UNITED STATES DEPARTMENT OF LABOR

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ADVISORY BOARD ON TOXIC SUBSTANCES AND WORKER HEALTH

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SUBCOMMITTEE ON EVIDENTIARY REQUIREMENTS FOR PART B LUNG CONDITIONS (AREA #3)

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MEETING

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WEDNESDAY,

DECEMBER 21, 2016

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The Subcommittee met telephonically at 2:30 p.m. Eastern Time, Dr. Carrie Redlich, Chair, presiding.

MEMBERS

SCIENTIFIC COMMUNITY:

JOHN M. DEMENT

MEDICAL COMMUNITY:

CARRIE A. REDLICH, Chair
LAURA WELCH

CLAIMANT COMMUNITY:

KIRK D. DOMINA

OTHER ADVISORY BOARD MEMBERS PRESENT

STEVEN MARKOWITZ

FAYE VLIEGER

DESIGNATED FEDERAL OFFICIAL:

CARRIE RHOADS

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

2:35 p.m.

MS. RHOADS: Hello, everybody. My name is Carrie Rhoads, and I would like to welcome you to today's teleconference meeting of the Department of Labor's Advisory Board on Toxic Substances and Worker Health, the Subcommittee on Part B Lung Conditions. I'm the Board's Designated Federal Officer, or DFO, for today's meeting.

First, we do appreciate the time our Board members have put in for preparing for the meeting and for the work they will do as a result.

I will introduce the Board members on this Subcommittee and I will do a quick roll call. I will ask each Board member to do a short introduction of themselves.

Dr. Carrie Redlich is the Chair of this Subcommittee.

Dr. Redlich, are you on the line?

CHAIR REDLICH: Yes, I am.

MS. RHOADS: Okay. And the members are Dr. John Dement.

MEMBER DEMENT: I'm here. Duke University Medical Center.

MS. RHOADS: Mr. Kirk Domina?

MEMBER DOMINA: Kirk Domina, Hanford Atomic Metal Trades Council in Richland, Washington.

MS. RHOADS: Dr. Laura Welch?

MEMBER WELCH: Yes, I'm here. Laurie Welch, and I'm an occupational physician, Buildings Trades Medical Training Program.

MS. RHOADS: Thank you.

Mr. James Turner is a member of the Subcommittee, but he cannot be on the call today.

And Dr. Steven Markowitz, who is also the Chair of the Board, is on the line.

MEMBER MARKOWITZ: Yes. Hi. Steve Markowitz, Occupational Medicine and Epidemiology from City University of New York.

MS. RHOADS: Great. Thanks.

We will meet today from 2:30 to 5:00

Eastern time, and we will have a short break sometime around 3:30, as the discussion allows.

In the room with me today is Melissa Schroeder from Sidem, our contractor, and Norman Spicer, an OWCP employee doing detail with our group.

Regarding the meeting today, copies of all meeting materials and any written public comments are or will be available on the Board website under the heading "Meetings" and the listing there for this Subcommittee meeting. The documents will also be up on the WebEx screen, so everyone can follow along with the discussion.

The Board website is dol.gov/owcp/energy/regs/compliance/advisoryboard.htm. If you haven't already visited the Board's website, I encourage you to do so. After clicking on today's meeting date, you can see a page dedicated entirely to today's meeting. The webpage contains publically-available material that were given to us in advance of the meeting. We will publish any materials that are provided

to the Subcommittee there. You should also find today's agenda as well as instructions for participating remotely. If you are participating remotely and you are having a problem, please email us at energyadvisoryboard@dol.gov.

If you are joining by WebEx, please note that the session is reviewing-only and will not be interactive. The phones will also be muted for non-Advisory Board members.

Please note that we do not have a scheduled public comment session today. The call-in information has been posted on the website, so the public may listen-in but not participate in the Subcommittee's discussion.

About meetings and transcripts, the Advisory Board voted at its April 2016 meeting that Subcommittee meetings should be open to the public. A transcript and minutes will be prepared from today's meeting.

During Board discussions today, since we are on a teleconference line, please speak clearly enough for the transcriber to understand.

When you begin speaking, especially at the start of the meeting, please state your name, so we can get an accurate record of the discussions.

Also, I would like to ask our transcriber to please let us know if you are having an issue with hearing or with the recording.

As DFO, I see that the minutes are prepared and, then, certified by the Chair. The minutes of today's meeting will be available on the Board website no later than 90 calendar days from today, per FACA regulations. But if they are ready soon, they will be published before the 90th day.

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

I would also like to remind the Advisory Board members that there are some materials that have been provided to you in your

capacity as special government employees and members of the Board which are not for public disclosure and cannot be shared or discussed publicly, including in this meeting. Please be aware of this as we continue with the meeting today. These materials can be discussed in a general way, which does not include using any personally-identifiable information, such as names, addresses, specific facilities, if a case is being discussed or documents named.

With that, I convene this meeting of the Advisory Board on Toxic Substances and Worker Health, the Subcommittee on Part B Lung Conditions, and I am turning it over to Dr. Redlich, who is the Chair.

CHAIR REDLICH: Thank you all for joining.

Everyone else I asked to say one word. So, I'm an occupational medicine and pulmonary physician and Director of the Yale Occupational Environmental Medical Program.

Thank you for joining.

I thought, as far as the agenda, that it would be best for us to start with reviewing it rather than the sarcoid presumption, just because I think we realize that there really already exists a presumption, but it is actually the implementation of that presumption that has created a lot of confusion, and I think a number of the cases reflect that.

I sat in on one of the other committees, and we have done a huge amount of work in terms of the number of cases that we have reviewed, which I think has been very helpful, because, organizationally, I tried to organize them to sort of pick out the ones that would be most useful to review. And I think some of them have some points that really address one of the key issues, which is the presumption with sarcoid and beryllium.

So, I know this is a little bit confusing because what I did was I went through all the cases and selected out the ones that people had indicated were worthwhile to review.

There may be some others, and there was some overlap because some cases ended up in more than one bucket.

But I think maybe it is easier for me to go in chronologic order. We did send another list that was numbered. We just didn't keep it in chronological order, but if you want to check with the actual number, you would have to look at the original list, if that is agreeable with everyone.

And I thought it wasn't so much to go into every detail of the case, but the point that we thought -- and I think there were a number or several that we had sort of concerns about the final decision or the process or some other aspect.

So, is everyone agreeable as far as the plan?

MEMBER WELCH: This is Laurie Welch.

I am. It is just that I haven't -- you know, you are going to have to, I think, guide the discussion because your notes on the

trial are a little bit cryptic. So, I will see what I can do as you go along.

CHAIR REDLICH: Well, I didn't want to send out everyone -- that is fine. I had based it on everyone's form that they had filled out. I was concerned about sending that around, if it had too much information.

MEMBER WELCH: Okay.

CHAIR REDLICH: So, that is why I didn't do that.

Okay. So, the first case that we have listed was actually, I think, Laurie, you had raised the question. The beryllium-sensitive patient diagnosis was, I think, straightforward. You had raised the question, I think an aside just as far as hearing loss, that the claim had not been accepted for. But I think we will pass on that.

I also just included this as a sort of marker, for I think that the beryllium sensitization cases were the ones that were most straightforward, in that it was generally in

terms of whether the test was positive or negative.

I know there has been an issue in terms of indeterminate, but I thought we should maybe leave that question for later. But the cases that we were given, we didn't have any other issues related to them.

MEMBER WELCH: Okay.

CHAIR REDLICH: That's in hindsight, when somebody dies.

Okay, and then, the next case on our list, Laurie and I both reviewed. This was a case that I think was an example. It was listed in the group of CBD cases, but it was an example where the sarcoid presumption was somewhat used. And I think it just illustrates some of the problem with that, where I think a more clear-cut presumption would be helpful.

And this is a little bit of a common scenario, where the sarcoid diagnosis is made several years in the past. In this case, it was made in 2010. This is someone where I think the

history of exposure to beryllium was not questioned. It just doesn't sound right. It was Los Alamos and that was assumed.

So, sarcoid was diagnosed in 2010, and the patient was treated with immunosuppressive therapy. It was also a pulmonary tissue that the granulomas was found.

And then, they applied for CBD, and it was initially denied because the BeLPT was negative. So, it was a situation where there are granulomas on one tissue and the BeLPT is negative for somebody who is on steroids.

So, eventually, three years later, in 2014, there was a Director's letter. So, it was finally accepted, but I think it was an example of the hoops that you have to go through and the time and effort. We are, hopefully, moving forward.

In this case, this person -- there are a number of others that are somewhat similar to this that ended up in the denied case, I think because there wasn't either knowledgeable

pulmonologist or someone to move it forward. So, this was, I guess, we could call it a successful example of the sarcoid presumption or you could also interpret it as a somewhat unsuccessful example because it took such effort, that if the presumption was more clear-cut back in 2012, the diagnosis could have -- the case could have just been resolved, and the time and effort spent over the following two years.

MEMBER WELCH: Though, Carrie -- this is Laurie again -- I think that the one thing about this case is that Director's letter because it lays out how --

CHAIR REDLICH: Yes, and by the Director's letter, you meant?

MEMBER WELCH: From Rachel Leiton, the timing has stuck to the case. You know, so this case was accepted as CBD for this reason. If I remember correctly, it kind of laid out how someone missed a diagnosis of sarcoidosis but a normal BeLPT, the case can be accepted under a presumption.

CHAIR REDLICH: Yes.

MEMBER WELCH: It is something to remember, I mean in some ways we could look at it again and say, is this -- because it is laid out very clearly this is a condition B policy. This is the best way to explain it. Because I think one of the things we found when we put together all the different language where in the Procedure Manual it refers to this presumption for sarcoid, it is confusing. So, I think this Director's letter may be a good layout in their own language.

CHAIR REDLICH: Okay.

MEMBER WELCH: Do you see what I mean? Just as a placeholder.

CHAIR REDLICH: Okay. Yes. I will review that because I did not see -- okay.

MEMBER WELCH: While you're talking, I'll see if I can find it.

CHAIR REDLICH: Okay. And then, the next one was another case that was accepted for CBD. I wanted to mention this one. It was

someone who had, again, in fact, in this case a positive BeLPT. So, that was not the question.

The two questions I had, just the CT scan was actually somewhat a typical pattern for CBD in ground glass and NSIP. But the person did have restriction and a low DLCO, what you would expect with interstitial lung disease.

And so, I think the key point to me was that it is going to have the positive BeLPT and they have evidence of interstitial lung disease, one, and functionally interstitial lung disease, that one doesn't necessarily have to worry that much about the exact -- you have met the criteria and the policy. Because one could have also said, well, it doesn't quite meet the description of this or the pathology, but I think that this was a correct decision.

And the other thing I thought was notable, not so much as an immediate issue that we address, was -- and there was another case, I think, like this -- it was a very perceptive pulmonary doctor who got the BeLPT findings after

they had obtained the exposure history. So, this person was not in a surveillance program at Brush Wellman's or now Materion. So, I think it also just raised the question of whether there was adequate surveillance of current employees, which may or may not be relevant to some other sites.

Because my understanding was that surveillance was something that was supposed to still be ongoing. So, if this pulmonary doctor had not obtained the history and personally sent off the BeLPT, then this person would not have been recognized.

Am I correct in terms of what ongoing surveillance is supposed to be happening? Is that clear-cut?

MEMBER WELCH: I don't know the answer.

CHAIR REDLICH: Steve, I don't know if you know.

MEMBER MARKOWITZ: I'm not sure. You know, not current worker, right, just former worker?

CHAIR REDLICH: For the current worker?

MEMBER MARKOWITZ: Current worker? Yes, I don't know what goes on exactly.

CHAIR REDLICH: Okay. But, then, a way to identify these would be more it is the appropriate surveillance. Because I think it also demonstrates that there are still ongoing cases that have just been recently recognized with -- you know, this is not super-historic, someone who started working in 1992, not in 1960.

Okay. The next case I only listed for -- someone was interested for historic goal or interest. It was a very well-described case of acute berylliosis in 1946, and CBD was diagnosed a year later in 1947. It wasn't actually, a claim, though, wasn't -- and then, the autopsy in 1989 that noted CBD -- a claim was not filed until by the survivors in 2014.

But there was, I think, by probably chance, the old records were still available. It was a path that was very well-documented. I

think it is probably somewhat unique, and it was also Dr. Nancy Sprintis in Boston.

I could imagine the scenario if the initial admission was more like a pneumonia, that the person could have actually gone on record, if they had not had that workup or been in that location.

Okay. And then, the next one was another one, was an example of sarcoid CBD. There may be confusion. In this case the person had exposure that was not at Savannah River, a BeLPT that was negative and was also on steroids. The person had a block in 1988 and a diagnosis of sarcoid. So, the sarcoid diagnosis was years before CBD was considered or recognized, and that was in 2013. Sorry. At that point, a pulmonologist wrote a strong letter that the person had a diagnosis of CBD.

Actually, my notes, okay. So, the question was -- let me just pull up my original notes on this. Because there was an initial acceptance -- let me just pull out this number.

Sorry.

I will say this: it raised with several, the issue of extra-pulmonary disease. Sorry. Okay.

Oh, so what was accepted on -- let me just clarify this. The claim, okay, I guess this one was -- I'm just checking what was denied. Excuse me. Okay. So, this ended up being -- again, it took a strong letter from the pulmonologist to explain the negative BeLPT and, then, it was accepted because there was, basically, pulmonary sarcoid.

The piece that actually was denied was a little bit separate, which was the asthma, the angio, the rhinitis folliculitis that had been a prior claim. But, actually, there was a strong letter and it did look work-related, but that one was denied based on the CMC report. So, it was another pulmonary condition, but the main one was accepted. And so, this was a situation of Be being accepted.

Okay. I think we should probably get

to -- the sarcoid ones in that other list had some of the problems where they were not accepted. The silicosis ILD claims, I don't think we necessarily need to go through all of them, but there were several -- and I think we raised this -- there was a consistent issue.

John, you, I think, got two of them. And if you wanted to comment on the issue of the exposure, the case number under the silicosis ILD, the second and the third ones?

MEMBER DEMENT: I did, Carrie, and I reviewed all of these. And one of the issues that I noted in sort of a consistency across some of these is uranium mining in association with silicosis.

There are sort of two issues that I saw. One is, based on the job classification, in some cases it went to the SEM. And the SEM really didn't list silicon as an exposure in uranium mining. It found aluminum exposure in two of the cases.

Based on that, the CMC opined that

aluminum, their condition wasn't related aluminum exposure, even though chest x-ray information showed in most cases both pleural and parenchymal changes that would be consistent with pneumoconiosis.

One of the other issues is -- and I found this really strange -- because they did not see specifically the term "silicosis," despite the diagnosis of pneumoconiosis, then the CMC opined that it was not related.

So, there are two issues for me, and I think SEM Committee needs to take this up. One is why -- silicosis associated with uranium mining is a known associated -- why would not a diagnosis of pneumoconiosis suffice with silicosis when in many cases we know that these individuals likely have mixed pneumoconiosis anyway? And I guess it goes through at least the first five of these cases.

CHAIR REDLICH: Yes, and I agree. I reviewed the two. In this case, and I would say as a general statement, for most of the most of

the ones that I reviewed I was actually impressed at the questionnaire that was provided and the description of the job categories, the location, the years of employment, additional comments about whether a respirator was used or a Dust Bee, and the like.

To me, I would say in almost all of the pulmonary cases I reviewed that that information was sufficient to come up with the correct conclusion; and that what the SEM did -- and it was most notable for these cases and, also, for a few of the others -- but was to actually, it is a little bit counterproductive because it was clear there was, you know, silica exposure; there was a lot of dust exposure. But, then, the SEM came up with the bizarre sort of exposure to aluminum.

MEMBER DEMENT: This is a specific case where the SEM really needs to be looked at very closely with regard to uranium mining. And most jobs that were uranium mines would have exposure to silica. All you need to do is look

at the published literature in this area and it becomes quite clear the silica exposure is pretty much across job categories in uranium mines.

CHAIR REDLICH: Yes, and I would guess this is maybe for our Committee, but for the SEM, but I would just weigh-in whether it is even needed to go that step; that if you knew someone worked as "X" job category, and the like, for "X" number of years as a miner or some of these other jobs, would that be sufficient information, given the clinical picture and the question that you are being asked? And I felt that all the cases I reviewed I didn't think there was a need for SEM.

MEMBER WELCH: But, Carrie, one of the problems is that the cases aren't being reviewed by knowledgeable physicians. They are being reviewed by the claims examiner. So, if the SEM included silica and exposure, it would make the whole process much easier.

It is obvious to you and it was obvious to me that there are two things to do. One of them is to have uranium mining be

associated, so they are in the SEM, and the other is to stop relying so heavily on the SEM. But I think in this particular case it is easy to add it to the SEM and that that would kind of assure the process for these cases. And you can make that recommendation.

MEMBER DEMENT: Another issue with these cases -- and it wasn't so much with the SEM -- is that when you have a chest x-ray with a perfusion change of 1/1 or even higher, but the specific term silicosis is not anywhere in the medical record, I can't see why a uranium miner with a 1/1 chest film and a diagnosis of silicosis, it would not suffice to consider that silicosis.

MEMBER WELCH: Absolutely. No, absolutely. I mean, there are a couple of these that I wasn't down as reviewing them, but I did look at them. This is one of these ones that makes me think, so where did they find these CMCs?

CHAIR REDLICH: Yes, and I was going

to bring this up later, but --

MEMBER WELCH: One other question I had, though, that relates to that, John, is -- there are two things. One of them is you could get accepted for silicosis or pneumoconiosis. You would be accepted for either one, I think.

So, for someone to kind of suffer with their silicosis, you know, the B reads clearly showed pneumoconiosis and the guy had duct exposure. So, it doesn't seem important to distinguish, although in one particular case they turned him down altogether, even though, as he pointed out, his ILS-1 showed markings and he had restrictive lung disease.

CHAIR REDLICH: Yes, I think, at least for me, part of the confusion was not necessarily solely the issue of some of these had a prior RECA claim that was accepted and others did not. I was not totally clear about that component.

MEMBER WELCH: You mean, if they had a RECA claim, how that affected their review or?

CHAIR REDLICH: Yes.

MEMBER WELCH: Because, I mean, what they could get under this was supplemental to what they would get under RECA.

CHAIR REDLICH: That's right. And so, I think that, because some of them had a RECA claim that was already accepted, so it was almost a secondary question --

MEMBER WELCH: That's right.

CHAIR REDLICH: -- is it the cause of death?

MEMBER MARKOWITZ: Hello. This is Steven. I just have a question.

Under Part B, silicosis is covered for Amchitka, I think, and Nevada Test Site as specified locations. So, under RECA, is silicosis covered under RECA?

MEMBER WELCH: I don't know. I think we looked at that when we looked at the cases. I will see what I can find right now.

MEMBER DEMENT: I think one of my notes states for the one, two, three, four, the fifth one down, it says it was accepted silicosis

under RECA.

I think the other issue which I don't think we necessarily have control over is there's a specific timeframe for exposure, that it has to be before a certain period of time in terms of years and, then, that there is also a minimum number of months in a mine. And I think that was an issue for the third case down. It was 9.88 months, and there is a very specific way that the number of months is defined.

I think, John, you know more about that.

MEMBER DEMENT: That particular case, you know, that was one that it is likely a marginal case at best, the only exposure. But it is perhaps a believable one if exposures are high enough.

So, that was, to me, one of the cases where it wasn't accepted under RECA, and I think the RECA actually is based on working a number of months, so a calculated radiation exposure. See, this person did not meet that threshold, but,

nonetheless, they had a subsequent B read many years later that was consistent with at least pneumoconiosis. I think it is a call based on short exposure. It was denied. But the purpose for denial, when I looked through it, was this assessment of aluminum exposure, and not really a consideration in great detail of silica and silicosis.

CHAIR REDLICH: That's right, but if a case is denied under RECA, can it be accepted here?

MEMBER WELCH: Yes, absolutely.

MEMBER DEMENT: Yes. I think it has to come mostly under the Part E, am I not correct?

MEMBER WELCH: Yes.

CHAIR REDLICH: Right. Okay. So, my understanding that it could be considered under E, but not B, if it has been denied.

MEMBER WELCH: No, I don't think that's true. It depends on where they worked. I mean, if they are a uranium miner and meet the

definition, then they should be covered. You know, it is sort of if they qualified for RECA and weren't accepted, then it suggests a problem with the medical documentation and it might not be accepted by the Department of Labor. But they might not qualify in terms of some of the employment characteristics. I think they're not exactly the same, but I can't find it quickly enough. So, I don't think we should speculate about it. We need to know the answer.

MEMBER MARKOWITZ: Right, but, at any rate -- this is Steven -- but, in any event, the essential limitation in some of these cases was that silica wasn't properly identified in the exposure assessment as being relevant.

CHAIR REDLICH: That's correct.

MEMBER WELCH: Neither in the SEM or by the CMC.

MEMBER DEMENT: Right.

MEMBER WELCH: And these were cases where you could see that process where the claims examiner creates a statement of accepted facts

and CMC relies on that, even though we would like to think that a physician with occupational training or pulmonary training who was hearing these cases would think, well, a uranium miner should have also had silica exposure, even if it wasn't in the statement of accepted facts. But it was, apparently, not part of their practice. But when they set the facts in and said it was aluminum, he said, "Well, no, I don't think so."

MEMBER DEMENT: Yes, and I think Carrie has also hit on an issue. In many of these instances, when you look at the completed occupational history questionnaire, most people would look at the job and say, this job was a mucker in a uranium mine for quite a number of years; therefore, it is silica exposure.

CHAIR REDLICH: Yes. This is Carrie.

I sort of feel that there is one particular CMC that has come up with a number of these bad conclusions. I mean, if a CMC does not know that working as a miner involves silica exposure, then they are not qualified to be a

CMC.

MEMBER WELCH: Well, then, why don't you send a note over to the CMC Committee?

(Laughter.)

Really, they've got a big problem because there is no quality review of the opinions of CMC. The quality review, the review of the contractor has to do with timeliness and if the claim, then, they feel has answered their question. But whether they got the answer right is not part of their review.

CHAIR REDLICH: I understand. Actually, that is sort of a secondary issue I was going to bring up later because there is one CMC that has reviewed, I think, about half, you know, a large number of these cases. And a number of his reviews I think are quite problematic. And no matter how many times you rewrite a manual, if the person who is interpreting and using the manual doesn't come up with the right conclusion, rewriting the manual five more times won't necessarily --

MEMBER WELCH: Right.

CHAIR REDLICH: -- solve the problem.

MEMBER WELCH: Right. Yes, but I just don't think we should get into that. We should send it to their Committee.

CHAIR REDLICH: Exactly. I just want them to be aware of it because I don't think that they've necessarily reviewed as many cases, and if they have come up with the same person's name, and I pulled out a couple of examples of them, that you realize it's a problem.

MEMBER DEMENT: This is Steven.

But isn't it a quicker or more efficient solution that, for any number of job titles that relate to this uranium mine work, that if there is a certain number of years in which they work, then it seems that silica exposure is so common, that there would be the presumption that job titles with a certain number of years and the diagnosis of something related to silicosis, that's simply --

CHAIR REDLICH: Right.

MEMBER DEMENT: -- the presumption they will hold, and we don't have to go through the whole CMC process?

CHAIR REDLICH: I mean, that would be my hope.

MEMBER WELCH: Yes, we can do that.

CHAIR REDLICH: That's exactly right. I feel that, if there was a presumption of "X" number of years, exactly, then really in any pneumoconiosis, whether it was, you know, pulmonary fibrosis, silicosis, would be a presumption, yes.

MEMBER DEMENT: I agree. This is John. I think this is one where a presumption would cut out a lot of this process, not to exclude the possibility, for example, of 9.8 months' exposure as possible, but that would be an unlikely person to be included in a presumption.

MEMBER WELCH: So, adding in the SEM and getting a good review would be important, but I think that having a presumption might help this

in a lot of other cases.

MEMBER DEMENT: Yes, I think the tracking just by a good presumption and correcting the SEM appropriately and educating the physicians on the uranium mining would help.

CHAIR REDLICH: Okay. And, yes, a presumption would help with that diagnosis.

The last two cases on the list are "other issue," which was that the CMC was asked not does this person have silicosis or pneumoconiosis, but did that disease contribute to their death. And the person, basically, sort of said that the prior -- acknowledged that there was, you know, a prior accepted claim for pneumoconiosis and silicosis, then said pulmonary function tests were not available.

And it also acknowledged that pulmonary fibrosis increases the risk of ischemic heart disease and various other diseases that this person ended up dying of. But, then, basically, said no pulmonary function tests were available. And so, then, that person's pulmonary

disease did not contribute to their death.

To me, this was going out of your way to sort of deny a claim. To question, you know, I mean, if it is an accepted silicosis/pneumoconiosis and there were a uranium worker and machine as well who, then, "dies," it is a condition that is felt to be associated with that, but no one has given you pulmonary function tests. But that is a poor reason to deny the claim.

So, I'm mentioning it not so much -- and there was another one similar to that where they, basically, questioned the prior RECA B determination that the person had pneumoconiosis. So, if you didn't have that, then you couldn't -- I think in this case where the lesion lies, to me, is not necessarily something we could -- and it is suggested the person doing, you know, the CMC.

MEMBER WELCH: Right. So, if you want to send those --

CHAIR REDLICH: Pass that on to the

CMC. My thought was that some of these cases we could pass on to the CMC Committee.

MEMBER WELCH: Yes, sure.

MEMBER DEMENT: I looked at these two as well, Carrie. The last one on the list was a question of whether or not pneumoconiosis contributed to the cause of death. I think this person already had acceptance under Part B of pneumoconiosis.

When I look at this case, the person actually had bladder cancer and pneumonia, and the B read that was taken in this case was pretty much at the time that the person was having complications from the bladder cancer and pneumonia. And so, the CMC, to the defense of the CMC, looked at this and said, you know, all along the way there have been different chest films taken, not likely read by a B reader, but none of them actually mention pneumoconiosis. And then, the cause of death really didn't, when you look at the death certificate, it didn't attribute that to pneumoconiosis. So, that, to

me, was a problematic case.

MEMBER WELCH: And difficult to discern.

MEMBER DEMENT: I'm sorry?

MEMBER WELCH: I mean, you think the CMC has made a reasonable decision?

MEMBER DEMENT: You know, I don't think it is unreasonable. I think this individual likely -- you know, the chance the B reading was taken within a few weeks, actually, of the actual demise. And so, there are many, many complications belonging there, including the possibility of metastatic issues.

CHAIR REDLICH: I thought it had been earlier. I thought it had been quite a bit earlier. I may be wrong, but I'll check that because I don't want to mix a line and I might be -- but I thought that there was a tag lag and that it had been an x-ray before the other medical issues reared their head.

MEMBER WELCH: I think the question, too, is whether -- you know, you are looking at

death certificate for cause of death, and if the cause of death was cardiopulmonary, then, how do you say that -- you know, it can be difficult to determine that something is a contributing cause to a death.

CHAIR REDLICH: Yes, and I think the other point, though, is also, if there is a prior accepted case that has been reviewed and accepted as just a process system, and we are trying to sort of, hopefully, streamline the process, to change the prior conclusion I think probably just is not an optimal approach as the reason. I think one could independently decide what you thought was contributing or not, but to change a prior final decision that had been made years previously as a process I find questionable.

MEMBER MARKOWITZ: Carrie, this is Steven.

It kind gives a whole new meaning to the statement of accepted facts.

MEMBER WELCH: Yes. Or maybe it is --

CHAIR REDLICH: I mean, I think that

could easily be solved. And again, I think this is more of a CMC -- one could simply say, you know, there was a prior decision that has been finalized and accepted that this person has "X," you know, that qualifies.

I think the thing is you don't need to readdress that question. Assuming that that is the case, we would like you to answer this additional question.

MEMBER WELCH: I guess I'm feeling a little lost because I feel like, if we go through all the cases -- I don't know if I'm finding this helpful.

CHAIR REDLICH: Okay. Anyway, you know what? Let's finish with this and go on to the -- I mean, to me, I think the CBD cases, we will get to the ones that I think were denied, were a problem in the other group because they were in the sarcoid. To me, the main take-home point was that there were cases that were denied because of the SEM problem that we already discussed that could be fixed with, just to

summarize, either a presumption in terms of silicosis and pneumoconiosis, and Laura had suggested the other way it could be fixed is the SEM split out silica.

MEMBER WELCH: Right. It would resolve --

CHAIR REDLICH: Yes, that is correct.

And then, the other issue as a general issue was simply, I would say not the qualifications, but the decision-making by certain CMCs and whether there needs to be some process to sort of review their decision-making without the details of the given one. And I think that was the key take-home messages of these.

And I guess, then, the final one, which sort of relates to the sarcoid, was sometimes the delay in finally making the CBD diagnosis, yes; and the beryllium sensitization was generally reasonable and straightforward.

MEMBER WELCH: Uh-hum.

CHAIR REDLICH: So, I think that is

sort of the bottom line for those. And so, if anyone else has any comments -- and, Kirk, I don't know if you have any before we move on to the sarcoid cases, but on any of the other, silicosis, ILD, or CBD, the ones that were in those groups.

MEMBER DOMINA: Here we are just talking about Case No. 12, is that correct, on the pneumoconiosis?

CHAIR REDLICH: Yes.

MEMBER DOMINA: Well, that one is a little confusing for me because for the simple fact, as I am looking at my disk right now, and there seems to be some confusion on the death certificate on my desk is for a female, not for a male. They are obviously related, but there is some confusion when I go back and look at this right now, as we are speaking. There is a problem.

So, unless you guys got another version, but, to me, when the case number is the same and the death certificate is for a female

and the case is talking about a male, there is an issue with that for me.

CHAIR REDLICH: Okay. Let me just quickly -- you are on top of things here. Hold on. I'm just pulling up the death certificate.

MEMBER DOMINA: Because it's very clear on the death certificate that the cause of death is not what you guys were just talking about.

MEMBER DEMENT: There's another file in that case. It is the SOF plus the medical records, and I think there is a different death certificate in there.

MEMBER DOMINA: Okay.

CHAIR REDLICH: Yes.

MEMBER DEMENT: I think they are different. I saw that, too, but --

MEMBER DOMINA: Okay. I just wanted to make sure because of some other things that I have seen on the third disk. I mean, I have to bring up questions on the next meeting in a week and a half. So, I'm just making sure because I'm

trying to follow along because some of these I didn't review because of computer issues and workload.

CHAIR REDLICH: It appears that that death certificate is a different person, but I think there was, as John said, another death certificate.

MEMBER DOMINA: Okay. All right. But the case number shouldn't be the same.

MEMBER DEMENT: No.

CHAIR REDLICH: There were a few cases where there were records of a different person in a file. I think it happened relatively infrequently when you consider how much scanning and the like --

MEMBER DOMINA: Right.

CHAIR REDLICH: I have raised the point that one has to carefully make sure that all the documents relate to the proper person.

MEMBER DOMINA: Right, especially when people have common names, or whatever. I mean, I see that, too, but when it is the individual

being involved, they are not so sensitive to that --

CHAIR REDLICH: Yes.

MEMBER DOMINA: -- I mean as far as wanting an excuse, or whatever the case might be.

CHAIR REDLICH: Okay.

MEMBER DOMINA: But I just wanted to make sure because I was having a little confusion here.

CHAIR REDLICH: Yes. Well, I did notice one or two, but, generally, I thought the right names were in the right places.

MEMBER DOMINA: Right.

CHAIR REDLICH: And there was also some confusion, I think as people know, with some numbers.

MEMBER DOMINA: Okay.

CHAIR REDLICH: Okay, but thank you. You've got good eyes there.

So, I think for me what was most helpful was some of the sarcoid cases in terms of addressing some of the issues as far as a

presumption. And I think the ones that were relevant, some of them, you know, it is a basic question, which if you had a history of exposure and you have granulomas, should that be presumed and not have to have an BeLPT.

And then, the other was a couple raised this issue of extrapulmonary versus extrapulmonary and pulmonary sarcoid. And also, you could have a scenario where it likely involved the one, but the actual gran biopsy was taken at another site because that may have been more accessible. And so, I think there is confusion around some of these issues.

So, the first case on the list, I think, John, you looked at this. Did you want to mention --

MEMBER DEMENT: I think I looked at this. This was an accepted case. So, I don't think I had a particular problem with myself the way the determination was made.

CHAIR REDLICH: Yes. You know what? That is correct. I added it on for two reasons.

One, it basically used the sarcoid presumption. The biopsy of the granuloma was on a -- there were four indeterminate, as you had noted, BeLPTs.

MEMBER DEMENT: Yes.

CHAIR REDLICH: The other thing is that this question, I raised it because there was some confusing wording as far as the lymph nodes versus lung tissue. So, this was an accepted claim, that they should have normal lung function. And it appeared that it was hilar adenopathy, basically, and an indeterminate BeLPT.

And so, in this case it was accepted. There has also been noted that you have to have lung involvement, like the lung tissue versus the lymph node in the chest. I personally think --

MEMBER DEMENT: I think one of the other ones, I think it is the last one on the list that I looked at, and that had to do with primarily sarcoid involving the spine. And the question for me -- and it is not a question that

I can answer; I'm not a physician -- but to what degree the sarcoid and the spine preclude also involvement of the lung? Or are they completely separate? You know, that is something we need to consider as sarcoid is non-pulmonary.

CHAIR REDLICH: Yes, so I think that is a question. Just getting to the one, I thought that it would be helpful if we had agreement -- and this may seem like a petty point, but it was in one of the sideline documents. To me, the actual wording in the manual talks if it is a lung biopsy or a lung, and I would consider it chest as part of the lung, so we are not getting into whether it was a hilar node that was biopsied or actual lung tissue, because I would say that that is part of the chest and the lungs. But I wanted to see if other people agreed with that or had a problem with that.

Because the reason I know this about testing, this was one of the areas I had highlighted in yellow in the actual, I guess it

is called manual or instructions. And they mentioned the mediastinal lymph node biopsy is not the equivalent of a lung biopsy and does not substitute for such in the assessment of a post-1993 thing. The evidence has to be lung pathology. A mediastinal lymph node is not a CBD in the same way as a lung biopsy.

MEMBER MARKOWITZ: Carrie, this is Steven.

So, you think that's wrong, right?

CHAIR REDLICH: I personally feel that that's wrong. But we should get clarity among ourselves about that question.

MEMBER MARKOWITZ: This is Steven.

But if the thinking is that it is wrong, I think we should just tell them.

CHAIR REDLICH: Well, I just want to see if Laura and everyone else agrees with that. That is why I am raising it.

MEMBER WELCH: Yes, a biopsy, a mediastinal, well, I think a lymph node biopsy that shows granulomas is indicative of sarcoid.

So, it should be accepted as done, not because of them.

MEMBER MARKOWITZ: This is Steven.

That would pass the standard. That would be the standard of proof in the practicing pulmonary community, right?

CHAIR REDLICH: Yes.

MEMBER MARKOWITZ: Yes, okay.

CHAIR REDLICH: Okay. I just assumed because it was made such a point of under No. 7 in the manual, I just wanted us to have a discussion about that. So, what else? Because they are distinguishing whether it is the lymph node versus the lung. In this case, it was the lymph node, and I just mention that.

Okay. So, that is something that I think we could, then, address in terms of needing some clarity as far as the workup and interpretation.

MEMBER MARKOWITZ: Right. This is Steven.

I'm just thinking. Actually, I'm

trying to recall the language of the statute, whether that is a problem. I will look it up as we continue the call.

CHAIR REDLICH: Yes. You know, I was thinking this question, like the language of the statute and, then, sort of how it has been interpreted. Because there are a number of things that have sort of busted the language of the statute. So, I thought we should give what we think we would recommend based on our expertise. And then, if it turns out that it is an issue with the language of the statute, they would let us know.

MEMBER MARKOWITZ: Well, yes. This is Steven.

Also, if the concern is the statute, obviously, that is a bigger hurdle, but, you know, there may be a number of technical issues like this that could be --

CHAIR REDLICH: But the thing is there are already things. Let's say that you have to a positive BeLPT. It is in the statute, but the

document had --

MEMBER MARKOWITZ: Right.

CHAIR REDLICH: -- already has given reasons not to have it.

MEMBER MARKOWITZ: Right. So, yes, we will give our best scientific opinion and, then, they figure out how to do it.

CHAIR REDLICH: That's right. Okay. Because all I'm saying is that there is, basically, already given an interpretation of that statute that is somewhat, you know, a little bit different than the original wording.

MEMBER MARKOWITZ: Right.

CHAIR REDLICH: Okay. So, John, going back, just so we clarify what was a part of the diaphragm and, then, part of the chest, this is helpful in terms of the adenopathy in the lung, as far as CBD.

Then, the other question that you were raising was the issue of extrapulmonary sarcoidosis and pulmonary sarcoidosis. And a couple of cases raised that question. Just in

terms of my reading the literature and also asking the opinion of several of our sarcoid ILD specialists here about that question, I think the feeling is that at least 90 percent of sarcoid involves the lung. So, the great majority of cases do.

Sometimes the pulmonary manifestation may occur at a later point in time or the extrapulmonary may be the most prominent characteristic, so that is what is being focused on. And also, there is nasal involvement or skin involvement. That may be easier to actually biopsy rather than going for something in the lungs. So, the fact that one was diagnosed, let's say, by a skin biopsy would not mean that it wasn't pulmonary. It would mean that the skin was the site of where they biopsied the granulomas. I suspect that is a small percentage, less than 10 percent, that may be solely extrapulmonary.

And I think it is an issue because there are claims that have been denied because of

the feeling that they didn't have pulmonary sarcoidosis. And so, it raises the question, to have CBD, does sarcoid have to involve your lungs? And I think most of us feel that CBD involves pulmonary condition and that it should involve the lungs.

MEMBER WELCH: Carrie, the thing is, isn't it reasonable to presume that, if you have a biopsy of the spinal cord or the skin that shows granulomas and somebody has a positive LPT, that they have, let's say, the diagnosis of sarcoidosis based on that biopsy outside the bone, that you can presume no involvement?

CHAIR REDLICH: Yes.

MEMBER WELCH: You know, you don't have to have a --

CHAIR REDLICH: Yes, I think if there is a positive BeLPT, wherever the biopsy is, then it is chronic beryllium disease. I think the more common scenario is, and where the questions have come up is, where there is predominantly extrapulmonary disease and the BeLPT is negative.

The third case from the bottom is one that falls into that category. And Laurie and I have reviewed that. So, I think this just shows what the problem is. And so, this was someone who was diagnosed with skin sarcoid in 2012. They had worked starting in 1990 up until 2013 at Savannah River Site at various locations.

And basically, the BeLPT was negative by the nodes. There was a pulmonary diagnosis for asthma. And so, this claim was denied.

Laura, you thought that was reasonable because it appeared to be skin sarcoid. I looked at the chest CT scan report that talked about some slightly enlarged lymph nodes in the chest. I think these are the types of cases that bring up, understandably, confusion. And the pulmonary function testing was okay.

So, my take on this would be that, yes, it is primarily skin sarcoid, and we have a negative, we have a clear beryllium exposure history and we have a negative BeLPT.

MEMBER WELCH: We don't have any

evidence of any lung disease.

CHAIR REDLICH: Yes. And so, then, what qualifies as -- I think where the gray zone or the areas that get confusing, and where I think it is worth discussing, is the presumption -- you know, one option would be, and I'm not advocating it, but the simplest option would simply be to say sarcoid-confirmed beryllium exposure diagnosis is CBD. That would be the simplest, most straightforward. It could conceivably include some people who had only, you know, that small number of people with sarcoid, that they had skin disease, but didn't have actual pulmonary disease.

The other is try and define what we mean by pulmonary involvement or pulmonary disease.

MEMBER WELCH: I think whatever you want to propose is fine. It is just there probably won't be another case like this.

CHAIR REDLICH: There are a couple. Also, actually, Sue sent me a couple. So, I do

think that the concept -- because I think it is not that uncommon for the actual biopsy to be taken from another site like the skin or the nose.

MEMBER WELCH: Well, I think what I would suggest is that it is the pulmonary doc, if it is the doctor's diagnosis of lung involvement in some way or another, they should accept it. They shouldn't require a biopsy of the lungs. But they do need something to say that there is some involvement. But, then, they still have to deal with CMC anyway. It is better that it comes in with a note from the doctor. I don't think we should say, if someone has a skin biopsy, you automatically get accepted for a CBD claim. I was going to use something else. That would be my recommendation.

CHAIR REDLICH: Okay. Okay. And so, the case that was shared with me and was actually presented at last week at sort of a joint conference was someone who had nasal sarcoid that was biopsied, a negative BeLPT. Their BeLPT has

been done on steroids. And the CT scan showed, you know, hilar changes and some non-specific stuff. The person's pulmonary function tests were, quote, "normal". You know, a normal PFT, you don't really know what the person was prior, you know, whether it is truly normal for that person.

But his feeling was that this was CBD and that the person did have clear beryllium exposure, the definite diagnosis of sarcoid, and probable lung involvement, even though the PFTs fell in the normal range. The case was denied because the person didn't have -- the fallout was that he didn't have pulmonary sarcoid. And it does seem that whoever is reviewing the cases is under the impression that the actual biopsy has to be taken from the lung.

MEMBER MARKOWITZ: Well, this is Steven.

Yes, I'm looking at the Act, the statute, and it says that actually. It says "a lung biopsy showing granulomas".

But I think the general point you are making is that finding of the typical granulomas at other sites should be considered equivalent finding the same in the lung, and I think that that should be written up with a brief rationale and unique, and submitted to them.

CHAIR REDLICH: Okay. I mean, I'm okay with that. The issue that Laura raised I am slightly ambivalent on in terms of, if we are thinking about administering a claims program and where there is a clear -- you know, there is a diagnosis of sarcoid quite clear, but the pulmonary component is less clear. A part of me feels that, just from the simplicity of running as a compensation system, if you just sort of blanketly accepted all those, you probably would have a few skin sarcoid cases that were not beryllium disease versus all of the effort to go through to educate people through all of the CT scans, PFTs, and sort of argue about whether there is actual pulmonary involvement.

So, I could actually argue both sides,

that the time and cost involved in picking out the few people who didn't have pulmonary involvement just make it sort of a more general presumption versus requesting documentation of the pulmonary involvement.

MEMBER MARKOWITZ: Well, yes. This is Steven.

But the problem, I might agree with you, but the problem is being constrained by a statute and what the statute says. So, the issue of efficiency and cost-effectiveness, you know, it is important, but there is this other consideration. But I don't want to defend it.

CHAIR REDLICH: I think the fact is we already have a problem with the issue of the biopsy in the nose versus the lung, because how do you interpret lung? So, that piece. You're right, but I think what we could do is make clear, because there is a misconception, and we need to resolve that the lung actually has to be what is biopsied versus --

MEMBER MARKOWITZ: I think we should

move on.

CHAIR REDLICH: I think this is where a lot of these cases run into issues because of the sarcoid is diagnosed first. But, okay, and I think that is about three or four of them on this list.

Okay. The other cases, I would say that there were several -- so, I would say the number one, two, three, four, number five from the bottom was an example of another issue that came up on a couple. And Kirk has also reviewed this one.

But it was basically where a diagnosis of sarcoid had been made in the past, in 2008, with a lung biopsy, and no BeLPT was done. The person had worked at Savannah River Site from 1981 to 2005 as a clerical worker in multiple different buildings.

The conclusion was that there was no beryllium exposure. And so, that seemed that there likely was beryllium exposure.

And I don't know if, Kirk, you wanted

to comment on that one?

MEMBER DOMINA: Yes, I am trying to pull it up here real quick, so I jar my memory.

CHAIR REDLICH: So, I think there were several that fell into the category and where it seemed pretty obvious that there should be beryllium exposure. And these did not involve SEM. One of them involved the same CMC.

So, I think that part, if we could help clarify the beryllium exposure piece, that would be helpful. So, maybe those cases should also go to the Exposure Subcommittee.

MEMBER WELCH: Well, I don't know. I don't think so. I mean, because beryllium exposure is separate from the SEM discussions.

Do you know when that case was reviewed?

CHAIR REDLICH: Yes, it was just in like, it was recent, 2014. What I could do is the ones that there was a question of no beryllium exposure should be, you know, where it seems like they are probably clearly was, to just

be aware that that fell through the cracks; that's all.

MEMBER WELCH: Yes, I don't know why the CMC has concluded there is no beryllium exposure at Savannah River. I don't know why.

CHAIR REDLICH: Yes.

MEMBER WELCH: John will remember it better than me, but, you know, there wasn't a lot of beryllium used at Savannah River. They didn't have an issue, et cetera, et cetera. But, then, we have had several people who were sensitized. Then, the staff within Savannah River did identify some specific operations that used beryllium for short periods of time. But I don't think that it is reasonable to assume that the people couldn't have been sensitized.

CHAIR REDLICH: Yes, because, actually, there were several cases in this group that were Savannah River with a positive BeLPT.

MEMBER WELCH: Actually, when I look at it, most of these people are Savannah River. Almost every one of them who has got a job

title --

CHAIR REDLICH: That's right.

MEMBER WELCH: -- for Savannah River on the first page.

CHAIR REDLICH: Yes. Exactly. Okay. And so, I guess I think the ones that were denied because of the beryllium piece, I mean, that has to be, I think, an issue.

And then, as far as the presumption, I think, how do people feel about simply the option of -- at least what we recommend and sort of the pulmonary involvement, or is simply a diagnosis of sarcoid sufficient?

All right. And I think, then, we would need to just define what we mean by pulmonary involvement.

MEMBER WELCH: Well, to get a diagnosis of CBD under the legislation, you have to have lung involvement. And so, you have to have --

CHAIR REDLICH: And is your interpretation of lung involvement, okay, is your

interpretation --

MEMBER WELCH: What I'm saying, not where the biopsy comes from. To be accepted for CBD, you have to have lung disease. That is written right into the legislation; you have to have lung disease.

And so, I don't think if you had a skin biopsy that is sarcoid, I think it would be a big stretch to get a presumption that turns that into lung disease. I think it is possible to say, if they have other lung disease and sarcoid diagnoses from another location, you can kind of make that case. But I think what you were suggesting was that you could, if they had sarcoid, wherever the biopsy was taken from, and there is acceptance of their status, they should be accepted CBD -- I think that can't happen, given the legislation.

I don't think we should recommend that, but I think you could recommend that a case of -- that you could accept a diagnosis of sarcoidosis is involved with the lung, even if

the biopsy was from some other part of the body if there is evidence of lung disease consistent with charcoal of the lung.

CHAIR REDLICH: Okay, I'm fine with that, but just the issue of -- just because of this current being about the adenopathy, I think a CT scan that showed hilar adenopathy that was consistent with sarcoid.

MEMBER WELCH: Yes, that's fine. And I think the only way it is really going to work is if there is a medical opinion that states that. I mean, we can try to write it up as some kind of presumption if it is worth doing. I don't think that the way sarcoid and LPT has been interpreted -- you know, generally, they want somebody outside that says this is CBD.

CHAIR REDLICH: I reason is that I think the current worry of lung involvement and how they describe that is having involvement of the lung parenchyma.

MEMBER WELCH: Not really.

CHAIR REDLICH: For post-1993, of all

of the things that they describe as possible patterns, they are interstitial things.

MEMBER WELCH: I think that we should suggest that they interpret in the legislation that, if there is a lung biopsy showing granulomas, that lymph nodes that drain the lung should be considered part of the lung.

CHAIR REDLICH: Yes, okay.

MEMBER WELCH: I think if you say it that way -- don't say, you know, lymph nodes that are by the chest -- just lymph nodes that drain the lungs, it is going to be, don't you think? I mean, that would be easier.

I got a case accepted, a case I opined on, you know, to tell them that maybe a spinal biopsy was the equivalent of a lung biopsy, and they accepted in the case.

CHAIR REDLICH: Yes.

MEMBER WELCH: It was somebody who had a possible --

CHAIR REDLICH: Okay. And I agree with that. So, we're okay with the fact that

adenopathy in the lung, because it is drains, it is involved in the chest, is evidence of lung involvement?

MEMBER WELCH: Yes.

CHAIR REDLICH: That would solve this problem.

MEMBER WELCH: Because it would be easier for them to be able to implement that if we tried to say that those lymph nodes are really part and parcel of the pathology in the lung.

CHAIR REDLICH: Okay. So, I think that having that sort of one caveat about pulmonary and, also, just clarify that the actual diagnosis does not have to be based on lung tissue if there is other evidence of lung involvement which could be A, B, and C.

MEMBER MARKOWITZ: Well, you know, the post-'93 criteria have these five variables that you look at. You need three out of the five. One is lung pathology and the others rest on other things which are reasonable.

CHAIR REDLICH: Yes, but none of those

other things are, let's say, hilar adenopathy on a chest x-ray.

MEMBER MARKOWITZ: I think one of them is CT scan evidence. I'm trying to find it, but I think --

CHAIR REDLICH: It is, but it is other things like diffuse nodules, tracheobronchitis. I am mentioning this because these are some cases people brought to my attention that have been denied because it might be the CT scan -- and this was Dr. Sue's (sic) case -- said hilar adenopathy, but not pulmonary fibrosis.

MEMBER MARKOWITZ: Well, you know -- this is Steven -- you know, DOL specifically asked us for assistance in proper interpretation of vague terms like "consistent with" and, yes, "characteristic of," including some of those five variables they looked at. So, that would be very useful for us to focus on that.

CHAIR REDLICH: I'm good with that.

MEMBER MARKOWITZ: Yes.

CHAIR REDLICH: I think this would be

simply solved by adding -- and that is actually the most common thing that you see with sarcoid. So, that would just help simplify these, and it would mean that there was pulmonary involvement. So, I think that would probably solve the great majority of some of these what appear to be more problematic cases.

MEMBER DEMENT: Yes, it will clarify three of the ones that I flagged in my review.

CHAIR REDLICH: Okay. And everyone else would be okay? We could clarify that the biopsy could be from another site; there has to be pulmonary involvement, which could be defined by -- and the main additional criteria that would be needed would be something like hilar adenopathy.

Okay, great. And I think those and, then, just the other issue that I think comes up with some of these cases that could be addressed in different ways is the scenario of the negative BeLPT.

So, in thinking about this, if it is

in a case that there is granulomas, one of the ones we just discussed, the sarcoid diagnosis, we have sort of dealt with that because, if there was a presumption, you wouldn't need to have the positive BeLPT.

The other scenarios I think right now absolutely you have to, post-1993, the statute about having positive beryllium incorporation tests, they are sort of reading the wording there two out, one being you are on steroids and the other being you are dead and didn't have it done or can't, you know, the blood test. And so, it raises the question of adequate or are there other reasons why there may be a negative test. But, having said that, I think that issue comes up more in the wording and not in the cases per se.

So, are there any other issues that anyone had that they want to discuss with any of the particular cases that they reviewed?

MEMBER DEMENT: This is John.

I think one of the issues that was

raised was the possibility of drilling exposure, and I think was the very last case that I reviewed. Or I think you reviewed it and I reviewed it was well. I think that actually hands down some of the language in the enabling legislation about a covered facility. And we're not going to have much impact on that one, you know, the work at this Linde Ceramics Plant. I think it was a question whether or not that was truly a carbon facility for purposes of the compensation program.

CHAIR REDLICH: Yes. You know what? I just turned that over, and you are correct. That person, this is someone, it was actually, who was diagnosed in 1971 with sarcoids. The description of the occupational history, when you look at the questionnaire, it seems like there was clearly beryllium exposure, but there was a question, that's right, of whether -- that was my interpretation of whether it was a covered facility. I couldn't quite tell from the amount of documentation we have whether someone thought

there just wasn't any beryllium or it wasn't a covered facility.

But it is, also, that he, then, died and the death certificate, it was idiopathic pulmonary fibrosis in 1992. And I think it is clear that his sarcoid progressed to idiopathic pulmonary fibrosis. So, by the time he died, it was just labeled as that. It did raise the question that IPS could be on a death certificate. Okay.

MEMBER DEMENT: Yes, I think it is probably, at least in mind, looking at it, there is probably no question at least that he likely at CBD. It is just I think the decision hinged on the technicalities of the legislation.

CHAIR REDLICH: Okay. Yes, I've got that. That is correct. I mean, I had the same, and I don't think we can necessarily do anything about that.

And then, just the one above that, two above that is, again, the issue of the we already discussed of it was denied because it was thought

to be extrapulmonary sarcoid, but the CT scan showed enlarged lymph nodes. So, that is another example of the one that we just discussed.

And I think also what was clear was that some of these were accepted because there was a letter written that was by someone more sort of knowledgeable that argued the case versus someone that didn't specifically argue the case in terms of sarcoid clear-cut exposure, but not a sort of letter arguing for a diagnosis.

MEMBER MARKOWITZ: And this is Steven.

Was that variation among the CMCs or was that there were differences between some treating physicians and some CMCs, or some mix?

CHAIR REDLICH: Well, I think it was more that there were people like National Jewish or Laura Welch, that those people could make the case. And if someone like that didn't make the case, then it wasn't made.

MEMBER MARKOWITZ: Okay.

CHAIR REDLICH: Because of the probably confusion over the presumption. So, if

the presumption, hopefully, could get clarified, because it seems more the exception rather than the rule that these cases were accepted.

Okay. What if we do this: I think what happens is that sort of the sections that I have highlighted in yellow on the actual manual, we don't necessarily need to go through in painful detail. But I think that that is why some of them have been denied, because of this lack of priority.

So, should we take -- it is already four o'clock, after 4:00 -- should we take a brief, five-minute break?

What I was hoping to do was to just point out a couple of areas in these documents that are just inconsistent, not that we are the ones that want to rewrite that, but I think that that may be part of what the problem is in sort of implementing.

MEMBER MARKOWITZ: Why don't we take a five-minute break?

MS. RHOADS: Okay, let's take a five-

minute break. But it is not necessary for anybody to disconnect or reconnect. Just put your phones on mute and we'll come back at 4:20. All right?

CHAIR REDLICH: Okay. Okay.

MS. RHOADS: Thank you.

(Whereupon, the above-entitled matter went off the record at 4:12 p.m. and resumed at 4:22 p.m.)

CHAIR REDLICH: The hour is already late.

The other two items we have are as far as the sarcoid presumption and the original request.

I didn't end up sending around the edited. I thought I had, but I realized before this meeting that I don't believe I had sent it.

Our basic recommendation for a presumption is already actually in the current document, but where I wanted to see if we were clear on was -- in the current, it is one of the documents that was sent again, the presumption

for B. I have to put it in front of me. It basically says that it is a presumption of -- let's just read it, if someone has it.

It has sarcoid as the presumption of beryllium disease, and that part is straightforward. It, then, says, however, you have to meet the requirement of either B or it, basically, says, however, then, you have to satisfy the criteria for pre- or post-CBD.

So, that is sort of a contradictory statement. Because if you have a presumption, then you don't necessarily need to fulfill the criteria. To me, if you looked at the EEOICPA circular from 2008, it basically says, the first paragraph, the purpose of a circular is to notify everyone that a diagnosis of sarcoid is not medically-appropriate if there is a history of beryllium exposure. In these situations it seems to consider sarcoids to be a diagnosis of CBD.

And then, there is this sentence, "However, the application of this presumption in the adjudication of a claim will differ between

Parts B and E of the Act." And then, it goes through the B and the E.

So, from our discussions, my understanding of presumption would be there was beryllium exposure; there was a clear diagnosis of sarcoids that involved the lung. And we discussed how the lung was involved, period.

Does that seem reasonable to everybody?

MEMBER WELCH: Medically, that would be reasonable. Whether, given the statute, that could be implemented -- I mean, I think what we see is, bending over backwards, is how to get around the requirements that beryllium sensitivity be present to diagnose CBD. Because the statute says beryllium sensitivity together with lung pathology consistent with chronic beryllium disease.

So, if it is in the statute, then they have kind of come up with the roles in which, if the LPT is negative, getting off into the history of previous ones and, you know, make a good-faith

effort to determine when the beryllium sensitivity is present.

CHAIR REDLICH: So, what I am wondering is if we would propose a presumption that was a careful statement of sarcoid exposure/lung involvement.

MEMBER WELCH: Beryllium exposure/sarcoid diagnosis.

CHAIR REDLICH: Yes, and with some evidence of the chest involved.

MEMBER WELCH: And that would be accepted as CBD.

CHAIR REDLICH: Right, that that would be if we are giving a recommendation.

MEMBER WELCH: Right. But I think that to have that be accepted as CBD they have to change the legislation.

CHAIR REDLICH: But I just think that there is a difference between proposing that as a presumption, because the amount of work to go through what basically ends up -- I mean, requesting a first be negative, then a second

negative BeLPT with a letter from the doctor stating you were on steroids. I mean, it seems to me we could make a recommendation that we think there should be this presumption. If the lawyers, and whatever, feel that that is not consistent, then, to me, that would be at least worth trying. If they say, no, this doesn't meet -- you know, we need A, B, and C, then we could --

MEMBER WELCH: I think that is a good idea.

CHAIR REDLICH: Because I think we had talked about presumption would -- maybe there is more openness now after 9/11 and other such things to the process of a presumption.

MEMBER WELCH: I think you should -- why don't we write up the presumption? And then, we could vote on it. And then, we will submit it and find out what happens. Because, otherwise, we will just talk about this forever.

CHAIR REDLICH: Okay. I would say that the presumption would basically be the

sentence that is already written. So, we could just use what has already been written, but just leave out it's Circular, you know, 8-07, and we just stop the presumption with "however".

MEMBER WELCH: Can you write something?

CHAIR REDLICH: Yes, I could, exactly. And then, I was going to say, if we try that presumption and the fact, then, was not accepted, then we could through the gyrations of how to get around the negative BeLPT.

Because what I was unclear of -- and maybe someone else on the phone knows -- I was unclear of all this complicated wording about having to redo the BeLPT and all of this, when in the bottom line, if there was a way around it, people would try to do that or is that merely done to mandate as far as the law.

MEMBER WELCH: I don't really understand what you just said.

CHAIR REDLICH: Well, the thing is the extent of language that is so confusing to

everyone about, you know, you could have a negative if you document on steroids, but, first, you have to get a second one and, then, document you're on steroids. Was that really all put in there because a lawyer or someone felt that was the only way it would be in compliance with the Act? Or was that just how this had evolved in terms of direction for the --

MEMBER WELCH: We would have to ask --

MEMBER MARKOWITZ: This is Steven.

Let me just ask a process question for a moment. So, we have about 30 minutes left. I don't know how much more there is on the agenda. But, if there is other stuff we want to cover, then maybe we should move on and just look at a draft of the thinking.

CHAIR REDLICH: Okay. So, that's fine. Why do we do this, then: I would favor us doing a draft of what we think is the best thing. And whether it is in compliance with the Act, we need that as a secondary condition. I mean, we first just recommend what we think would be best

and vote on that.

MEMBER MARKOWITZ: We will leave it as consequential condition, right.

CHAIR REDLICH: But not presuming we can't have a presumption ahead of time, right. Well, that won't be in compliance with the Act, so we can't recommend that?

MEMBER WELCH: Well, I think we just propose a presumption as you suggested and see what happens.

CHAIR REDLICH: Okay. I'm sorry, my screen froze in terms of bringing it up.

I think that at this point it was the justification piece that we wanted clarification.

MS. RHOADS: Dr. Redlich, it sounds like you're going in and out of the recording.

CHAIR REDLICH: Okay. Because I'm having trouble hearing with the background noise.

MS. RHOADS: Yes. Does everyone have their phones on mute?

CHAIR REDLICH: It's quieter now.

MS. RHOADS: All right. It sounds

quieter to me, too.

CHAIR REDLICH: Okay. So, as a process, I would suggest that I will send around a presumption based on our discussion. And then, the question is voting on that.

Steve, are you there?

MEMBER MARKOWITZ: Yes, I am here. I am here. I was just on mute.

CHAIR REDLICH: Okay. So, could we have voted on the presumption?

I'm freezing my computer.

But we had gotten, I think, in terms of why to justify it as far as potentially the Act.

MEMBER MARKOWITZ: Yes, I think you should send around a draft.

CHAIR REDLICH: Okay.

MEMBER MARKOWITZ: And then, we come to consensus about that. Then, we can figure out the next step.

CHAIR REDLICH: I think, then, we would be clearer on the presumption. The

questions I have that I wanted on consensus on in terms of, you know, I think we're clear on.

Then, the other piece, the questions that this letter addressed that we had received and our original document, the original Subcommittee draft, I apologize because I thought I had sent around the comments and recommendations for those questions that had been asked, and I did not.

So, I think that we have actually discussed almost every point on the original request. One that wouldn't come up that we haven't, Laurie, was the indeterminate BeLPTs. And, Laurie, I was hoping you could address that question.

MEMBER WELCH: Well, I had sent back a note about the borderline.

CHAIR REDLICH: And that is borderline, yes.

MEMBER WELCH: Borderline, because indeterminates and uninterpretable are definitions.

The modeling done by -- I can't think of his name -- Middleton --

MEMBER MARKOWITZ: Middleton, yes.

MEMBER WELCH: -- that suggested that three borderlines is the equivalent of one abnormal and one borderline. I mean, we could recommend either three borderlines or two borderlines -- we would have to just send the paper around -- is the equivalent of a single positive. Because, apparently, a number of workers have multiple borderlines, and I think those should be accepted as sensitive.

CHAIR REDLICH: That's right. And there was one of the cases that we reviewed that had that scenario, and there was a letter that addressed it also that was effective.

MEMBER WELCH: Okay.

CHAIR REDLICH: And so, one of those cases, just as you said, that other case was an example of how to address it.

MEMBER WELCH: Yes. Do you know which one it was, so I can take a look at that and see

if it helps? Well, I will just write up something and send it to you, Carrie.

CHAIR REDLICH: And I will send around the document that addressed the other questions that were asked, which I think we have really been over just about every one of them.

To me, the problem that has happened I think is that the description in the circular of directions actually is internally sort of inconsistent in the way that is written. And so, I think we could just, I was thinking we could point out the pieces that we found to be inconsistent because I think that that is part of the problem, and even the PowerPoint description which has, then, created the confusion for a lot of the cases.

MEMBER MARKOWITZ: This is Steven.

So, I had a question. In the draft responses to the questions that DOL asked of us, it seems like a bunch of the problems in the past have stemmed from the language of the Act which is transferred over to the Policy Manual, you

know, words like "characteristic," characteristic chest x-ray findings" or "clinical course consistent with chronic respiratory disease," that these are very vague terms. But the Procedure Manual puts some definitions to them, but the question is, should the details be in some sense modified, expanded? Are they too restrictive in the way that these terms are interpreted? So, my question really, Carrie, is whether the draft response, whether we take on that specific issue of the "consistent with" and "characteristic" language.

CHAIR REDLICH: Well, the thing is I looked over and, generally speaking, I think most of the wording, there were just one or two areas, such as like the CT scan that actually doesn't mention hilar adenopathy. So, I think that there are a few areas where there could be clarification.

In looking over these cases, I think where the problem is -- and I was trying to think, if you are giving a manual, about to do

this -- it is not so much finding 10 other things to write down, there are already so many of the characteristics of the CT scan. And I started to make a little chart of this.

So, if you have, let's say, a positive BeLPT and you've got abnormal restrictive low BLCO, PFTs, with a positive BeLPT, there is a comment you need A, B, and C, but there is, actually, a caveat that you don't have to have the biopsy.

In other words, I think the problem is that you have got a clear positive BeLPT and you have got a interstitial lung process. Then, that is really enough in terms of -- and there is a caveat for that, which is, you know, that basically we already give this out. And so, in a way, then, like the same thing with the sarcoid, if there is a presumption that you don't have a positive BeLPT, you don't have to get into all the variations about that BeLPT. So, I think that some of these cases have gotten lost in the weeds of one little piece of it, which, if you

step back, you actually met the criteria.

MEMBER MARKOWITZ: This is Steven.

I assume the problem in the past has been where CBD claims have been denied because their criteria haven't been met. And then, there are different views of whether the criteria have been met or not.

And I'm looking at the list, the summary list of cases, and it looks like the cases of the CBD cases that were provided, there were a total of four, and all of them were accepted. Then, I wonder whether we get some insight if we looked at some CBD cases that were refused, denied, and the issue was that they didn't meet the -- the issue wasn't primarily BeLPT, but it was these other problem areas of "consistent with clinical course," "characteristic of".

CHAIR REDLICH: Yes. You know what? We had listed the ones that people felt were worth discussing. There were some that were denied because it was clear-cut.

So, I think that a common denial, looking at all them, is interstitial lung disease, sarcoid, with a negative BeLPT. And that one we discussed. So, I think that is the biggest batch of the ones that are denied. And so, that is how the presumption would help with that.

And then, the other ones, when they are in -- to clarify, it already gives the option of where you may not have been able to get lung tissue.

Meeting what they were wording, it turns out that there is actually quite a list. I think some of the cases it looked like it was more of the CMC's interpretation of it rather than what is in the wording. Because, currently, other than I have added one or two words that were just really to make that simpler, but it is pretty much already a rather thorough list of "characteristic of".

Okay?

MEMBER MARKOWITZ: Yes, yes, I hear

you. I hear you.

CHAIR REDLICH: That's what I didn't do -- there were two more words, but it is almost like it is A, B, C, D, E, F, and G. And there aren't that many other things that a biopsy could look like. And then, it is how the CMC is, then, interpreting that information.

So, I think part of that would be helpful to send. I think that the oversight of some of the CMCs is where part of the problem is.

MEMBER MARKOWITZ: So, you're saying it was the way the CMCs applied the --

CHAIR REDLICH: That's right.

MEMBER MARKOWITZ: Right. Okay.

CHAIR REDLICH: And it leaves a number if there were one single CMC.

But what if I send around -- I mean, I have drawn the wording in one or two places. But, as you noted, already under CT scan there is a long list of things.

MEMBER MARKOWITZ: Right.

CHAIR REDLICH: It is the same for

chest x-ray.

And so, what is happening is just more ability to put together these different pieces of information in terms of some basic common sense.

Also, the cases that I have heard from other physicians who put a complaint to me, and I had asked them to send me cases that have been denied, all of those have been in the setting of a negative BeLPT. And so, I think that issue, I personally feel like right now it already worded you could have a negative BeLPT if you are on steroids. And I think that that wording could be slightly tweaked or this can happen in other conditions such to open that opportunity. Because it may be that the person doesn't know for sure whether the person was on steroids or not at the time the BeLPT was done. So, I think that, if all the other components were -- I think that is really where the issue is there.

Then, the other issue is the cause of the BeLPT where the evidence of actual lung disease is very minimal. That, I think there is

a category of beryllium sensitization. I think that that goes into that bucket. If it progresses to beryllium disease, then it would create a claim. And so, someone who basically has beryllium sensitization and no other lung disease, it is denied. That I think is not an understanding of it is sensitization and not CBD.

Okay. In terms of our agenda, I think we have been over the presumption, the cases, the original request. In terms of additional data or information needs, I have heard from the field that we have gotten a relatively good feel for what is happening in many of these cases.

John, I don't know if you felt that additional information or data on the data side --

MEMBER DEMENT: I don't think it is going to clarify anything for us. I think we have got some issues that we need to really start with developing some presumptions and clarifying some categories of lung involvement. But, other than that, I don't think the new data is going to

help.

You know, where we have learned the most is from the denied cases that we have gone into detail, and not the ones that have been approved. I think, for the most part, because I went through the approved cases, I didn't have any problem with most of the approvals.

CHAIR REDLICH: I think that what might be helpful would be maybe 10 or 20 more denied cases. We don't need any more approved ones.

MEMBER DEMENT: I don't know if that is going to help.

Laura, what do you think in terms of reviewing additional cases? Is that going to clarify issues for us?

MEMBER WELCH: No, I don't this so.

MEMBER DEMENT: I think we need to start putting stuff on paper and --

CHAIR REDLICH: I'm okay with not another, and I think I agree.

The other area that I think there is

a problem with is -- and I think we should just mention it -- just the denials because of the question of really whether there was beryllium exposure. But we could address by clarifying the exposure side. But I agree; I think we can define the presumption and clarify the "such as...."

I also feel that, you know, that's true; I was only thinking more cases, as some of them are -- I somehow feel that it would be good, that it is the education of the people carrying it out, and that the cases, I think all of us just putting in a bucket the cases that were denied that we disagree with, I think that whoever is actually doing the work or overseeing it and the quality of it should review some of the cases. And we could make that a recommendation because I think the way to realize is to give some examples of we disagree with this final decision and these are the reasons.

MEMBER MARKOWITZ: Well, this is Steven.

So, that would be important to articulate that as a recommendation, and not just put it over onto the IH and CMC Subcommittees. Because if it is a finding of this Subcommittee, you know, in addition to that Committee, it is a little bit stronger.

Another separate point is that we have skirted a little bit of this issue of documented beryllium exposure. If we are not clear about how they apply that, we should ask for clarification.

CHAIR REDLICH: I just think, you know, that clarification of --

MEMBER MARKOWITZ: You know, there is a point at which they require documented beryllium exposure. I can't remember where it is exactly, but we saw it today. And then, we saw a case in which a clerical worker was denied based on no exposure. So, I think we should ask for clarification about how they apply the term.

CHAIR REDLICH: Okay. And I was also unclear on a couple of them where the

determination was no beryllium. I wasn't quite clear where that came from, at which point.

MEMBER WELCH: That would be in the statement of accepted facts or something. And then, I think it is the claims examiner that makes that determination.

CHAIR REDLICH: Okay.

MEMBER WELCH: But somebody may have to go back and look at those files, I think. I don't think I looked at those.

CHAIR REDLICH: Okay. It seems to me personally that, again, I was under the assumption that there was some presumptions with beryllium, but I think is where the problem arises, because, oh, this person worked in an office, so they didn't have beryllium exposure. So, we probably want clarification of that determination.

MEMBER MARKOWITZ: This is Steven.

A separate comment. So, how many denied CBD cases have we had the opportunity to look at?

CHAIR REDLICH: I think there were 10, some of which were sarcoid cases that were denied. There was a total of 10. I had picked out the ones that there was a question. I think that the sarcoid and those have to be lumped together with the sarcoid as denied CBD cases. I could make a list of the reason for each denial and whether we agreed with it. At least half of them were sarcoids that the presumption was, hopefully, addressed. And then, with the others, some of them were probably appropriate and some were the question of exposure.

MEMBER MARKOWITZ: This is Steven.

The other comment I have is one of the other subcommittees focused in on kind of getting a summary of the public comments in relation to the issues they were looking at. And I know there were a number of public comments on beryllium, particularly at the first meeting. It might be useful to get -- I don't know how we achieve this exactly; I'm speaking to Carrie Rhoads here -- but to get a summary of some of

those comments, so that if there are issues that have not yet been discussed that should be discussed, we should make sure that we cover them.

CHAIR REDLICH: Okay.

MS. RHOADS: Excuse me.

The other Subcommittee from last week went over all the public comments from the October meeting. Are you talking about the public comments from the April meeting also? Because I don't think anybody has gone over them from before.

MEMBER MARKOWITZ: Yes. I know there were a bunch of comments --

MS. RHOADS: Yes.

MEMBER MARKOWITZ: -- in April about beryllium.

MS. RHOADS: Okay. I can read over those and send you a list or page numbers, or something, of when people mentioned them, if you would like.

CHAIR REDLICH: Okay.

MEMBER MARKOWITZ: Yes, that would be a good start, yes.

MS. RHOADS: Okay.

CHAIR REDLICH: Then, we can use the ones that were similar and make sure we have addressed them.

But your point I think is about the CMC, I mean in terms of just not understanding. Like there was someone who wrote that, well, a chest x-ray 10 years earlier didn't show silicosis. Well, if it happened, it should have been present 10 years earlier because that was closer to when they were at work. That is just not understanding chronic pneumoconiosis. So, the problem there isn't what is written in any of the sort of guidance, but it is the person giving the opinion.

MEMBER MARKOWITZ: Right. This is Steven. So, yes, if that is a finding of the group, incompetence on the part of the CMCs for this application, then that should be pointed out.

CHAIR REDLICH: Okay. Or the concept that there was misconception on several of them that, if you had extrapulmonary sarcoid, it could not be CBD. So, that is different, having extrapulmonary and pulmonary, meaning, well, the extrapulmonary just excludes you. So, that is something that could be clarified. But I have started to feel like clarifying every one of these, I think if you had a process where you reviewed the quality of the CMCs and got rid of the bad ones, that that would be more effective than anticipating everything that they might do that doesn't necessarily make sense.

MEMBER MARKOWITZ: Sure.

CHAIR REDLICH: I had requested -- and I guess this is not available -- I was sort of curious, for this whole group of diseases, my understanding is questions we have asked about the CMCs, we haven't gotten a lot of information on. Because if you look at the total number of cases in the pulmonary realm, it is not that huge.

And if they had three or four good CMCs that could handle that volume of claims, but if we knew how many they were using, and even if you looked at if they had these 10, I understand you can't give a percentage acceptance rate for each one because of the conditions, the questions that are asked. But you could ask, on the basis of their report, was it accepted or denied, and someone could review as a group, you know, this A, B, C from those A, B, C different CMCs.

So, we could put that in a recommendation, because I really feel that the review of the CMCs' disease conditions, if there were problems with them, then one could educate that person and, then, the oversight of that, because they are really a little bit more formulaic if the person sort of understands the disease process.

MEMBER VLIEGER: Dr. Redlich, this is Faye here. I have been listening in the whole time, and I beg the Committee's indulgence.

I did present Kirk and my findings of

the review of the first two disks, and that one particular doctor was being sent the CBD cases, and his usual answer was no. And I presented that information at the October meeting.

So, I think they are trying to funnel them to one or two doctors. Unfortunately, the outcome from those doctors presently is not what we would expect.

CHAIR REDLICH: Exactly.

MEMBER VLIEGER: And then, one final thing and, then, I'll give you back to your Committee work. In my discussions with claims examiners, when they referred to a CMC for a lung condition or for CBD, I asked them, are they made aware of the provisions in the law and in the Procedure Manual? And I'm always told they get training to be a CMC; it's not our job to tell them how to do their job.

So, many times what we see in the CBD decisions is that they are following their medical school training and not the provisions under the law, in that they are requiring four or

five conditions in order to be diagnosed versus the positive blood test and two items.

So, I think part of it is you may have good CMCs out there, but they are not given all the guidance they need in order to do the adjudication under this program.

CHAIR REDLICH: Thank you. I agree.

So, I guess we could make a recommendation with the other Subcommittee on the specific areas that we are concerned about the CMCs as it relates to the Part B condition.

MEMBER VLIEGER: Yes, I would think that would be appropriate.

CHAIR REDLICH: Okay. And any that I had collected I think the ones where there was a problem -- but, if anyone else has one where they are concerned about the CMC, I think we could flag those because I may omit some.

Would it be okay if we passed those to the CMC Committee?

MEMBER MARKOWITZ: I'm sorry, what do you want to pass off to them?

CHAIR REDLICH: Would that be okay to show them which of the CMC reports that we have concerns about?

MEMBER MARKOWITZ: Sure. That would be great.

This is Steven.

CHAIR REDLICH: Okay. So, I will do that. If anyone could just email me the number of the ones, in case I missed any of them that they noticed, because there could have been a problem with that where you didn't flag the whole chart?

Okay. I think we have covered -- so, I will send out the draft responses that I have later today and, also, the sarcoid presumption draft.

And then, Carrie, you're going to sum up the different comments?

MS. RHOADS: Yes, I will take a look at the public comments from the April meeting and send you a list of where they talk about CBD.

CHAIR REDLICH: Okay. And right now,

for now, we have sufficient data. Okay.

Other new items, anyone?

(No response.)

Okay. Thank you. I know this was very long and it got a little detailed, but it was helpful for me to see where I think we got consensus on what the issues are with the cases that we reviewed.

Okay. Any other issues/comments?

(No response.)

So, should we just go, then -- people, we could do edits to the draft as far as the sarcoid and the response to their initial comments? And do that, all right, we send it by email to Carrie?

MEMBER WELCH: You mean for the presumption proposal?

CHAIR REDLICH: That's right. Carrie will send it out and, then, we could just circulate edits to it.

MEMBER WELCH: Okay.

CHAIR REDLICH: And the same with the

response, initial response to their questions that they had asked.

And I think what would be helpful for me is if people just add any areas that they feel we need much further explanations, because some of them I was just brief on.

Okay. Any other? Any other comments?

(No response.)

Carrie, are you here?

MS. RHOADS: Yes.

CHAIR REDLICH: Okay. Does anyone have any other items?

(No response.)

So, we are done? Last chance.

Steve?

(No response.)

Oh, Carrie, still working on Carrie?

(Interruption by phone.)

MS. RHOADS: I think we just heard Dr. Markowitz's hold music.

MEMBER MARKOWITZ: I'm sorry. Yes. No, I'm sorry. I'm sorry. I'm back. I made a

mistake.

(Laughter.)

CHAIR REDLICH: Okay. Okay. So, I guess we're done. I just wanted to check if you have anything else.

MEMBER MARKOWITZ: No. Sorry about that. No, it's fine.

CHAIR REDLICH: Okay. I think we have a plan. I thank everybody for all the time.

MEMBER MARKOWITZ: Thank you.

CHAIR REDLICH: And I would just reiterate the problem of the CMCs. I don't know how it gets fixed, but we can raise that.

MEMBER MARKOWITZ: Right.

CHAIR REDLICH: Okay. Thank you.

MEMBER MARKOWITZ: Okay. Bye now.

MS. RHOADS: Thanks, everybody.

(Whereupon, the above-entitled matter went off the record at 5:12 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Evidentiary Requirements for Part B Lung Conditions (Area #3)

Before: Toxic Substances and Worker Health Adv. Comm.

Date: 12-21-16

Place: teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter