some comments that we included about this.

We're not going to vote on the rationale. We're just going to vote on the recommendation. If anybody has any suggestions on the rationale today -- I mean, on this call,

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that's fine. Otherwise, in the next day or two, if you have additional suggestions. If you could just go down a little bit more.

Just want to show the full report, get a sense. This is from the Procedure Manual. This is what I just showed. Now hold on here. Back up for a moment. I just want to show this.

This is the usual way we look at these things. And I'm sorry, but it's in small print here. But these are the same job titles with PMRs. But now they're in descending order of PMR.

So you can see -- that's good. So you can see the insulators topped the list with a sky high PMR, and then you go down. All of the job titles on this list had elevated PMRs that were statistically significant. And you see most of them in the 200 to 300 range. But in any case, it's the usual way we look at these in the terms of studies. But what I showed before was by overall occupational to the major group in order to show that it's not just construction workers but other workers who have exposure to asbestos.

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Just keep going down a little bit to see if there's anything to show. Okay. Keep going.

So this is the Mazurek study. Keep going. But we also provide -- keep going. I already discussed this. This was the 2006 study. But here's the Tomasallo study from Wisconsin where they list the occupations and industry. And then we start getting into important -- this is a Peto study in 1995. It made a big splash. Go up just a little bit more.

This is a PMR approach in England. You can see a list of elevated PMRs. This was done five years ago actually. So if you could go back to the top of this page. Stay on the word, version, but go back to the top of it all.

So if you want, I can read the -- let me read the recommendation very quickly. So we recommend the Department of Labor evaluate the job categories and associated aliases for all DOE sites in the Site Exposure Matrices and revise its list of occupations presumed pre-1995 asbestos exposure to reflect current knowledge as

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summarized in the rationale below and associated data and references. Supervisors of the listed job categories should also be considered for inclusion. A Committee of the Board should work with the Department to conduct this exercise and achieve a consensus on a revised list of occupations with presumed pre-1995 asbestos exposure. Okay. So is there a move to accept this recommendation?

MEMBER SILVER: This is Ken Silver. I move that we accept it.

CHAIR MARKOWITZ: Okay. Is there a second?

MEMBER MAHS: This is Ron. I second.

CHAIR MARKOWITZ: Okay. So open for discussion.

MEMBER DEMENT: This is John. I think just one point. The current list of jobs considered asbestos exposure actually aim from an older ATSDR document. And if you look at that document, those lists basically came from the same information, the same data set. So the

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prior list is, in large part, really based on an older set of the same data that we're looking at now.

It's subdated February 4 to include greater numbers. We're also looking more in detail at mesothelioma, and that's possible because of ICD 10 and a specific code for mesothelioma. So it gives us, I think, a lot more focused attention to specific jobs and a lot more data to base the determinations on.

CHAIR MARKOWITZ: Well, the NOMS data we showed was based on about 6,000 mesothelioma deaths whereas the publication in 2016 was based on 1,800. So you just get more dense. You get more statistical power and just look at a lot more occupations. By the way, those occupations that don't appear to have excess risk on this doesn't necessarily mean that people in those who have done those jobs don't have excess risk. It could be a number of things. It may mean that the exposure wasn't sufficient widespread in that occupation to cause a risk -- elevated risk or

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some other reasons. Other discussion?

MEMBER SILVER: Ken Silver here. Outside the four corners of this list, if I remember correctly, the Department of Labor accepted one of our other recommendations so that 30 days of employment at a DOE site was sufficient for meso. Is that correct?

CHAIR MARKOWITZ: Yes.

MEMBER SILVER: So it would be 30 days in one of these job titles?

CHAIR MARKOWITZ: Yes. I mean, well -

-

MEMBER SILVER: Okay. Thank you.

CHAIR MARKOWITZ: -- approximately, yeah. I mean, they have to, they had to translate this list into DOE job title list. Other comments, questions, suggestions?

MEMBER GOLDMAN: This is Rose Goldman again. I just had a question. I'm trying to look at this list. But I know that for a number of custodians, for example, there was some early literature about custodians with pleural plaques

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and asbestos. Not asbestosis but having pretty significant asbestos exposure because they're always down in the basements and they're not a boilermaker repairing things or plumbers. But they're just sort of always down there and sweeping.

And I would think -- I mean, anybody who gets mesothelioma, 99 percent of the time, if not 99.9, it's due to asbestos. And I'm just wondering if you could have a phrase in there that even if they're not on that list. Like, custodians aren't there, unless that comes under maintenance. But that's sort of an ignored group sometimes for low level chronic asbestos exposure where people could have mesothelioma.

And I could see where somebody who is like a custodian who got it, they wouldn't necessarily been seen. I don't know. Would they come under maintenance because that's a group, for example -- I don't know. Somehow, I think for mesothelioma, there just has to be a really careful look because there are almost always some

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asbestos exposure. And it isn't from their house or environmental which is highly unusual. It would be from work.

CHAIR MARKOWITZ: Well, this is Steven. I agree with you that as a rule, custodians in the heyday of asbestos would've routinely had exposure. I'm actually going to -- as we speak, I'm going to look up -- try to look up on the Census coding system where custodians appear under what job title. Yeah, there's a job title called janitors and building cleaners.

MEMBER GOLDMAN: So do they have an increased risk than other janitors and building cleaners? Did I miss that in all of your charts then?

CHAIR MARKOWITZ: They do not appear in the charts. And with a little bit more time, I could look up their PMR. But I think it wasn't elevated because otherwise they would have appeared.

MEMBER GOLDMAN: So then I'm just going to add something. Then perhaps even though

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these are the jobs that you make the presumption, could there be a phrase that says even if they're not that job but they did a job where they potentially could've had asbestos exposure. If they have mesothelioma, there needs to be, like, additional questioning from the IH or somebody, I mean, because that's so often -- I mean, almost always associated. And it's sneaky sometimes how people got it.

So I don't know that -- I mean, this is a fantastic effort to put down jobs so you would have the presumption. But maybe to put a line in there. Even if you're not listed on that job that you could still have had it. And so you still need additional inquiry and questioning.

CHAIR MARKOWITZ: So yeah, so that's like the phrase of a sentence that was in the Parkinson's disease recommendation that even if you don't need these presumptive criteria, then a close look at the person's prior exposures should be undertaken in order to ascertain whether there's causation. We could certainly add that

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to this.

My hesitation about adding janitors, per se, is because we'd have to provide the underlying studies. And then we get into the asbestosis literature and then we never finished the job is my concern. I mean, I agree with you about custodians, and they don't appear here.

MEMBER GOLDMAN: Well, there may be a way to phrase it. I don't want to drag this out further. But with that phrase, I mean, it's really different. Like, trichloroethylene and Parkinson's, it's not necessarily a slam dunk. It's an increased risk.

With mesothelioma, I mean, you really need to -- I mean, to emphasize that this is almost always related to asbestos exposure. And so even if the person isn't in that group, particularly for that diagnosis, there should be a great effort to do additional interviewing to see whatever their job was in the DOE, there was a potential for asbestos exposure.

CHAIR MARKOWITZ: Okay. So Kevin,

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let's see. We're looking at the Word version, right?

MR. BIRD: Yes.

CHAIR MARKOWITZ: Okay. So the fifth line down after the word, inclusion. Okay. Let's try to get some language which can capture this. Let me take a stab and then we can modify it. So for other job titles with mesothelioma -- well, I guess that claims in relation to asbestos exposure. Claims in relation to -- I'm sorry, yeah. No, in relation to asbestos exposure, comma, a careful investigation of possible occupational sources of asbestos exposure should be undertaken.

MEMBER GOLDMAN: Well, I guess -- I don't know if this form is just for asbestos exposure in general for many things like lung cancer, or this recommendation is directed for mesothelioma. But if it's for more general asbestos exposure, then what you might consider is for that phrase saying maybe -- pointing out that for mesothelioma maybe to say, in the case

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of mesothelioma, comma, with a greater than 90-plus whatever, 99 percent relationship to asbestos, greater effort should be made to inquire about a job-related asbestos exposure, even if the -- it doesn't fit into one of the categories, the presumptive categories.

MR. BIRD: Apologies, Dr. Goldman. I lost you a little bit there in the middle of that.

MEMBER GOLDMAN: Oh, okay. Sorry. So I'm just saying rather -- I mean, because this is a document I believe in general for asbestos exposure for other things, asbestosis, lung cancer, I think that it would behoove us, even though that the mesothelioma data was used to identify which jobs really have asbestos exposure. By the same token, anybody who has mesothelioma to me, you could presumptively say it's related to asbestos exposure.

So I mean, I would pull that out from, like, lung cancer and other things and maybe to make a statement that in the case of

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mesothelioma, there's such a strong presumption greater than 95 percent that it's related to some asbestos exposure, that greater effort should be made to interview the person about potential work-related asbestos exposure, even if their job category is not in one of the presumptive categories.

MEMBER REDLICH: I mean, this is Carrie Redlich. I agree with Rose. It just seems that mesothelioma, remember is really a very rare cancer. And if someone was at a site - - and in terms of general other practice, if someone was at a site that had asbestos and it's a rare person that gets mesothelioma, we assume it's related to that site. But dose response is just not the same as for other cancers. And --

(Simultaneous speaking.)

MEMBER GOLDMAN: Right. I'm not even sure you -- I agree. And I'm not even sure you need X number of years. I mean, there have been --

MEMBER REDLICH: That's what I'm

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saying because I don't think --

MEMBER GOLDMAN: Yeah.

MEMBER REDLICH: -- you need X number of years or a specific -- I mean, if you got mesothelioma and the latency is such that it would fall, and it's a wide latency, during the period that you worked at a DOE site that anywhere at that site had asbestos during that time, I think that would be very appropriate. There's no other cancer --

CHAIR MARKOWITZ: First of all --

MEMBER REDLICH: -- that it's so tightly linked to an exposure.

CHAIR MARKOWITZ: Yeah. So the Procedure Manual has for mesothelioma 30 days of exposure and a latency of 15 years. So let me --

MEMBER REDLICH: Okay. Well, that's okay.

CHAIR MARKOWITZ: Yeah. So what if we took the sentence -- if we go back, Kevin, to the sentence that I added, should be undertaken. And we added after should be undertaken something

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like with a very high degree of suspicion for malignant mesothelioma. Would that address the point?

MEMBER GOLDMAN: Well, I think the starting point actually isn't a high degree of suspicion from malignant mesothelioma. I mean, I would consider starting with the cases of mesothelioma. I would consider in the case of malignant, starting that sentence a little bit differently.

Like, instead of for other job titles, blah, blah, blah, I would just start after that considered for inclusion. And then after that sentence inclusion, period, I would say, in the case of mesothelioma, comma, with greater than 90 percent linkage to asbestos exposure, comma, all cases should have additional inquiry into potential asbestos exposure even if not among the presumptive job titles for asbestos exposure. Something along that line just because like Carrie said, I mean, you could -- it's such a strange thing.

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It is very rare, but it's almost always -- and it's the kind of cancer people say, well, I never had it. But if you dig deep enough, you find it. Like, I can still remember a case, for example, when I did a rotation with Dr. Selikoff, I saw a woman who had mesothelioma and she worked at the Metropolitan Opera.

She was a dancer. And I said, well, how in the world did you get it? And said, well, we were dancing and the curtains were lined with asbestos. And we would be dancing, and there's a lot of harder than you think plunking down on the stage, and there was dust always there. So she had years of asbestos exposure, and who would've thought of that in a ballerina, right?

And so I think that just having that diagnosis of mesothelioma means one has to be prompted to go further in the inquiry because even what we might consider small exposures and maybe that's why it didn't come out with the custodians because it's just there are many, many more custodians and mesothelioma is really rare.

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But I just think that should be the prompt, that it really is different than an increased risk of some percentages for lung cancer, whatever. This is, like, really -- we really have to presume that there's an asbestos exposure. You just have to ask more questions about it.

CHAIR MARKOWITZ: Okay, so. Kevin, where it says, should be undertaken, if you could take out remove with a very high degree of suspicion of -- just a little bit, yeah. That's it. And then put a period there. And then take Dr. Goldman's new sentence and insert it after undertaken. Okay, okay. So does that capture the thought now?

MEMBER GOLDMAN: Yes, I think that -- let me just -- yes, I like that. I don't know if others agree, but I think that captures it for that specific -- and it's a very rare exposure. It's not going to come up that often. But I think we just have to really make that presumption that if you have mesothelioma, it's related to asbestos.

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CHAIR MARKOWITZ: Right. By the way, at the end of that sentence which says, among the presumptive job titles for asbestos exposure, if you could change that to among the job titles with presumed asbestos exposure. Do you see that?

MR. BIRD: Sorry, Dr. Markowitz. Say that again. Where exactly?

CHAIR MARKOWITZ: Go down two lines, which is presumptive job titles. Yeah, okay, okay. Take out the presumptive. Okay, okay. And then right before asbestos in that, put in presumed. Okay. Other additional comments? Discussion about the recommendation?

MEMBER SILVER: Yeah, Ken Silver here. I love the PMR approach. I wonder if there'd be any wisdom in codifying the overall approach. The epi literature doesn't stand still. There may be future PMR studies that reveal additional occupations. And perhaps we could slip in a sentence, advising DOL to keep an eye on the occupational epi literature for occupations that

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meet the same criteria.

CHAIR MARKOWITZ: Yeah, the --

MEMBER DEMENT: This is John.

CHAIR MARKOWITZ: When we put -- yeah, go ahead, John.

MEMBER DEMENT: Why couldn't we just add that in the rationale as opposed directly in a recommendation?

MEMBER SILVER: Works for me.

CHAIR MARKOWITZ: Okay.

MEMBER DEMENT: I think it's just better in the rationale.

CHAIR MARKOWITZ: Okay, yeah. I can add that. That's fine. Any other comments, discussion?

MEMBER REDLICH: This is Carrie. I had one minor suggestion. I think it's the fifth line down for other job titles with claims in relation. Do you want to say for other job titles for other employees?

CHAIR MARKOWITZ: It's really for people who have other job titles, right?

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MEMBER REDLICH: Yeah, so maybe.

CHAIR MARKOWITZ: Yeah, yeah. So why don't we just add for people who have other job titles. I agree. It's very awkward. Yeah.

MEMBER REDLICH: Thanks.

CHAIR MARKOWITZ: Thank you. Okay. Any other comments, discussion? Otherwise, we'll close it and vote.

Okay. Anybody want me to re-read this recommendation? Or can we just take a vote?

(No response.)

CHAIR MARKOWITZ: Okay. Let's move to a vote if we could do a roll call.

MS. RHOADS: Okay. I can do that. Dr. Berenji?

MEMBER BERENJI: Yes.

MS. RHOADS: Thank you. Dr. Dement?

MEMBER DEMENT: Yes.

MS. RHOADS: Thank you. Mr. Domina?

MEMBER DOMINA: Yes.

MS. RHOADS: Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Yes.

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MS. RHOADS: Dr. Goldman?

MEMBER GOLDMAN: Yes.

MS. RHOADS: Mr. Mahs?

MEMBER MAHS: Yes.

MS. RHOADS: Dr. Markowitz?

CHAIR MARKOWITZ: Yes.

MS. RHOADS: Dr. Mikulski?

MEMBER MIKULSKI: Yes.

MS. RHOADS: Ms. Pope?

MEMBER POPE: Yes.

MS. RHOADS: Dr. Redlich?

MEMBER REDLICH: Yes.

MS. RHOADS: Dr. Silver?

MEMBER SILVER: Yes.

MS. RHOADS: Mr. Tebay?

MEMBER TEBAY: Yes.

MS. RHOADS: Okay. That's everyone,
and unanimous again.

CHAIR MARKOWITZ: Okay. Thank you.
So let's move -- we're right on schedule
actually. Let's move to Dr. Berenji. Kevin, I
think you can -- you can go back to the agenda on

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the screen. But Dr. Berenji?

MEMBER BERENJI: Yes. Can everyone hear me?

CHAIR MARKOWITZ: Yes.

MEMBER BERENJI: Great. So this is our work group presentation on whether IARC Group 2A Carcinogen should be added to the SEM and specifically linking them to particular cancers. Our working group had a chance to convene over the last few months, virtually, of course. And I know we've all been busy with our other work activities.

So I just wanted to thank Rose, George, and Duronda for all your patience and your continued contributions to this effort. We actually did produce a working draft of our report, and I did submit the draft to my colleagues in the work group as well as Dr. Markowitz whom I believe had a chance to review it briefly. Is that correct?

CHAIR MARKOWITZ: Sure.

MEMBER BERENJI: Okay. I can go ahead

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and just summarize the report because I know I sent it in late last week. And I'm not sure if Kevin has had a chance to get a copy. But I'm happy to review it verbally. Or if you want me to share it with Kevin, Dr. Markowitz, I'm happy to do that as well.

CHAIR MARKOWITZ: You know what? Let me -- I think I have it. Let me send it to Kevin, and why don't you just keep talking. How about that?

MEMBER BERENJI: Okay. So really our working orders are to really look at the Group 2A carcinogen. And for purposes of this review, we specifically focused on the most recent agents that were recently reviewed by IARC in the last -- I would say last five to ten years. So I was able to actually go to the IARC website, and I was able to download an Excel spreadsheet with all the recent 2A carcinogens that were reviewed by IARC.

So I believe I presented this information at our last virtual Board meeting in

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the form of a PowerPoint. But just to summarize briefly, we identified 22 agents in total. These are 22 Group 2A agents that were assessed by IARC, and these are between the years of 2016 through 2019.

And over the last few months, Rose, George, Duronda and I have had a chance to kind of go through this list. Rose was actually very helpful in reviewing the particular pesticides. Rose, did you have any comment or any other feedback on your analyses of the Group 2A carcinogens, specifically the pesticides?

MEMBER GOLDMAN: I don't see the draft in front. I mean, in terms of what we wrote?

MEMBER BERENJI: Yes, I believe you had actually -- if I'm not mistaken, I believe you actually put together --

MEMBER GOLDMAN: Oh, yeah. Let me -- I tell you what. Let me just pull up what I found. I tried to -- circle back to me. Oh, and here it is.

MEMBER BERENJI: Sure.

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MEMBER GOLDMAN: And should you include what I, the things that I found?

MEMBER BERENJI: Yes.

MEMBER GOLDMAN: I'll just pull that up.

MEMBER BERENJI: Yes, I actually incorporated your analyses of those three particular pesticides into the draft. And I apologize. Did you all receive the draft because I had emailed that last Tuesday night?

MEMBER GOLDMAN: I don't think I got it, but I'm going to circle back to see the pesticide thing that I wrote to you. So come back to me.

MEMBER BERENJI: Sure. And I know George had some really good feedback as well, especially as it pertains to the quality of the IARC analyses. George, did you want to provide some additional feedback on that?

MEMBER FRIEDMAN-JIMENEZ: A few things. First, the presumption of causation -- causality, I would call it causation. I think we

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should make a statement similar to the one that was in the asbestos document qualifying what we mean by presumption of causation, specifically that it's when you classify a person as having a work-related disease without medical review because they have particularly strong evidence of exposure to a toxic substance that in which there's really no controversy.

And the point here is that presumption of causation really only identifies the minority of cases for which there is causation. It's the minority for which you don't even have to do a medical evaluation. It's just so obvious.

But what I don't want to see is that presumption of causation turns into the level of evidence that is expected in order to judge it as causal. So in other words, if we set the bar at a certain height, if a person doesn't make that level of evidence, that definitely does not mean that there is not causation or there's not enough evidence for causation. What it means is that they then go to the next step which is a medical

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evaluation which involves a doctor taking a lot of information and making a judgment based on the literature and the patient's presentation and exposure history whether there is causation or not.

And I'm just concerned that if we don't make a strong statement about that, that it's going to evolve into the minimum amount that's required to judge causation and not the amount that sort of skims the slam dunk cases off the top to make it more cost effective, quick and easy to identify these most obvious cases and not have to do the full evaluation. Presumption of causation is really just a tool to streamline the process for a small minority of people. But there's going to be a lot more for which it's questionable.

And when you actually look at the data, then you can decide whether there's sufficient evidence in that person or not because it's very hard up front to make that decision and draw that cut point without knowing the details

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of that case. In other words, people who don't make evidence of presumption need to be judged on a case-by-case basis whether there's causation or not. That doesn't mean that it's presumed that there is no causation.

So I can work on a statement like that, shorter than what I just said. But I think we need to have something in there to define what we mean by presumption of causation, that it's really just a part, a minority of the cases that we're identifying that make it without even having a medical evaluation. These cases can be decided by the claims examiner, someone that doesn't have technical knowledge. So that's one point I wanted to make.

The other one is I think the EPA does make judgments on causation for chemicals. But as far as I can tell, their process is not as detailed, as well documented, and certainly not as transparent as either IARC or the National Toxicology Program. I was unable to find for glyphosate, I just took as an example, the

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committee that made the decision, the names of the members, and more importantly, what disciplines they represented.

How many toxicologists? How many epidemiologists? Where they were from? How many mechanistic people? How many statisticians? I wasn't even able to find the document where the glyphosate evaluation was clearly defined on the EPA website. And whereas IARC publishes a monograph, really detailed monograph on each of these evaluations, and the National Toxicology Program also publishes their usually biannual report on carcinogens.

So I think that the best committees, the best expert committees are really the IARC and the National Toxicology Program. And we need to find out more about the EPA because it's nowhere near as transparent as the other two. So that's a concern that I had about making these decisions based on largely EPA evaluations.

MEMBER GOLDMAN: Well, this is a good moment for me to follow up because now I have the

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piece of paper so I can be specific. So I just want to speak to two organophosphates, malathion and diazinon, and then glyphosate, both of which were categorized by IARC as 2A probable carcinogens and their monograph 2014. And they give for malathion limited evidence of carcinogenicity in humans for non-Hodgkin's lymphoma and prostate cancer, diazinon for non-Hodgkin's lymphoma and lung cancer, and glyphosate, non-Hodgkin's lymphoma, and they go through this.

But here's where it's apropos of what George was saying. So then I hadn't really heard this other than glyphosate which is in the news a lot. So I went to think, well, why hadn't I heard this? So I went to see what other -- what EPA and others said.

So then I went to, for example, here. No conclusive proof malathion causes cancer in humans, although some studies found increased incidence in some people who are regularly exposed, animal studies. So that was ATSDR. But

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actually it was written in 2003 and last updated in 2014, so prior to IARC coming out.

And then the other thing is -- are you still there -- malathion was classified by EPA. Now here's something interesting. If you google it, it says, suggestive evidence of carcinogenicity on the Google Line. But then if you go to EPA and to IRIS in 2004 Federal Registry, pesticides would not be reassessed by IRIS. So you can't look for that.

So then I went to the National Pesticide Information Center which hasn't updated any of its fact sheets since 2011. Then I went to the National Toxicology Program and there really was almost nothing there, malathion and cancer, some old reports of bioassays from 1978.

And then I went to the report on carcinogens in which malathion and diazinon and glyphosate were not even listed.

And so now there's also an EPA draft risk assessment for glyphosate which is from 12-18-2017. And I actually have the link to it, and

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it says it's releasing for public comment the draft on health and ecological risk assessment for glyphosate. And it says that it's not likely to be carcinogenic in humans, and it's found no meaningful risk to human health when it's used according to the pesticide label.

And so here's the problem that we're facing I think in terms of us coming out with something. IARC basically gives malathion and diazinon and glyphosate are probable human carcinogens. And they're used widely or at least in the past they were used widely, and yet we have EPA, ATSDR not putting out that they're potential carcinogens -- human carcinogens. And we have missing in action National Toxicology Program.

So I think in terms of getting to that presumption, I mean, if we really want to give the weight to IARC, then there would be a presumption that if you had exposure to malathion and you've got non-Hodgkin's lymphoma, would we say that's a presumption if it's strong enough?

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What about prostate cancer because that's incredibly common, anybody who may have had some exposure and then for how long? And I think it's sort of hard to come up with a clear cut presumption and for which cancers and for these agents.

So I'm undecided where we should come down on this other than to say these are potential human carcinogens. And maybe there should be added -- definitely added history-taking for people perhaps who did the grounds work or who were around using these things, to make that causal connection. But I'm not quite sure about the presumption part.

MEMBER FRIEDMAN-JIMENEZ: This is George. I'd like to comment on Rose's question here. I think this gets at the very heart of what we mean by presumption. And if we're going to make a presumption of causation, that involves both a presumption of general causation in populations that the toxic substance can cause the cancer. We need strong evidence of that.

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And the presumption of exposure in the individual. In other words, their job is strongly believed to have given sufficient exposure to cause the cancer.

But I have a big concern about including IARC 2A carcinogens under presumption. 2A by definition means limited evidence in humans. In other words, epidemiologic evidence is not completely conclusive. There's room for some bias that's unexplained, very few studies, whatever the reason is that the committee didn't believe that the evidence was conclusive in humans.

And sufficient evidence in animals. In other words, we know it causes cancer. But it's just not clear whether it causes cancer in humans and in which organs. And there are some interspecies differences that the biologists understand and others that they don't understand.

But my point is that I think the presumption should be seen as really a slam dunk case. And I don't think that 2A carcinogens are

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adequately certain to be a slam dunk case. So I think we should leave the presumptions for really Class 1 carcinogens for which evidence in humans is sufficient and make a very, very strong point that people that have 2A carcinogen exposures and there's a question need to be evaluated case by case by a competent physician with the training to do these kinds of evaluations which is labor and time intensive and requires a lot of resources. And that's is what we're trying streamline.

But I think you cannot streamline it and be adequately accurate when you have 2A carcinogens because it's just not certain enough. That's my opinion. I'd like to know what other people think about that.

MEMBER BERENJI: Thank you, George, and thank you, Rose. Duronda, did you want to comment on your experiences, especially with pesticides at Rocky Flats or other sites that you're familiar with?

MEMBER POPE: Yes, sure. It has been

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my experience at Rocky Flats in particular that the workers out there were not protected. So they were exposed to many, many pesticides that they were spreading out on the ground out there. But I think it's very critical when George was speaking about these presumptions and the way we craft this language. It's going to be critical in terms of how they're building this case, and this information is all going to weigh heavily on how that is interpreted.

MEMBER DEMENT: This is John. Can I make a comment? I think there's two areas here that I think George touched on. One is just general causation. And I think what the DOL is really asking us is, is there sufficient evidence for some of these 2A carcinogens to make the link in the SEM that if you put that exposure, it's going to say, it can cause this cancer.

It's not necessarily a presumption. We're not going to a presumption. We're just saying there's a link in the SEM. That's my understand of what we're supposed to be doing.

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MEMBER FRIEDMAN-JIMENEZ: I agree completely, John. And I think having a substance listed in the SEM is not equivalent to having a presumption. The presumptions need to be spelled out clearly and carefully in the Procedure Manual. But there should be the 2A carcinogens and maybe even some 2B where there's no question should be in the SEM and it should be understood that the SEM is there for doctors to see what the possible links are and then look at the literature themselves and make the judgment.

That's what we do in occupational medicine. We do individual level causation judgments. And that's probably going to be a large part of the cases that don't have slam dunk level evidence but for which when you look at the case carefully, the evidence is pretty clear. And most doctors would come down on the side of saying there's a causal relationship in that individual. So I agree completely with what John is saying. I think there's a very big difference between being listed in the SEM and being a

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presumption of causation.

MS. POND: This is Rachel. I just want to -- I would agree with that assessment as well. It is kind of what we're looking for here.

CHAIR MARKOWITZ: So this is Steven. So if we remove presumption from the discussion, it's a lot easier. But I want to get back to the point that I think it was said that a 2A carcinogen, it's not clear actually whether it's a carcinogen.

So I think IARC is rating it as a probable human carcinogen. I think we should take that at face value because I have to make the link, particular cancer sites. And that can be challenging, and it may not be possible for all the 2A carcinogens.

But when IARC pronounces it and if it's a relatively recent evaluation, I frankly don't see the point in going back to older evaluations from ATSDR or any other source to question the IARC decision. The IARC really is a transparent, high quality decision making

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process. So I think we should be able to rely on IARC.

Glyphosate's a special case because it's hugely politicized and there's some disagreement. But putting aside glyphosate or the other issues, I think we should be able to rely on IARC for determination of general causation as a probable human carcinogen.

MEMBER GOLDMAN: So can we -- just to be sure then, we could list it under the SEM that if somebody has those conditions that they should inquire if they had a job with these exposures. And then it would be up to them -- up to the treating physician to determine if there was a linkage. And we could list that, but it would not have to be as a presumption. Is that correct?

CHAIR MARKOWITZ: That's correct. So I think that the group has done an outstanding job actually on their seven-page review of the various relevant 2A carcinogens. And I think the only -- from my point of view, the only piece

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that needs to go a little further is actually trying to make a decision on which cancer sites can be reasonably related to the 2A carcinogens which isn't -- I'm not really entirely clear from this document. It's an outstanding document, but needs a step forward.

MEMBER BERENJI: Thank you, Steven. So unfortunately, I'm going to be stepping down from the Advisory Board. So perhaps if this work is to be continued, Steven, perhaps we should identify a new person who's going to spearhead this effort.

CHAIR MARKOWITZ: Unless the Board votes you in as an honorary member. Yeah, we'll get to that. We'll get to that.

MEMBER GOLDMAN: So in terms of -- just to answer that. Is it too difficult just to -- I mean, we listed some of the things, both in -- Mani, she had a spreadsheet, and I just listed the latest on IARC on these three pesticides just to say -- just to extract it out of here non-Hodgkin's lymphoma, prostate cancer, malathion

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probable 2A, possible 2A carcinogen in humans. Or just to take -- for those cancers, just extract it, like, what we have and just list those -- or I mean, for those diseases? Is that what you were thinking of?

CHAIR MARKOWITZ: This is Steven. So the way it's written now is by 2A carcinogen, brief reviews of each. And I would just -- in each section just come to some conclusion if possible that that particular agent is reasonable to consider related to cancer X, for each of the agents.

That's the single, in my view, the single step that's still needed and could be done by mid-July before the Board term ends. We didn't vote on it, but to complete that step would be terrific. It would be a nice to hand off to the next Board.

MEMBER FRIEDMAN-JIMENEZ: This is George Friedman-Jimenez. I think that we could do this as a simple table. The IARC monographs are incredibly detailed and well referenced with

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hundreds of references and lots of details on exposure and on all of the science, the different scientific disciplines, evidence.

I think all we need to do is extract from each IARC monograph or each substance that we're talking about which organ system has sufficient evidence in humans, which organ systems have limited evidence in humans, and which have sufficient evidence in animals, and just put that table into the SEM. And it would be a pretty complete list of what the overall world literature is showing.

There are a few, I think, that NTP has classified that IARC has not. But almost everything that NTP classifies has already been classified by IARC. So I think just going through the IARC monographs and making a table, a simple table of one, two, or three organ systems for which the cancers have been judged to be sufficient evidence or limited evidence for 2A and the name of the chemical. And then that can go into the SEM, and that will be the basis for

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the -- and with references to the monographs because if someone wants to look up the cancer, the best reference is almost always going to be the IARC.

Second references, we haven't talked about yet, are textbooks of cancer epidemiology. For example, Schottenfeld and Fraumeni fourth edition has excellent discussions of some of these occupational carcinogens. So if a doctor is making one of these evaluations, they should be able to get the references quickly from the SEM for a particular cancer site and a particular toxic substance. So that's what I would recommend, just a simple table of all the IARC 1 and 2A carcinogens.

CHAIR MARKOWITZ: Well, this is Steven. We've been asked to provide a rationale. And frankly, it's already written. The group has already written it. So I agree, add a table to the rationale. But I would keep the rationale because a lot of work has gone into it.

MEMBER FRIEDMAN-JIMENEZ: It's a huge

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amount of work to do that for all of those 1 and 2A carcinogens.

CHAIR MARKOWITZ: Well, I think we were just addressing the relevant 2A carcinogens.

And I wasn't suggesting any work beyond what's already been done actually, so with reference to all the IARC monographs.

MEMBER BERENJI: Steven, I think I completely understand what you're saying here. And honestly, like you already alluded to, the work has been done. I think we just have to specifically state for each particular 2A carcinogen that we evaluate it whether there's a direct link to a particular cancer in humans. And honestly, the information is already summarized. It's just we have to actually state it clearly. So that's relatively easy to do.

(Simultaneous speaking.)

CHAIR MARKOWITZ: Go ahead.

MEMBER REDLICH: Oh, no. Go ahead.

CHAIR MARKOWITZ: I was just going to say the Group 1 carcinogens are already in the

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SEM. So I think we really can just focus on the 2As.

MEMBER FRIEDMAN-JIMENEZ: Are all the Group 1 carcinogens in the SEM with all of the cancer sites?

CHAIR MARKOWITZ: We've been told they are by DOL. But when we come up with a recommendation in relation to this work on 2A, we can add a line that DOL should assure that all Group 1 carcinogens are included in the SEM.

MEMBER FRIEDMAN-JIMENEZ: Okay. That's good. Although there are more 2A than there are 1, so --

MEMBER REDLICH: Yeah, I sent everyone just now. There's a template that IARC has that organizes by organ site which I think is helpful because clinicians probably see someone with a specific cancer.

MEMBER BERENJI: Oh, this is great, Carrie. Thank you.

MEMBER REDLICH: I think something like this. This one doesn't differentiate 1 and

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2A.

MEMBER GOLDMAN: I didn't see it. Did you send it by email, or is it up there?

MEMBER REDLICH: I sent it by email.

MEMBER FRIEDMAN-JIMENEZ: She just emailed it.

MEMBER GOLDMAN: Okay, yes. I just got it.

MEMBER FRIEDMAN-JIMENEZ: I think this table is great. Many of these are not occupational. They're booze or drugs. So it's a subset of this. But this is great, yeah.

MEMBER REDLICH: We can just edit it or something similar, just as an idea.

MEMBER FRIEDMAN-JIMENEZ: I think there's a list of all of the occupational carcinogens of the subset so we can find that already listed.

CHAIR MARKOWITZ: There's a publication by Loomis that addresses that.

MEMBER REDLICH: Yeah, I have that one also.

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CHAIR MARKOWITZ: Okay, yeah. So okay. So we need to come to some closure here. Dr. Berenji, any other comments or --

MEMBER BERENJI: At least from my standpoint, I think I'm going to incorporate the PDF that Carrie just sent us and try to create something similar for at least the purposes of this report. And then I will go back to the draft of the report and try to summarize succinctly what we are discussing here which is to kind of point out whether there's enough evidence in humans to be able to incorporate into the SEM. I mean, that's kind of my understanding. Rose, George, Duronda, any other comments?

MEMBER GOLDMAN: Well, I'm looking over the list that Carrie just sent. Thank you very much. Very informative. And frankly, what we could do is look at this list and just delete stuff that doesn't apply. But actually from -- or just post this because actually they had leukemia and lymphoma. They listed diazinon.

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They listed glyphosate. So they listed these pesticides that we were talking about for 2A. And maybe the thing to do, I mean, why not just post this?

MEMBER REDLICH: Well, I sent another article that also is occupational. So anyway, I think it is helpful sometimes to differentiate 1A and 2. This is meant as not, as one example.

MEMBER GOLDMAN: Where did this come from? This is really good.

MEMBER REDLICH: It's from IARC. If you google it, you can find it. But it's literally a PDF. But it doesn't --

MEMBER GOLDMAN: Okay.

MEMBER REDLICH: -- it doesn't cite it. But it's from IARC. I could send the web page if I can find it.

CHAIR MARKOWITZ: At the bottom of the table is the citation actually. So again, the most important piece, I think, the final step in the document that this group has already worked up is to name the cancer sites in -- if possible,

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in relation to the particular 2A agent. And if that step could be done in the next month, that would be terrific.

MEMBER BERENJI: Sure. I think that's relatively easy to do.

MEMBER GOLDMAN: Yeah.

CHAIR MARKOWITZ: Okay, great.

MEMBER GOLDMAN: And I think it's really important because people tend to not understand that a given chemical doesn't cause cancer in every organ.

MEMBER REDLICH: Well, and also that it's more of an increased risk.

MEMBER GOLDMAN: Yeah.

MEMBER REDLICH: Yeah. I mean, but that would be good to do something like this.

CHAIR MARKOWITZ: Okay. So is there any further discussion on this?

(No response.)

CHAIR MARKOWITZ: Okay. So we're going to take a break for 15 minutes. It's 2:25, so we'll take a break until 2:40. We're just

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about on time. So we will see -- don't hang up. Just stay on the phone and we'll see you in 15 minutes.

(Whereupon, the above-entitled matter went off the record at 2:25 p.m. and resumed at 2:41 p.m.)

CHAIR MARKOWITZ: So let's get started. Actually, so Kevin, thank you for bringing this up, it looks very small. I don't know if you could make it any larger.

MR. BIRD: Yeah, I could. Is that better?

CHAIR MARKOWITZ: Okay, yes, that works. So Ken, you want me to just lead off and initiate the discussion, or?

MEMBER SILVER: If you don't mind, yes.

CHAIR MARKOWITZ: Yes, okay. So this has to do with the Board's idea of requesting resources from the Department. And Ken and I talked about, we tried to come up with a reasonable and succinct description of what it is

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that we think we need resources for. And so that's, we have all of a page, a page and a half. We understand the request is going to have be more involved, more detailed, a better rationale, et cetera.

But it is important that the Board agree on what it is that we want. And so there are two items. One is it's organizing, reviewing, extracting data from claims, analyzing those data. This may be fresh in your mind, for those of you who looked at some of these lung cancer or post-1995 claims.

But the path to acquire or to organize and develop a database for the extracted claims data, organize an in-depth claims for review, review and abstract selected data from claims, enter and organize the data, and then analyze and describe whatever it is that we've learned from those claims.

And that these tasks would require certain expertise, administrative assistance to organize and enter data, expertise in

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occupational medicine and epidemiology, as well as industrial hygiene. And then some limited data analysis and description. So that's the first bit of tasks.

The second one has to do with scientific and technical reviews. But we -- Ken, if you have any amendments on what I just present it -- otherwise, we can just open the floor and see if this captures what it is that we think we're after.

MEMBER SILVER: No amendments.

CHAIR MARKOWITZ: Is there anything we forgot?

MEMBER SILVER: That question is directed to the Board members.

CHAIR MARKOWITZ: Correct, correct. And have we captured the set of skills needed to do this work.

Okay, so while people are thinking about that, let's move on to the second area, which is we've been asked and sometimes on our own addressed issues involving scientific and

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technical subjects in relation to various topics.

We just discussed 2A carcinogens, we discussed Parkinson's Disease, and in the past week discussed any number of other issues, and which would require a fair amount of work of over I think the last two terms of Board. And it would be, it would accelerate the work if we were able to get certain resources to help us.

And a particular task or the search and identify relevant literature in this particular request for them to review and objectively summarize, in a very focused way, the relevant literature, with some provisional conclusions to the queries that the Board is trying to address. And then the expertise needed is research assistance, and then kind of the same spectrum of occupational medicine, epidemiology and industrial hygiene of expertise.

I suppose we could add toxicology to that, but I think it's -- that expertise may not overlap with the others, and there are only so many experts you can really get. So I'm not sure

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I'd add that interaction.

So any thoughts about this?

MEMBER DEMENT: This is John. I think you've captured some of the tasks that's taken so much of the Board's time, and that is trying to review these claims that are thousands of pages without having the benefit of at least some pointers to the places in the documents where the key documents are.

It's, I would say at least 50 or more percent of my time at least is spent trying those pieces of information. That would be of great assistance.

I think the skills, you're going to have somebody with some data management skills. I'm not sure that, up under skills/expertise, it's going to be somebody who has some data management skills.

CHAIR MARKOWITZ: Okay, okay, that's good.

MEMBER FRIEDMAN-JIMENEZ: This is George. I think the data management skills can

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be a research assistant who will search and retrieve relevant literature and also can put together the database. I also think that the occupational medicine/epidemiology person needs to be able to do more than just read and summarize.

They need to really critically evaluate some of the literature. Because it's not always going to be the case that there's a single opinion from IARC. Sometimes the opinions will disagree, and the person's going to have to make some judgements as to which is the better review, whether it's IR for NTP or EPA or ACGIH or whatever.

So I think it goes beyond just reading and summarizing and needs to be critical evaluation of the literature and the reviews.

CHAIR MARKOWITZ: Okay, both those suggestions are great and they've been accepted. We're not voting on a recommendation now, but I have captured both data management and critical evaluation in a revision that's not showing on

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the screen, but I had it in a Word file, so that's great. Anything else?

MEMBER FRIEDMAN-JIMENEZ: Question for John. Do you have any recommendations for the qualifications of the person doing the industrial hygiene review? Do you have any suggestions beyond what's being done already, or do you think the people that are doing it now would be the right people to do it?

MEMBER DEMENT: You mean the people who are doing now within the contracts?

MEMBER FRIEDMAN-JIMENEZ: Yeah.

MEMBER DEMENT: Well, you know, we've discussed this a lot. I, now certainly somebody who's certified in the comprehensive practice of industrial hygiene is important as a qualification. But I think it goes further than that. I think it has to be an industrial hygienist who deals with more than just taking samples.

It has to be somebody who is also somewhat familiar with the epidemiology and

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causation. I don't know how you write that into the skillset that's needed, but I think we have occupational medicine combined expertise with Epi. In some ways, the industrial hygienist has to speak the same language. And the same language in many cases is the EpiData.

CHAIR MARKOWITZ: But what if we call that exposure, in addition to industrial hygiene exposure assessment?

MEMBER DEMENT: Yes.

CHAIR MARKOWITZ: Okay. Because that's, you know, sort of a science.

MEMBER SILVER: To narrow it even further, should we throw in the phrase medical-legal decision making? Because that is what we're doing here.

CHAIR MARKOWITZ: Well, you know, I don't know that we need that from outside consultants or contractors in terms of, you know, kind of the brute work that you need to get done. The way I view this help is that, it's to either get at information in claims or get at literature

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that we then can use.

And in considering the medical-legal or you know, framework as it applies to EEOICPA claims. But I'm not sure that we need the outside input into that, if that makes sense.

MEMBER SILVER: I was triggered by John excluding industrial hygienists who just take samples, wondering what kind of added savvy would qualify card-carrying industrial hygienist who is strong in exposure assessment. And that was one thing that came to mind. And another is familiarity with the DOE complex.

I think one of the shortcomings of the contract CIHs is a little bit naive about the complexity and rarity of some of the processes at DOE facilities. And it would be good if at least one of the disciplines represented in this, the doctors, the IH, the administrative people had some track record in the DOE complex.

CHAIR MARKOWITZ: So why don't we, under skills/expertise, add item C, something like familiarity with DOE complex.

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MEMBER SILVER: All right, thank you.

CHAIR MARKOWITZ: Yes. Anything else? Okay, well, this helps. The Board or the next Board will see another version of this. I mean some board at some point is going to have to make an official request. So this will be, this write-up will be amplified. But this helps in identifying core functions.

So I think then if there -- are any other comments? Otherwise we can move on to the next issue.

Okay, the next is listed as the contract medical consultant and industrial hygiene assessment or evaluation. And so there's a separate file, Kevin, on this. This is the workgroup that consists of Duronda Pope, Ron Mahs, John Dement, and myself. And again, this is preliminary. We're not going to vote on this. We want to see if we get some of the initial approach down, we want some feedback.

But in addition when, as we worked this up, we realized that we really had to

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understand specifically what the current assessment or evaluation of the industrial hygiene and medical expertise within the program is. The particular task assigned to the Board is to evaluate the quality, objectivity, and consistency of the industrial hygiene in contract medical evaluations.

So that's what led to a request to the Department for the specific language of the contracts with the industrial hygienist, hygiene contractor called Banda, and the medical contractor, which is QTC, I think.

And so those are the materials that have just been provided to us. We haven't really had a chance to look at them. At least, I think many of us haven't. And we're not going to discuss those in specific details anyway.

But now that we have them actually, we can better describe here what it is that, if anything, what needs to be done, what gaps need to be filled. So then, let me read some of this so we can discuss, or at least briefly run

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through it.

So as a preliminary thought, the Board recommended the Department develop an ongoing, independent, third-party-based system of periodic evaluation of the objectivity, consistency, and equality of individual claims assessments provided by program industrial hygienists and physicians.

By the way, when we say program, that's not limited to the DOL employees, but that means all of the contractors as well.

And so the rationale, we note that the program currently assesses aspects of the contract, the medical reports, the quarterly review of approximately 50 claims by the Medical Director of the program. And there's a table we provide results of the Medical Director's audit from, these were the most recent ones available, as of a couple months ago.

And this would need to be updated if additional ones are available. But looked at 250 audits, claims. I don't see any CMC reports.

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And this is how it breaks down in terms of the type of report and then the percentage that need improvement.

This notion of needing improvement doesn't, in this table, separate out to minor versus major. But you can see there's a pretty clear pattern, which we've discussed before, which is that causation is generally not seen to be, represent much of a problem in terms of the current reports.

But in the other areas, quite a few, quite a high percentage, actually, of reports need improvement. Again, some of that improvement might be minor. This evaluation here is not making a big distinction here. And so those two findings are noted in the next paragraph on medical review.

One interesting thing which we haven't, we need some understanding of is when the Medical Director finds -- has a finding of needs improvement, it's reviewed by the Policy Chief or the Policy staff, who agrees or doesn't

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agree. And then I think that feedback is passed along to the contractor.

But the question is, aside from perhaps some improvement in that particular claim, to what extent did the generic problems, which are identified through this review, are addressed more broadly. And that's something that we need some clarification from the Department about.

Because frankly, if you have 23, 28 percent problems that means there's a, you know, just a systematic problem that needs to be addressed. So we need some clarification about what the Department does about that.

And on the industrial hygiene side, Kevin, let's go to the next page. And so our understanding of industrial hygiene assessment is that there's not this kind of quarterly sit-down look, the way the Medical Director does, but that each report, as it's submitted to the program, is evaluated by the federal Industrial Hygienist, who looks at it for consistency and quality. And

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then puts their stamp of approval on it or requires some correction.

And we see that in the claims, that the federal IH doing a low-process evaluation. And so but there's no look-back, really, on sample of claims to see if there are the broad directions that require some intervention to look at whether there are some errors or overlooked items that occur on a reasonable basis, reasonable frequency and require correction.

And so we note that they share these different approaches to be on the medical side versus the industrial hygiene side.

One last note here is that we still have to look at the Banda and CTC quality reviews to see how what they do impacts on our understanding of the process.

In any case, so let me open the floor here and see if people have other thoughts. And if you could scroll back up, Kevin. I think what we also want is some feedback on whether this ongoing, independent, third-party-based approach

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is reasonable and necessary.

You have, for instance, right now the Medical Director doing these quarterly reports. I mean, I'm sorry, you have individual reports review. Do we need to recommend that somehow this process be made more independent, or what? So, the floor is open.

MEMBER DEMENT: I'll start. This is John. I guess I feel like there needs to be an independent assessment. We, based on, you know, reviewing a lot of claims over the last few years and there seem -- for some industrial hygienists and some CMCs, there seems to be a pattern at the review of them.

And sometimes a pattern is just one of a relatively brief and shallow report. In some cases, industrial hygienist, for example, it's not clear based on my review in more detail of the cases, that some of the claimants' statements are being considered.

So I just think that it's almost at an individual level. There needs to be some level

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of oversight of each CMC and industrial hygienist to make sure there's not a systematic set of errors that they're making. So I think an independent review is necessary.

MEMBER SILVER: This is Ken Silver. I agree with John. And one of the claims that I reviewed for today makes me raise this question. Is there any evidence that after a DOL denial is reversed on appeal or at the Final Adjudication Branch, that the CMC or the IH get feedback on what they missed when they contributed to a recommended denial? What new evidence or what new interpretation was presented at the last stage of the process to overturn their work?

I don't want to incentivize the IHs and CMCs to try to, quote unquote, beat the claimant, but it seems like there would be a lot of value in making sure that feedback loop is closed. It was eye-opening for me that a family doctor in a rural community in Tennessee is better at accessing and interpreting occupational epi studies than the contract medical consultant.

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MS. POND: So this is Rachel. You know, most of our CMCs are op med doctors or certain specialists, depending on what we're referring them for. And we do get family physicians that will send information in. And sometimes that information is -- really, it depends.

I mean, we get web -- we get a lot of different analyses that doesn't always have the backup, or it's got backup that isn't based on the kinds of occupational things that we're looking at. So, you know, we do have doctors that are specialized in it.

But when we get something from a family doctor who knows the claimant and has evaluated claimant and has more familiarity with their history than the CMC and provides more information, then we will weigh that and oftentimes remand the case or reopen a case for further evaluation.

MEMBER SILVER: Well, it probably doesn't happen every day, but I really did see a

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case where the FAB weighed the family doctor's opinion submitted on appeal versus the CMC's opinion and decided that the family doctor's opinion had more probative value. But I'm asking more of a procedural question. In case like that however rare, once the dust has settled, would the CMC get to look at what happened?

MS. POND: No, we don't usually send -- we don't usually send the reports from. So in this case, what I just described, where we do have -- and we are actually relying more heavily on treating doctors when we can, just because as I said, they have more of the history of the claimant. And if they can provide us with rationale that's sufficient to reopen the case or accept the case, then we will rely on that.

We'll oftentimes send the CMC report to a treating doctor to say this is what the CMC said, what is your opinion on this based on your knowledge of the claimant. So that is one trend that has moved, been, we've kind of been drilling into our CEs to make sure that they're paying

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attention to what the treating is saying so that we don't weigh a onetime visit from a CMC too heavily.

But as to your question, we don't normally send treating physicians' rebuttals or contradictions back to a CMC because we pay them on a per, you know, a per claimant basis. They will look at the claim, they'll review it. And we do try to take lessons learned.

We have calls with CMCs to talk about things that we've found in general on a regular basis, but that's about as far as we go at this time.

MEMBER POPE: This is Duronda. Is it the Board's job to be the independent third-party audit?

CHAIR MARKOWITZ: Yes. This is Steven. I think the keyword there is job, right?

I don't -- I'm not sure that's a reasonable or unreasonable interpretation of our charter.

MEMBER POPE: Sort of like what we're doing.

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CHAIR MARKOWITZ: You know, to the extent that it needs to be on an ongoing basis and really relied upon by the program, not as advice but as, you know, a real evaluation, I think it should be something that has a different relationship with the program than we do. I mean, I think we can provide advice on what that should look like.

But if -- but this is a really a specific ongoing function that I don't really see as part of the Board's domain. But I'm open to other, you know, opinions.

MEMBER SILVER: Most auditors get prescription eyeglass benefit plans, don't they?

And if the next board were to get a contractor, the contractor would provide employees with what they need to get through these massive case files and derive statistically relevant sample of files to review.

So we're not really set up to have auditing as our job. We can raise the questions and gather preliminary evidence how to address

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them more systematically, but I don't think we can really be the auditor.

MEMBER POPE: Point taken.

CHAIR MARKOWITZ: However tempting that might be. Okay, any other comments or? Okay, so the plan here then is for this working group is to take a look at the provisions of the contract with the medical and the industrial hygienist contractors somehow appropriately, properly fold that into the rationale here. And then formulate a draft recommendation, which would go the next Board form them to do whatever they want with it. But we'll, we can push it as far as we can within the allowed timeframe.

Any final comments on this before we move to claims review? Okay, so we were given, sent a number of claims. We have requested, I think we got 20 lung cancer claims and about ten post-1995 claims. Just a reminder of the background. By the way, there's no, I'm not aware of anything we have, Kevin, to show at this time. Although we are definitely not on break.

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But the just, by way of reminding you about on the lung cancer claims. So one of the reports from the Department, the report 682, has listed a large number of lung cancer claims, with certain information about those claims, including a job title, when people were hired, when they were -- when their job was finished, when their cancer was diagnosed.

And on the surface, it looked like a lot of these lung cancer claims, they're from a group that was denied. And it looked like, given the presumptions in the procedure manual, that they didn't understand why they were denied because they looked like they should be. See, that's the presumption that it should be accepted. So do you want to take a look at that, we'll try to understand it better.

And then on the post-'95 claims, these were people whose employment began at the Department of Energy after 1995, and we wanted to see how their exposure was viewed in the claims evaluation process. So let's start with the lung

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cancer claims. And we had a number of volunteers. And so including Dr. Silver, Dr. Redlich, Dr. Domina, Dr. Dement and myself.

Anybody want to start?

MEMBER SILVER: Well, I have an easy one. Ken Silver here, a very easy one. It was only 18 pages with no real meat. And that hasn't happened before in any other --

CHAIR MARKOWITZ: What's the last four digits? What's the last four digits?

MEMBER SILVER: Three digits.

CHAIR MARKOWITZ: Okay.

MEMBER SILVER: 6-4-6.

CHAIR MARKOWITZ: Okay, thanks.

MEMBER SILVER: So that hasn't happened before with any of our other case file retrievals, but let me sink my teeth into anything there.

MEMBER GOLDMAN: So are we -- this is Rose, are we supposed to be putting the CD in and looking as you're talking, or are we going to see a summary? I'm just wondering what we should be

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doing.

CHAIR MARKOWITZ: Don't put the CD in and look because you'll get a little lost.

MEMBER GOLDMAN: Okay.

CHAIR MARKOWITZ: We really are after just some summary assessments of the claims that people looked at.

MEMBER DEMENT: This is John, you want me to go second?

CHAIR MARKOWITZ: Sure.

MEMBER DEMENT: Well, I had four claims, only three of which were all on my CD. It must have been a misnumber on one. But when I looked at the claims with regard to the asbestos presumption, I can't say that, you know, they made an error in applying the presumption with regard to work duration prior to 1995 and the outcome in question.

But I did look at the claims in more detail, because these were lung cancer claims that were denied. And there's one claim that I found to be particularly troublesome, and it's

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number 0541. This is an individual who worked at the Idaho National Lab about 11 years, between '80 and 2012. It is heavy equipment operator, operating engineer, a working operator foreman. And basically an operating engineer.

Only had about a month of employment before 1995, most of it was after 1995. And so the claim was reviewed by the Industrial Hygienist, who actually had a initial report and then some supplemental reports. The SEM identified asbestos as an exposure. It also identified silica, diesel, and several metals, including cadmium and nickel and beryllium.

So the Industrial Hygienist basically finds that exposures post-1995 would not be in excess of applicable standards and regulations. A usual, it's pretty much a usual statement.

The CMC in this case reviewed the industrial hygiene report and looked at the data for causation. The CMC report is totally confused. It basically confuses diesel fuel with diesel exhaust exposure, and it then states that

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diesel exhaust are categorized as IARC Group 3, but it was in fact categorized as a Group 1 in 2012.

And the CMC does the same thing with cadmium. Cadmium was a Group 1 carcinogen in 2012. So you know, given, this is one of the reports that there are significant factual errors, in my opinion, with regard to the CMC report, both on individual compounds, as well as just considering all these materials in totality with regards to causation.

This individual was, I think was a nonsmoking individual, or well, a former smoker, but he quit smoking many years ago, before his diagnosis of lung cancer. This is one of the reports that really, when I looked at with the CMC report, really was cut and paste some materials from the internet that had to do with diesel fuel.

It talks about aquatic toxicity, irrelevant material stuck in the report. It was one that was a red flag to me that in my opinion

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this CMC report should be looked at in detail. Others as well.

CHAIR MARKOWITZ: So this is Steven. I looked at some of these files and claims so I can review a couple. They're claims that end in 1985, that's the number. This one was easy. The person was a cafeteria worker with lung cancer.

And I've no idea why this was subsequently reported as being a labor because the person didn't appear to be that, there was no documentation of that. So this was just not a claim that we intended to review.

Another claim, 9032, was interesting, a very interesting claim, actually. This was a roofer and janitor at DOE for I think from 2003 to 2014 and didn't meet the criteria for latency. So I can understand why they weren't accepted as the presumption.

The statement of accepted facts, I couldn't find an industrial hygiene report, but the statement of accepted facts says that the exposures were within regulatory limits. And

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this was quoted by the CMC as -- accepted by the CMC and stated as the reason why there would be no occupational contribution from a roofer and janitor during those 12 years or so.

There is a personal physician who wrote a strong report in opposition to the CMC's conclusions. And the Director of the, I think District Office, overruled the denial, citing the personal physician's strong letter, strong support of, in opposition to the CMC.

So I don't have quite the chronology correct because you know how it is that the Director overruled the denial, I'm not sure. But in any event, it was in my view an inadequate job by the CMC and a reliance of the Claims Examiner, perhaps Industrial Hygienist, I'm not sure, but at a minimum the Claims Examiner on this post-1995 but within regulatory limits.

I'll tell you another claim, 5648. This is a lung cancer 2013, which was denied appropriately because they only worked for a very short period of time as a glazier, a glassworker.

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Interestingly, when I looked up glazier on the SEM, in the construction -- under the construction rubric, the glazier is not listed as having a link to lung cancer. At least I couldn't find that.

But in Exhibit 15.4, which we reviewed earlier, the glazier is one who's recognized as having significant exposure to asbestos prior to 1995. So it may be that this, there, the Department needs to look at the SEM, in the SEM at the rates for glazier, because it should be linked to lung cancer if Exhibit 15.4 is going to be maintained, so.

Any other claims anybody wants to talk about?

MEMBER SILVER: This is Ken again. I have an issue that arose in two claims. Question for the doctors on the Board, the CMC's asserted in both claims, lung cancer claims, that because there was no radiographic evidence of asbestosis or pleural plaques, the lung cancer could not have arisen on asbestos exposure.

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In other words, lung scarring is an obligate step on the way to lung cancer. I understand that it's a marker of exposure and if it's there it says whoa, this person had a lot of asbestos, but is that a contested issue, or is it pretty well settled you can develop asbestos-related lung cancer without fibrosis or plaques?

CHAIR MARKOWITZ: It's a settled issue that the risk exists in the absence of nonmalignant disease. But there's a certain subset of physicians out there who are involved in litigation who don't believe it. And it's possible that you encountered a couple of them. But it really is really thinking that you don't need to have any scarring due to asbestos, too.

MEMBER GOLDMAN: This is Rose. I think it also depends if the person was a cigarette smoker or not. If it's a nonsmoker it's easier legally to make the case for, you know, perhaps, you know, the role.

What happens in a lot of people if the person's a cigarette smoker, then they just

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dismiss the asbestos exposure, although you shouldn't really because it's potentially a multiplicative effect. But I think there's been a lot of arguments over that one.

MEMBER SILVER: So that argument probably shows up all the time in tort cases, right, when there are very large amounts of money on the line. But in a claimant-friendly administrative compensation program is it appropriate for this setting? I believe both of these workers were in fact smokers.

CHAIR MARKOWITZ: Well, this is Steven. In a science-based evaluation, presence of nonmalignant disease should not be required to draw a causal relation between exposure -- asbestos exposure and lung cancer.

MEMBER SILVER: Thank you.

MEMBER GOLDMAN: Could you repeat that? It didn't come through, it was very soft. Could you just repeat that?

CHAIR MARKOWITZ: If you want to make -- the decision is based on science and the

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weight of the evidence, then you would not require the presence of nonmalignant disease in nonmalignant scarring in particular among asbestos-exposed to conclude that a person had asbestos exposure and that it's causal with their lung cancer.

MR. BIRD: Sorry to chime in here, this is Kevin. Just a quick reminder to everyone to, if you're not speaking, if you could keep yourself on mute that would be great. Thank you.

CHAIR MARKOWITZ: All right, let me add another claim, claim 7497. Interesting. Nine months as a carpenter, so the person did not meet the presumption of 250 days of exposure to asbestos. So the decision was correct from the point of view of presumption, did not meet the presumption.

The CMC decided that nine months as a carpenter wasn't sufficient to contribute to a lung cancer, which, you know, I'm sure there's variation in thinking about that.

But the CMC report hosted, cited a

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number of reasons why there couldn't be any causality. One was that no air monitoring results were available. That's an unreasonable criterion on which to base the decision. And the CMC with many of these claims cites the cigarette smoking as critical to the development of lung cancer.

Although we've been told by the program that the consideration should be apart from the initial cigarette smoking, that message hasn't gotten through to a number of the CMCs.

And then one final, before we move to post-'95 claims I just want to cite one other claim, 6018. This is an ironworker for a long time. I mean, a career ironworker, but only had a year and a half work as an ironworker within the Department of Energy. So he met the 250-day presumption criteria for asbestos but did not meet the 15-year latency requirement because the latency was 14 years, eight months from the time of his work at the DOE.

And so strictly speaking it didn't

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come under a presumption. The CMC noted that this wasn't sufficient contribution, quoting low level exposure for a short period of time. And I think of we gave that case to five different CMCs, we'd probably get half of them deciding one way and half of them deciding another way, which gets to the issue of consistency.

So what my take-home from these reviews is that we've got considerable variation in the quality of the CMC. And to some extent, some of that's understandable because it's discussing opinion, but some of it is due to the inadequacy of some of the CMCs.

Can we move to post-'95 claims? Did anybody look at some post-'95 claims?

MEMBER DEMENT: This is John, I looked at a number of them. You know, the issue of post-'95, looking at the post-'95 claims was sort of in response to our comments that it looked like the circular or the memo with regards to post-'95 exposure assumptions of being within regulatory standards, that memo was rescinded.

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But we see the same statement over and over again in the industrial hygiene report.

So we responded that we thought that that was not appropriate. The DOL responded back to us saying that, I think mistakenly saying that we were wanting them to assume exposures, significant exposures post-1995, which we're not. Really just saying you just don't presume that they weren't there.

There's one statement in the DOL response I think is particularly important. They, you know, the discussion of considering all the information, and in the DOL response they say, in other circumstances employees' descriptions of specific exposure activities and/or work processes will be such, will be of such convincing quality to warrant affirmation of significant exposures in the absence of monitoring data.

But basically the way that DOL reports go, industrial hygiene reports, they say in absence of in an area, again post-'95, the

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exposure's assumed to be within regulatory standards. So what happened with that of course is that statement is then used by the CMC in some cases to assume not significant exposures and make a negative determination.

There's one that, there's a couple reports that I looked at that I think are worthy of some discussion. One was number 5756. This was a claim for COPD and a never-smoker who was a pipefitter at Portsmouth, with most of his work being post-1995. The claimant on the OHQ talked about multiple exposures, including welding fumes at the DOE, doing DOE site work.

In fact, providing some handwritten statements that were available in the claims file describing he and coworkers doing welding in an unrelated shop and also welding within confined, sometimes confined spaces, that is, within a large pipe trench. The IH assessment relied on the SEM and it used post-1995 statements with regard to exposures, not exceeding regulatory standards.

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In this particular case, the CMC used the industrial hygiene report and that statement to find lack of causation. But most disturbingly is a CMC statement in addition to the industrial hygiene basically not looking at this or considering this specific description of the work.

The CMC says that current occupational safety and health standards are designed so that no harm -- to cause no harm and no more than one in a million people exposed. This, I've seen other CMC reports and I assume for the person. This individual clearly doesn't know the basis for occupational safety and health standards and risk assessment. And in my view, this assessment's clearly off base.

For two reasons. One is the CMC's assumptions and also the industrial hygienist's lack of considering specific exposure circumstances, including welding, within compliance basis for a period of about eight years.

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There's a similar case, and this is a more difficult case. Number 4550. This is a person who worked as a quality control position. Basically I think more data quality control.

But they worked away from the Yucca Mountain site but had to come on site and be at a site trailer for several times during the month, and in some cases go into the actual work areas, including an area that was described as the exploratory studies facility.

This individual had a document in the file that I reviewed that described just driving to the sort of remote site. It was dusty, the site itself was dusty. The trailer was dusty, the work area was dusty.

This individual was a never-smoker who was diagnosed with silicosis based on a chest X-ray and a B read, with a very supporting physician's report that basically ruled out other causes and thought that this exposure to silica during the Yucca Mountain site, doing some work, was at least contributory to this person's

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silicosis.

This is another case where it's not clear to me that the industrial hygienist actually considered anything beyond the job title and the SEM report in making, make a determination for no exposure. In this case, the comment was, would have been passing and incidental.

So again, I, you know, we are not trying to say that post-1995 exposures are assumed to be significant. And sometimes they are, and I think the industrial hygienists really need to look closely at more than just the SEM, more than just a job description in trying to make some of these determinations.

It may be that end of the day, the determinations still would be denied, but in this case I really don't think the record was given full view.

CHAIR MARKOWITZ: John, I have a question, Steven. In both those cases, was there sufficient information in the file for the

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industrial hygienist to depart from the idea that post-'95 exposure levels were safe?

MEMBER DEMENT: I think in this case, as a industrial hygienist, to me there was enough information in the file to, if I were reviewing this file, to make me go back and say let me explore this further.

I think with regard to welding within a shop, a fairly small shop, with no ventilation, and they actually, he had coworker statements confirming the fact that that was the case, should have been convincing enough, at least on the industrial hygiene side, to take a harder look.

And you know, we have made recommendations and DOL has adopted procedures for talking with the claimant directly, and I think that needed to happen in this case. Probably in both of these cases.

MEMBER SILVER: John, this is Ken. Was there any recognition in the claim file that out at Yucca Mountain we have the isomorphs of

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silica that are presumed to be more potent cristobalite and tridymite?

MEMBER DEMENT: Actually, the physician, the person's physician made those not specific statements, but acknowledged that that, those sites you know, had silica, based on cases that this individual had reviewed before in surface soils.

CHAIR MARKOWITZ: This is Steven. Well, that's interesting because you know previously we had been thinking that the essential problem was that Yucca's case-specific exposure information didn't really enter the record from the point of view of the claimant, such that either the claims examiner or the IH could really make a complete determination about exposure.

And that's in the past why we have, we recommended that interviews be conducted with claimants for some, and also that the OHQ be included, so that the quality of the information in the evaluation process is improved.

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But here actually you are looking at a couple of claims in which the information was probably there, but underutilized by the industrial hygienist.

MEMBER DEMENT: Yeah, I am saying the information was there, Steven, at least in my view raised the red flag. You know, the Yucca Mountain situation, if I am just given that this person was an individual who was occasionally on site and developed silicosis, yeah, you know, it probably wouldn't be difficult to conclude that it's unlikely that it related to the exposure.

Except the physician eliminated other exposures and there was documents in the file that showed more than just, that showed casts (phonetic) that would have caused exposures to silica that could have contributed to this outcome.

CHAIR MARKOWITZ: Okay. Anybody else look at the post-'95 claims?

MEMBER REDLICH: This is Carrie. You know, several of these claims just have some of

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the same themes that we have had before, such as number. So the COPD, let's see, 2876. But I believe there is just a comment that, you know, they are acknowledging exposure to, you know, what was it here, asbestos dust. Some of them work at the uranium mines in Colorado.

And but basically the SEM acknowledged exposure, but then there was a comment that after exposed to diesel exhaust, asbestos, cement, crystalline silica, welding fumes, that then that the CCIH opined that exposures to any of those after March 11, 1996 would not have exceeded regulatory standards. And the CMC then opined that there was not significant, the exposures were not a significant factor in contributing or causing COPD.

And then, you know, the claimants sort of appealed and gave a description of the work that they did in terms of you know, just a lot of dusty exposures, being very close to an excavator and the like. And that to me seemed like sufficient exposure.

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So I think it's an example where it seems that the CMC is, you know, potentially overly influenced by the IH report. This happens to be one of the particular physicians we have raised questions about before in our prior review of claims. So it's a little disheartening that this same person (telephonic interference) claims after we have raised questions about this particular physician.

I've got a bit of a sore throat, so I'll stop there.

CHAIR MARKOWITZ: Okay.

MEMBER SILVER: This is Ken. Linking this back to the quality issue we had on the agenda a moment ago, my analogy is that the best football teams after a couple of days sit down and look at the reruns and analyze their fumbles, their interceptions. And Dr. Redlich makes an excellent point, we've raised these same issues over and over again.

And I saw an example where the FAB overruled the CMC once a better analysis came

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from the family doctor. It seems that good management if you want to be a winning program would, you know, take a look at the fumbles and the interceptions with the player in the room.

MEMBER DEMENT: This is John. One of the themes that I find very difficult with regard to some of the outcomes, particularly COPD, you know, there's a number of claims where there would be maybe four or five different exposures actually identified in the SEM as related to that job category and linked to COPD, actually.

And then the determination by the industrial hygienist that, you know, then they're either low exposure or passing exposures or within regulatory standards. But nobody, including the CMCs, ever says but wait, there were five of them, not one, and looks at the totality of the exposure appropriately.

MEMBER REDLICH: You know, that's exactly the situation on the last one that I --

CHAIR MARKOWITZ: Yeah, I mean, this is Steven. Part of the problem is, you know, the

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CMC is sitting there and it is hard to judge exposure.

And so but the fault is hey, let's look in the industrial hygiene report or the statement of accepted fact version of the IH report that says low frequency, nothing above regulatory level. And that makes the decisionmaking very easy for the CMC. No significant exposure.

MEMBER DEMENT: Especially if you have the opinion that if they're within regulatory standards, only one in a million exposed people would be affected.

CHAIR MARKOWITZ: But that's, you know, that's a misinformed CMC.

MEMBER DEMENT: Yeah. But to -- the point I think Carrie's making too, this is a misinformed CMC who makes these recommendations over and over. We see them in many reports, you know. Somewhere somebody, some other doctor needs to look at that and say wait, this is off-base and we need to make a change.

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CHAIR MARKOWITZ: Well, you know, we saw it in the --

(Simultaneous speaking.)

MEMBER REDLICH: -- Position there is no other physician, and I've reviewed a lot of these records, that comes close to reviewing the same number of claims as this physician, at least among the subset that we have been given. So it's a sizable number of claims by a single physician.

MEMBER MAHS: Doesn't that mean he makes a little more money?

MEMBER SILVER: I think they are paid piece rate, yeah.

MEMBER MAHS: That's what I was getting at, they're paid by the client.

MEMBER SILVER: Regarding COPD, I know the Department of Labor wasn't open to pay for gas and fumes of being incorporated into the regulations or the procedure manual, because it has to be a specific toxic substance. But I wonder if a middle ground approach would be

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guidance to the IH and the CMC in cases of COPD to consider as many credibly documented exposures as possible.

I had Case 4457 of a lab technician at Portsmouth. And because of the SEM, he was only allowed ammonia, asbestos, and chlorine exposures. But elsewhere in the case file, there's pretty solid evidence that he was exposed to hydrogen fluoride. The company's medical surveillance program indicated that he had that exposure years before he developed COPD.

It's documented on the occupational health questionnaire that he worked with isocyanates for the last ten years on and off and had exposure to magnesium chloride pellets described as a very dusty operation. Perchloric acid, nitric acid. I mentioned hydrofluoric, right?

But to evaluate the claim, they only considered ammonia, asbestos, and chlorine. So maybe some guidance could be developed for COPD claims to consider as many credible exposures as

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possible, you know, lead them right up to the cusp of VGDF even if they don't spell it out.

CHAIR MARKOWITZ: Okay, so we probably need to move on. But I think these comments actually can feed into our report on consistency, quality and objectivity of the industrial hygiene and CMC reports. So some of these observations will be built into that rationale and recommendation.

MEMBER DEMENT: This is John. I actually like Ken's suggestion for COPD. You know, maybe there's a middle ground that we, you know, we've already written the rationale for VGDF, just a guidance document, a statement.

MEMBER SILVER: For a while, QTC was trying to cap the number of exposures considered at seven. In this case, didn't even, they limited it to three. But maybe we're recommending that they list the cap and consider as many credible exposures as are contained in the claims documentation.

If one of the CMCs stays up on the

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literature, they'll say wow, you got 15 vapors, gasses, dust, and fumes here. My professional judgement, it might have caused or contributed to this.

CHAIR MARKOWITZ: So what's the follow-up on this, for this?

MEMBER SILVER: I don't know, do we need a recommendation down the road or? It's kind of hard with the Board wrapping up its business to have an idea like this now.

CHAIR MARKOWITZ: But you know, regardless, for continuity, we can certainly send along some, an observation that, you know, they can take up. Otherwise it'll disappear, so that's a shame.

MEMBER SILVER: In cases of COPD, do not limit the IH evaluation to exposures in the SEM. Consider all exposure, inhalation exposures that are credibly documented in the case file.

CHAIR MARKOWITZ: So let's follow up on that. We're not going to formulate a specific recommendation I think, and be able to vote on it

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now. But let's, we'll offline sharpen that up and make sure it's in our exit report, how about that?

MEMBER SILVER: Okay.

MEMBER REDLICH: Some of these are appropriate denials. I mean, this is, some of these are so -- and they go through so much effort. Then we just sort of, maybe we could make some, I don't know, common sense, you know, the greater the years of employment need to have a closer look.

If it's only one or two months of employment, it's going to be less likely that COPD is going to be related to that employment. So someone has, you know, 15 years in a industrial, dusty environment. It's just some of the, I just sort of feel like maybe they've just been sort of common sense checks on the system.

MEMBER DEMENT: This is John. I agree, Carrie, you know, some of files are extremely long for a few months of exposure. It was a lot of work to come to a conclusion that

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probably should have been short-circuited, but nonetheless it took a lot of time.

CHAIR MARKOWITZ: Okay, so let's move on. DOL's requested some helpfulness on trying to get providers to be more responsive. I thought maybe some Board members hadn't had a chance to review the development letters, we could take a look at a couple to kick off the discussion.

Ken, I sent you some files. If you could go to redaction letter number 5.

MR. BIRD: Yeah.

CHAIR MARKOWITZ: I'll just, if there's a way -- this is a short letter. Actually, we don't need to see this topic, it's so much, if you could just scroll it up some. It's a one-page letter. And on Parkinson's Disease. And apparently they've gotten medical statements. Can you scroll up so we can see the rest of the letter.

Okay, so that's the whole letter and it states what the problem is, what the past

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action by that provider was. They enclosed the IH report and asked specific questions, this is in the fourth paragraph, provide us with opinion about, you know, whether these exposures met the standard.

I thought this was an excellent letter. I'm going to show you other letters which I think they're a bit problematic, but this one is to the point and provides necessary information. It's bureaucratic, but that's the nature of the beast, I think. So I thought this was a pretty good letter.

Maybe it didn't get a response, I don't know. But as opposed to, say, let's look at another letter, redaction letter, the development letter, whatever it's called, number 6 or 8. Why don't you try 8.

Here is my view of this. It's if you're going to write to a provider, okay, so here is a letter, it's about neuropathy and these are dates of when the neuropathy was diagnosed and the employment dates. And then we go into

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what a well-rationalized support consists of.

It may ask for, okay, submit a letter where they go into the occupational history, what the medical opinion previously showed. Keep going to the next.

And then talked about referrals to the IH. And then formulate some questions separating out contributed or aggravated from causal. So here's my problem with this letter. If you could scroll up, please. It's pretty simple, doctors don't like to read, and they especially don't like to read bureaucratic language.

I would right up front in the letter state what you want from that provider, what you're asking of that provider right off. I mean, it can be the second sentence or not, second paragraph, not necessarily the first. But this is what we're asking of you.

And then I would summarize, try to get it on one page, I would summarize whatever you want to show. If you need a definition of well-rationalized, include a second page, not part of

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the letter, but you know, a helpful glossary, guide, whatever, that gives definitions or if you want to include that IH report, include that as a separate thing.

But strip it down as much as possible so the doctor can see exactly what it is you want from them and what it is they need to use and produce without a lot of the overly descriptive terms. That won't you guarantee you a response but at least it'll guarantee you there's more that's read.

Also one other letter, letter number 6.

MEMBER GOLDMAN: Before you leave that, Steve, I hear what you're saying, but sometimes it's really helpful to have the detail there so the person really knows what's wanted. And I'm wondering if there's not a middle ground where you write that first paragraph like you said, with the key things, this is what we want you to know.

And here is some important supporting

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information to take into consideration your opinion. Because there's a lot of records, as you all have pointed out, and sometime that's a nice little guide that's there. Perhaps something like that.

CHAIR MARKOWITZ: Yeah, I mean they have to tease out the elements by which the provider's making his decision and then organize the information they're trying to provide by those elements, kind of spoonfeeding into what a well-rationalized letter would look like, right. And that could be done within the body of the letter, it could be done kind of on a separate sheet, just kind of a summary thing.

MEMBER GOLDMAN: Right, I think that might be a good idea, have the bullet, the big picture, like you're saying, but then this other attachment as a guide to what information is really wanted and desired, so that when the person constructs the letter, you get what you're asking for.

CHAIR MARKOWITZ: The other thing that

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strikes me is these letters are very labor intensive. I mean, the Claims Examiner puts, I think, puts a lot of effort into summarizing and getting the details right. And it's probably necessary, but it should be done in a way that the provider can use those same details, abstract them quickly, and insert into, you know, her or his letter.

MEMBER FRIEDMAN-JIMENEZ: This is George, I have a question. This letter doesn't seem too bad, in fact, it provides a lot of information to the physician. But one thing that strikes me is the two questions at the end, trying to tease apart whether the exposures contributed to, aggravated, or caused the neuropathy.

I think it's unnecessarily complex. I mean, I think it's not possible to tease that apart in most cases because we don't have enough information to say whether it was contributing to or the primary cause. We don't know exactly how these different chemicals interact with each

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other or with other things like diabetes or other potential causes of neuropathy.

And without having that level of scientific understanding of how the different causes interact or compete with each other, it's not possible to distinguish between being a primary cause, a single cause, or being a contributing cause. And it's not clear to me why they're asking the doctor to distinguish here.

Does anyone know why they would try and separate these apart? Because the OSHA standard --

MEMBER GOLDMAN: That's a good point.

MEMBER FRIEDMAN-JIMENEZ: The OSHA's definition of work-related does not distinguish. It lists cause, contribute to, or aggravated in one sentence. And it's not realistic.

MEMBER GOLDMAN: Isn't that the one sentence you're supposed to say anyway, that's in this thing? I mean, you don't have to distinguish it, I thought it was just if it was any of those in that one sentence and it either

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caused or contributed or exacerbated an underlying condition.

MEMBER FRIEDMAN-JIMENEZ: Right. It's not clear what they're going to do with this information. Are they going to deny the claim that the doctor says no, it didn't cause but yes, it contributed to or aggravated? Or what, why are they asking these two questions separately?

MS. POND: So this is Rachel. You know, everybody usually ask this question in various ways. My take on this is that they probably did that because sometimes it is easier for a doctor to rationalize or come to a conclusion and say yes when we don't include that causation piece. They're a little bit more hesitant to say yes to a question like this if we say cause.

So by separating it out, the doctor can say okay, I feel more comfortable saying this, this was a contributing factor, a significant factor in contributing to or aggravating, but I'm not as comfortable saying it

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caused this.

A lot of our questions, you know, we used to just lump them all together, and then we found that that to be the case with the doctors, that they don't want to say caused but they're more comfortable with saying aggravated or contributed to.

MEMBER FRIEDMAN-JIMENEZ: But then they would just answer yes to the combined question, cause, contributed to, or aggravated. And it makes you a little uncomfortable here because you don't know how that information's going to be used.

MS. POND: Well, as I --

MEMBER FRIEDMAN-JIMENEZ: I understand what you're saying --

MS. POND: I'm sorry, I didn't mean to cut you off. If they say yes to either one, that gives us the, that gives us what we need to satisfy the statutory requirements. So that would be why they separated out. Again, if they said no because they didn't think that it caused

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but maybe they thought it could aggravate or contributed to it, they might have said yes in a situation where they said no. You see what I'm saying?

MEMBER FRIEDMAN-JIMENEZ: Yeah.

MEMBER GOLDMAN: I don't -- I think it's feasible to do what the Department of Labor's doing. It's just dividing up the wording of the part B into two questions. And my understanding is if you answered yes to either of the two, then that would be sufficient.

MS. POND: Right.

CHAIR MARKOWITZ: This is Steven. I think there are a lot of doctors, particularly those who aren't trained in occupational medicine, who just don't feel comfortable with the whole causal framework. But they're willing to in their own mind agree to something softer.

And that's why separating them out gives them that option. Maybe I'm just repeating what Rachel said, but it does make sense to me. It's illogical, but it makes sense to me.

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MEMBER GOLDMAN: I agree.

CHAIR MARKOWITZ: Kevin, can you put up letter 6? This is the last letter I just want to show you. And again, it's just the amount of effort that goes into these letters. I understand now why you couldn't, the Department didn't just send us generic letters. Because these don't really look so pinpoint-driven that really look very custom.

Looks like people are putting a lot of -- I want to scroll down and look at this. This is a three-page letter and it's, well, let's go back to the first page, actually. Could you scroll down so we could see the bottom of the first page, if there is.

MR. BIRD: Right now we're looking at the bottom of the first page.

CHAIR MARKOWITZ: Okay, fine, let's go to the next page then. Yeah, so you know, they cite what the SEM shows. And then when they have an IH report, they enclose the IH report, scroll down. And then they want you to answer this

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question, below rationalized narrative. And then if you scroll down you'll see the repeat on the same exposures.

I don't know if you can scroll down there, Kevin, so we can take a -- all right, so you can shrink this letter a little bit and we can see more of the whole page at the same time. Or not. Can you scroll down, Kevin? Okay, it really is. Is this letter number 6?

MR. BIRD: Yes, yup.

CHAIR MARKOWITZ: Okay, well, I have it on a PDF, and the first page is much longer than what you've showed.

MR. BIRD: Here, I can share the PDF separately, hold on one second.

CHAIR MARKOWITZ: Okay. Anyway, my point is this is a three-page letter, two-and-a-half-page letter, which is just the kind of letter that on the one hand usefully provides a lot of information, the other hand it's just so easy for the provider to get lost in it. And so I just think that there needs to be some approach

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that organizes it better for that provider than it currently is.

It says here, it gives a standard in paragraph three, the long paragraph about sort of what we, what kind of evidence we need. And let's go to page 2, it goes into the SEM. I'm not sure the provider cares about what a SEM is or what a SEM does. I think we can just affirmatively tell a person that, you know, we think they're exposed to asbestos, silicon dioxide, wood dust.

And then get to, sort of get to the question. At the end of the second page they cite chapter, maybe even verse too, about what a well-rationalized report is.

So anyway, I just think that you can write up a much shorter, less time-intensive letter for the Claims Examiner that would get to the point and give the, spoonfeed the information that the provider needs to write the letter or not so that they can turn it around in a way that doesn't require a whole lot of effort.

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Anyway, that's my two cents.

MEMBER DEMENT: This is John. Yeah, I looked at a couple of these too, Steven, and my comment is more to the maybe substance of it rather than the format. Could you put number 2 up, Kevin.

CHAIR MARKOWITZ: Okay, so he --

MR. BIRD: Sorry, do you mean page 2, or you mean --

MEMBER DEMENT: No, it's report, the example number 2.

CHAIR MARKOWITZ: Okay, so Kevin, I'll have to find it. Kevin doesn't have those, I'm going to have to send it to him, which I'll do.

MEMBER DEMENT: I could just describe it, Steven, that's fine. This is a individual who had a claim for COPD as a welder at Portsmouth. The SEM lists asbestos, phosgene, SO2 and welding fumes for his exposures that were linked to COPD. But the, or the request for the development letter, this asked the treating physician to develop a well-rationalized opinion

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with regard to asbestos.

And I know why, you know, asbestos has a presumption if you meet it, it's a lot of exposure and a long period of time. It seems to me this one was off the mark, it should have asked for a well-rationalized opinion with regard to the exposures of interest.

The other thing that sort of struck me as I went through is sometimes, and almost all of the letters I saw, it limits the assessments of exposures of interest to those that were either identified by the industrial hygienist or the SEM. And in some cases, if this is a treating physician and they actually have had the opportunity to have discussed exposures with this individual, they may have an idea about different exposures.

And I think that should be a little -- the development letter should be left a bit open-ended in that regard, if they know of exposures that they've assessed themselves with the individual.

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There was one other one, that was number 3. And this was, it's not so much -- it's not so much a letter as far as the process. This is a person who was claiming for cirrhosis of the liver and had worked at Portsmouth for a long period of time between '74 and 2005.

The worker was a maintenance worker, a maintenance mechanic, laborer. Anyway, it was a maintenance worker who, if you look at the SEM, it has lots of exposures to solvents, including carbon -- TCE. But the letter going back to the physician said there were no exposures found linked to this outcome.

The MD had already provided a first letter in which he said there were, he found no personal lifestyle or risk factors to account for this cirrhosis of the liver.

It's a question for the SEM, I guess. Is liver cirrhosis in the -- the physicians on our panel can talk about cirrhosis of the liver solvent exposures, whether or not it's different in presentation from alcohol-related or not.

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MEMBER GOLDMAN: This is Rose. I mean, there are very few solvents that really lead to cirrhosis of the liver. You know, dimethylformamide and there's a few, it's a handful. Lots of solvents, it's my understanding, can lead to some inflammation and you get some abnormal liver function tests.

But to really go on to scarring, there's less, you know, tetra, what is it, hydrofluoric -- no, not hydrofluoric. Carbon tetrachloride, DMF, dimethylformamide. I mean, I can pull a couple out of my mind. But it's not that many that really lead to actual cirrhosis, unless somebody else has other information that I don't have. And whether this person really had cirrhosis or just chronic elevated liver function tests.

MEMBER DEMENT: Yeah, I'm just pointing out that the letters that went back, even though if you go into the SEM and you pull up maintenance mechanic for Portsmouth, it lists carbon tet and TCE. It lists a lot of

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chlorinated solvents. But those weren't --

MEMBER GOLDMAN: Carbon tetrachloride is one of the ones that will cause that. TCE to my knowledge doesn't really lead to cirrhosis, but carbon tetrachloride is one of the oldie goldies that could lead to that.

MEMBER DEMENT: Anyway, that's just a comment for, you know, what's in the SEM or not. Apparently there must not be a linkage for cirrhosis of the liver with solvent.

MEMBER REDLICH: I would just second the comments. I mean, I think this is an issue that we did raise before, which was that the question that the -- and given some similar specific examples where what they should be asked is did the person's work at whatever site or, you know, period DOE-covered work, contribute to their cause or disease and not presupposed specific exposures.

You know, or if one wanted to highlight, you know, one could say or other exposures. I mean, this came up when, you know,

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when -- now already several years ago with, you know, mining exposure COPD where the question was aluminum, the cause is the person's COPD. And this person has simply been asked if their work in the mine contributed. So this seems to be an easily fixable issue.

CHAIR MARKOWITZ: I've got a question -- Steven. That language doesn't address what the Department wants, based on the law, which is tied to the magic words of caused by toxic, caused, aggravated, continued by toxic substances. You know, not just work, but by toxic substances, that has to be there somewhere.

MEMBER REDLICH: But it could be or another toxic substance, you know, just leaving it open for -- so because it's, otherwise it's the question has already been narrowed. And that's putting the part of the IH, the part of really the decisionmaking that would appropriate for a physician with the appropriate expertise in terms of what types, what exposures can cause what diseases.

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And the IH is already taking liberties based on the links in the SEM and the right to select the exposures they think are the relevant ones.

CHAIR MARKOWITZ: So you're saying that, you know, the letter would say based on the information that we have and are providing to you, but also based on your own interview of the patient and what you've learned in that manner, please answer the question about, you know, the contribution of toxic substances. Is that what you're saying?

MEMBER REDLICH: Yeah, I mean, you know, frequently the ones that are identified are very appropriate, it could just be a little bit more open-ended or other, you know, toxic substances that based upon your assessment, you know, could be contributing.

CHAIR MARKOWITZ: Okay. Any other comments? By the way, Kevin, which one do you, do you have -- is this one of the ones that Dr. Dement wanted to look at, or?

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MR. BIRD: So I have 2, 5, 6, and 8.

CHAIR MARKOWITZ: Okay, okay. Is it 2?

MR. BIRD: Right now we are looking at 2, yes.

CHAIR MARKOWITZ: Yeah.

MEMBER DEMENT: Yeah, that's the one, that's the case where COPD with multiple exposures. The physician was asked to comment on asbestos.

CHAIR MARKOWITZ: Okay, any other comments on this topic? Otherwise we'll move on. Okay. The, so, I will summarize some of these, any other comments that we've made and I'll pass, they can be passed along. One issue that we have never dealt with but I don't think we need to deal with at this meeting but I want to keep on the radar is our review of prepublication policy revisions.

I actually don't know whether there were any sent to us in the last two months, not since the last meeting. Anybody from DOL

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know whether we were sent any?

MS. POND: I'm sorry, can you repeat the question?

CHAIR MARKOWITZ: You know how we're supposed to have access to looking at prepublication policy revisions in the manual, you know, ten days prior to publication. I don't know whether we've received any in the last two months or not. But yeah.

MS. POND: I believe you would have received the last one, but that was I'm not sure. Carrie, do you know when that was that we sent that to them?

MS. RHOADS: It was a while ago. Was it one of the emergency ones for COVID?

MS. POND: I think that was the bulletin, so we did, that was a really short turnaround, I'm not even sure we gave you enough time for that. But we needed to get that out so we could do the --

(Simultaneous speaking.)

MS. RHOADS: Yeah. There was one

other one after that, I thought.

MS. POND: I thought the last update was like 3 point -- I'm pretty sure we still provided it to them, but there wasn't significant changes. They were mostly related to changing some titles and things like that, but.

MS. RHOADS: Okay.

MS. POND: I know if you said -- hold on. Yeah, we've been providing them every time we have an update, so you should have it, Carrie.

MS. RHOADS: I'll look for it. What's it -- I'll look for the last one I sent.

MS. POND: All right, thank you.

CHAIR MARKOWITZ: Okay, thanks. My point actually was that the next board should develop a mechanism for making sure that these are discussed by the Board, either a person on the Board who agrees to triage them and point out, you know, the extent to which they're relevant for other Board members, or some mechanism to make sure that it's done.

Because the timing is odd, we meet

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every few months. These prepublication things come out roughly ten days before publication, so that's just going to be some advice we'll pass along to the next board.

The final topic on the agenda is a work plan to be, work we need to get done in the next month. So I just want to go down the list here, make sure that we agree. We finished the Parkinson's disease and the asbestos job titles, and I will submit them to the Department.

The working group on IARC Group 2A, I think, is going to make some progress on trying to pinpoint which chemicals, or excuse me, which cancer sites are caused by the 2A chemicals and maybe attach an abridged table to their report. Did I get that right, Dr. Berenji?

MEMBER BERENJI: Yes, that's correct.

CHAIR MARKOWITZ: Okay, thank you. On the issue of the Board resource request and the CMC and IH assessment, the respective working groups will make some progress on this, based on the discussion here. And then pass along

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whatever draft recommendations or observations they have.

The claims review, you know, I think those observations are mostly feedback into the issue of the CMC and the IH assessment as far as I can tell. And then the provider outreach, you know, I'll assemble some of the, a few of the observations we made and we can circulate them.

But that's about it. Did I, now, did I leave anything off the radar for the next month? Okay. I understand just in terms of continuity or flow, is there some estimate from the Department as to how soon a new board might be identified?

MS. RHOADS: Well, we're, we can't really say. We're hoping to not have any gaps between this board's term and the next term.

CHAIR MARKOWITZ: Okay.

MS. RHOADS: But that will depend on how fast it goes through the process.

CHAIR MARKOWITZ: Okay, so we're going to close the meeting soon. Are there any other

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issues that people would like to raise, any comments, any ideas about transition that people want to mention?

So fair enough. From the Department's point of view, any items that we haven't addressed that were put to us or that we sort of promised to deliver that you want to remind us about?

MS. POND: This is Rachel. No, I don't think so at this point. Mike?

MR. CHANCE: No, I don't think so. I think the -- and to Carrie's point, I think we've done everything we can do to move the, all the information along about selecting the new board. So I believe we're doing everything that we can on our end.

MS. POND: And I just will say, this is Rachel again, that I do appreciate this. I know that some of you opted out for the next term, so I appreciate all the work that you have contributed to the Board while you have been with us, and I just wanted to mention that. So thank

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you.

CHAIR MARKOWITZ: Actually, there is something that we haven't, that we need to keep on the radar, which is our request for the documentation in the SEM for the health physicists and the security guards from the gaseous diffusion plants. But that's not, it's not a topic we're going to address today. But I --

MS. POND: Well, Dr. Markowitz, we did send you a letter back, because I think you should have that, in which we talked a little bit about what we can provide and what we're willing, what we're going to be providing. Carrie, they've got that letter, right?

MS. RHOADS: They should, yes.

CHAIR MARKOWITZ: Yeah. No, I wasn't saying that, commenting on the status as much as just I wanted to make sure it stayed on the radar, on our radar.

MS. POND: Okay.

CHAIR MARKOWITZ: As something to deal

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with, that's all. So let me say that I want to thank Board members for all the work and really working together over the last couple of years on some interesting, I think, and sometimes difficult issues.

You know, it's, we have the opportunity to provide advice to the Department, but also to impact the program that's extremely meaningful to a lot of people across the country. And to come up with, you know, concrete advice that can really make an impact on the program.

We've tried to do that, and I've enjoyed working with everyone in doing that. We don't know who's going to be on the next board. In the event that, for those who don't get to work together, I'll regret not being able to continue to work together. But so it goes. I just wanted to thank you all for your work and making contributions.

I also want to thank the Department for the, really, the cooperation, for interaction, for really the back and forth on

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some of these things. For helping us, particularly the newer members of the Board, to understand the process, a complicated process you've worked on for the past 16 years or so.

And I think I want to especially thank Carrie Rhoads and Michael Chance as the liaisons to the Department. And of course Kevin Bird, who makes all this production happen. So thank you very much.

MR. CHANCE: Great, thank you, Dr. Markowitz. And I guess with that, we will close the record. Thank you very much, everyone, have a great day.

(Whereupon, the above-entitled matter went off the record at 4:31 p.m.)