

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

+ + + + +

WEDNESDAY,

DECEMBER 21, 2016

+ + + + +

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

2 2:35 p.m.

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

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

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

19 Dr. Carrie Redlich is the Chair of
20 this Subcommittee.

21 Dr. Redlich, are you on the line?

22 CHAIR REDLICH: Yes, I am.

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

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

5 MS. RHOADS: Mr. Kirk Domina?

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

9 MS. RHOADS: Dr. Laura Welch?

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

13 MS. RHOADS: Thank you.

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

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

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

21 MS. RHOADS: Great. Thanks.

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

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

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

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

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

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

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

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

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

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

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

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

8 As DFO, I see that the minutes are
9 prepared and, then, certified by the Chair. The
10 minutes of today's meeting will be available on
11 the Board website no later than 90 calendar days
12 from today, per FACA regulations. But if they
13 are ready soon, they will be published before the
14 90th day.

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

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

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

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

16 CHAIR REDLICH: Thank you all for
17 joining.

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

22 Thank you for joining.

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

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

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

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

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

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

17 So, is everyone agreeable as far as
18 the plan?

19 MEMBER WELCH: This is Laurie Welch.

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

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

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

8 MEMBER WELCH: Okay.

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

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

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

1 terms of whether the test was positive or
2 negative.

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

8 MEMBER WELCH: Okay.

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

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

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

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

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

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

13 So, eventually, three years later, in
14 2014, there was a Director's letter. So, it was
15 finally accepted, but I think it was an example
16 of the hoops that you have to go through and the
17 time and effort. We are, hopefully, moving
18 forward.

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

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

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

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

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

1 CHAIR REDLICH: Yes.

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

13 CHAIR REDLICH: Okay.

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

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

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

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

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

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

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

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

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

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

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

16 MEMBER WELCH: I don't know the
17 answer.

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

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

1 CHAIR REDLICH: For the current
2 worker?

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

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

12 Okay. The next case I only listed for
13 -- someone was interested for historic goal or
14 interest. It was a very well-described case of
15 acute berylliosis in 1946, and CBD was diagnosed
16 a year later in 1947. It wasn't actually, a
17 claim, though, wasn't -- and then, the autopsy in
18 1989 that noted CBD -- a claim was not filed
19 until by the survivors in 2014.

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

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

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

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

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

1 Sorry.

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

4 Sorry. Okay.

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

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

22 Okay. I think we should probably get

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

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

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

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

22 Based on that, the CMC opined that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 CHAIR REDLICH: Yes, and I was going

1 to bring this up later, but --

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

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

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

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

22 CHAIR REDLICH: Yes.

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

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

8 MEMBER WELCH: That's right.

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

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

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

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

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

1 under RECA.

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

11 I think, John, you know more about
12 that.

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

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

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

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

12 MEMBER WELCH: Yes, absolutely.

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

16 MEMBER WELCH: Yes.

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

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

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

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

16 CHAIR REDLICH: That's correct.

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

19 MEMBER DEMENT: Right.

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

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

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

17 CHAIR REDLICH: Yes. This is Carrie.

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

1 CMC.

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

4 (Laughter.)

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

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

1 MEMBER WELCH: Right.

2 CHAIR REDLICH: -- solve the problem.

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

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

12 MEMBER DEMENT: This is Steven.

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

22 CHAIR REDLICH: Right.

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

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

6 MEMBER WELCH: Yes, we can do that.

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

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

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

1 in a lot of other cases.

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

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

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

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

1 disease did not contribute to their death.

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

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

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

22 CHAIR REDLICH: Pass that on to the

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

3 MEMBER WELCH: Yes, sure.

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

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

1 me, was a problematic case.

2 MEMBER WELCH: And difficult to
3 discern.

4 MEMBER DEMENT: I'm sorry?

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

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

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

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

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

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

17 MEMBER MARKOWITZ: Carrie, this is
18 Steven.

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

21 MEMBER WELCH: Yes. Or maybe it is --

22 CHAIR REDLICH: I mean, I think that

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

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

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

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

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

5 MEMBER WELCH: Right. It would
6 resolve --

7 CHAIR REDLICH: Yes, that is correct.

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

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

21 MEMBER WELCH: Uh-hum.

22 CHAIR REDLICH: So, I think that is

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

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

10 CHAIR REDLICH: Yes.

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

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

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

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

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

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

14 MEMBER DOMINA: Okay.

15 CHAIR REDLICH: Yes.

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

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

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

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

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

10 MEMBER DEMENT: No.

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

16 MEMBER DOMINA: Right.

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

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

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

3 CHAIR REDLICH: Yes.

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

6 CHAIR REDLICH: Okay.

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

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

13 MEMBER DOMINA: Right.

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

17 MEMBER DOMINA: Okay.

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

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

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

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

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

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

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

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

5 MEMBER DEMENT: Yes.

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

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

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

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

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

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

1 is called manual or instructions. And they
2 mentioned the mediastinal lymph node biopsy is
3 not the equivalent of a lung biopsy and does not
4 substitute for such in the assessment of a post-
5 1993 thing. The evidence has to be lung
6 pathology. A mediastinal lymph node is not a CBD
7 in the same way as a lung biopsy.

8 MEMBER MARKOWITZ: Carrie, this is
9 Steven.

10 So, you think that's wrong, right?

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

14 MEMBER MARKOWITZ: This is Steven.

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

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

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

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

3 MEMBER MARKOWITZ: This is Steven.

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

7 CHAIR REDLICH: Yes.

8 MEMBER MARKOWITZ: Yes, okay.

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

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

20 MEMBER MARKOWITZ: Right. This is
21 Steven.

22 I'm just thinking. Actually, I'm

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

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

14 MEMBER MARKOWITZ: Well, yes. This is
15 Steven.

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

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

1 document had --

2 MEMBER MARKOWITZ: Right.

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

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

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

13 MEMBER MARKOWITZ: Right.

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

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

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

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

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

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

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

14 CHAIR REDLICH: Yes.

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

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

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

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

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

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

22 MEMBER WELCH: We don't have any

1 evidence of any lung disease.

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

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

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

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

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

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

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

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

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

18 MEMBER MARKOWITZ: Well, this is
19 Steven.

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

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

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

22 So, I could actually argue both sides,

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

6 MEMBER MARKOWITZ: Well, yes. This is
7 Steven.

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

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

22 MEMBER MARKOWITZ: I think we should

1 move on.

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

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

13 But it was basically where a diagnosis
14 of sarcoid had been made in the past, in 2008,
15 with a lung biopsy, and no BeLPT was done. The
16 person had worked at Savannah River Site from
17 1981 to 2005 as a clerical worker in multiple
18 different buildings.

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

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

1 to comment on that one?

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

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

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

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

16 Do you know when that case was
17 reviewed?

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

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

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

6 CHAIR REDLICH: Yes.

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

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

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

1 title --

2 CHAIR REDLICH: That's right.

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

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

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

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

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

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

1 interpretation --

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

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

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

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

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

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

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

21 MEMBER WELCH: Not really.

22 CHAIR REDLICH: For post-1993, of all

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

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

8 CHAIR REDLICH: Yes, okay.

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

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

18 CHAIR REDLICH: Yes.

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

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

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

4 MEMBER WELCH: Yes.

5 CHAIR REDLICH: That would solve this
6 problem.

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

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

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

22 CHAIR REDLICH: Yes, but none of those

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

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

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

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

20 CHAIR REDLICH: I'm good with that.

21 MEMBER MARKOWITZ: Yes.

22 CHAIR REDLICH: I think this would be

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

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

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

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

22 So, in thinking about this, if it is

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

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

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

21 MEMBER DEMENT: This is John.

22 I think one of the issues that was

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

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

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

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

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

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

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

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

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

11 MEMBER MARKOWITZ: And this is Steven.

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

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

20 MEMBER MARKOWITZ: Okay.

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

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

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

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

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

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

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

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

5 CHAIR REDLICH: Okay. Okay.

6 MS. RHOADS: Thank you.

7 (Whereupon, the above-entitled matter
8 went off the record at 4:12 p.m. and resumed at
9 4:22 p.m.)

10 CHAIR REDLICH: The hour is already
11 late.

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

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

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

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

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

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

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

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

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

8 Does that seem reasonable to
9 everybody?

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

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

1 effort to determine when the beryllium
2 sensitivity is present.

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

7 MEMBER WELCH: Beryllium
8 exposure/sarcoid diagnosis.

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

11 MEMBER WELCH: And that would be
12 accepted as CBD.

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

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

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

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

10 MEMBER WELCH: I think that is a good
11 idea.

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

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

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

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

5 MEMBER WELCH: Can you write
6 something?

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

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

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

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

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

9 MEMBER WELCH: We would have to ask --

10 MEMBER MARKOWITZ: This is Steven.

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

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

1 and vote on that.

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

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

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

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

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

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

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

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

21 CHAIR REDLICH: It's quieter now.

22 MS. RHOADS: All right. It sounds

1 quieter to me, too.

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

6 Steve, are you there?

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

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

11 I'm freezing my computer.

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

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

17 CHAIR REDLICH: Okay.

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

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

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

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

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

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

18 CHAIR REDLICH: And that is
19 borderline, yes.

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

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

3 MEMBER MARKOWITZ: Middleton, yes.

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

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

17 MEMBER WELCH: Okay.

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

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

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

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

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

17 MEMBER MARKOWITZ: This is Steven.

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

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

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

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

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

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

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

1 step back, you actually met the criteria.

2 MEMBER MARKOWITZ: This is Steven.

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

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

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

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

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

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

21 Okay?

22 MEMBER MARKOWITZ: Yes, yes, I hear

1 you. I hear you.

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

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

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

13 CHAIR REDLICH: That's right.

14 MEMBER MARKOWITZ: Right. Okay.

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

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

21 MEMBER MARKOWITZ: Right.

22 CHAIR REDLICH: It is the same for

1 chest x-ray.

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

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

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

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

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

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

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

1 help.

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

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

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

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

17 MEMBER WELCH: No, I don't think so.

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

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

22 The other area that I think there is

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

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

21 MEMBER MARKOWITZ: Well, this is
22 Steven.

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

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

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

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

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

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

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

7 CHAIR REDLICH: Okay.

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

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

19 MEMBER MARKOWITZ: This is Steven.
20 A separate comment. So, how many
21 denied CBD cases have we had the opportunity to
22 look at?

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

13 MEMBER MARKOWITZ: This is Steven.

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

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

5 CHAIR REDLICH: Okay.

6 MS. RHOADS: Excuse me.

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

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

15 MS. RHOADS: Yes.

16 MEMBER MARKOWITZ: -- in April about
17 beryllium.

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

22 CHAIR REDLICH: Okay.

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

3 MS. RHOADS: Okay.

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

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

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

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

14 MEMBER MARKOWITZ: Sure.

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

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

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

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

22 I did present Kirk and my findings of

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

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

9 CHAIR REDLICH: Exactly.

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

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

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

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

7 CHAIR REDLICH: Thank you. I agree.

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

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

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

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

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

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

4 MEMBER MARKOWITZ: Sure. That would
5 be great.

6 This is Steven.

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

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

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

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

22 CHAIR REDLICH: Okay. And right now,

1 for now, we have sufficient data. Okay.

2 Other new items, anyone?

3 (No response.)

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

9 Okay. Any other issues/comments?

10 (No response.)

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

16 MEMBER WELCH: You mean for the
17 presumption proposal?

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

21 MEMBER WELCH: Okay.

22 CHAIR REDLICH: And the same with the

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

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

7 Okay. Any other? Any other comments?

8 (No response.)

9 Carrie, are you here?

10 MS. RHOADS: Yes.

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

13 (No response.)

14 So, we are done? Last chance.

15 Steve?

16 (No response.)

17 Oh, Carrie, still working on Carrie?

18 (Interruption by phone.)

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

21 MEMBER MARKOWITZ: I'm sorry. Yes.

22 No, I'm sorry. I'm sorry. I'm back. I made a

1 mistake.

2 (Laughter.)

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

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

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

10 MEMBER MARKOWITZ: Thank you.

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

14 MEMBER MARKOWITZ: Right.

15 CHAIR REDLICH: Okay. Thank you.

16 MEMBER MARKOWITZ: Okay. Bye now.

17 MS. RHOADS: Thanks, everybody.

18 (Whereupon, the above-entitled matter
19 went off the record at 5:12 p.m.)
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21
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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
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Court Reporter

NEAL R. GROSS

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