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COSMETIC SYMPOSIUM
"Asbestos in Talc"

TRANSCRIPT OF CONCURRENT BREAKOUT SESSION B

MEASUREMENT CRITERIA FOR IDENTIFICATION AND FIBER COUNTING

Moderators: Arthur M. Langer

- and -

Anne G. Wylie

Location: The Hotel at the University of Maryland

7777 Baltimore Avenue

College Park, Maryland 20740

Time: 1:42 P.M.

1 COLLEGE PARK, MARYLAND

2 Wednesday, November 28, 2018, 1:42 P.M.

3

4 MR. LANGER: This is the session to establish
5 concurrence on morphological criteria for identification
6 of mineral fibers in the analysis of cosmetics
7 containing talc. Use of reference standards will also
8 be discussed.

9 You heard many presentations this morning.
10 You heard Van Gosen talk about various deposits and
11 geological characteristics and criteria. The
12 interesting part of his presentation is that the
13 Yellowstone talc has no amphibole. The Yellowstone talc
14 may have been used in cosmetics. All of the other talcs
15 that he described, whether from Death Valley or Texas or
16 New York State, all contain amphiboles. They've never
17 been used -- not most deposits, Allamore, Texas, or
18 Gouverneur in New York State or the Talc Bill which lies
19 to the east of the Gouverneur deposit, these all contain
20 fibers, fragments predominantly in Gouverneur. But
21 they've never been used as a cosmetic source.

1 Interestingly I think Dr. Van Gosen added that
2 he was not in a position to recommend this Yellowstone
3 talc. That's mountain. Yellowstone, Beaverhead is a
4 very pure talc. It has been used in the industrial
5 setting but only in paper making, because it contains no
6 grit. It has no amphibole materials.

7 Dr. Meeker suggested that the federal asbestos
8 standard is incomplete. He's right. There are other
9 asbestos amphibole materials that have been identified
10 and reported on in the literature, whether it's
11 winchite-asbestos in Allamore or whether it's richterite
12 and winchite in Libby, Montana, or the fluoro-edenite,
13 which is implicated in mesothelioma in Italy, or the
14 bentonite asbestos, another amphibole, implicated in the
15 Ural mountain mesotheliomas.

16 MS. WYLIE: Do you have a sample of that?

17 MR. LANGER: Say again?

18 MS. WYLIE: Do you have a sample of that?

19 MR. LANGER: No, I do not. No. That's a very
20 good question.

21 MS. WYLIE: I would add it to my collection.

1 MR. LANGER: Speaking of collections, Dr. Nolan,
2 who is here in attendance, has all of the UICC standards
3 in 5-pound or 10-pound bags, the original materials. We
4 took that out of Sinai when we left. But we also had
5 about 80 canisters of talcum products. The first
6 20-some-odd were reported years back. But we have those
7 samples, and many are interested in reanalyzing the
8 pallets. We understand why.

9 The -- as an example, the litigations today
10 with Johnson & Johnson really has nothing to do with
11 science. It has to do with their corporate
12 communications amongst themselves, which are damning,
13 meaning that they generated the enemies lists and
14 they -- some people they relied on, others not.

15 So the -- Johnson & Johnson, they took it on
16 the chin with Jackie Fox in St. Louis and the cases out
17 in Los Angeles as well in which the rewards were just
18 huge.

19 Rutstein described the methods. He did not
20 endorse any one specifically, other than you see a lot
21 more with an analytical electron microscope. And, of

1 course, Dr. Harper stressed statistical analysis of the
2 data and the number of fibers required to characterize
3 the material.

4 These are important issues today, meaning that
5 the limit of detection -- what is it actually telling
6 you? Is the limit of detection of the mineral content
7 important? Or are we dealing with -- are we dealing
8 with the issue of risk analysis? Meaning that, if we --
9 if we looked at risk analysis, we're looking at a
10 certain material contaminated or associated with mineral
11 fiber. Let's assume anthophyllite or tremolite
12 asbestos. What is the risk?

13 If your analysis indicates that you're dealing
14 with .01 percent level of fiber and someone is using
15 this for 15 minutes a day and the exposure level is .15
16 per cc, which is the current standard, the protective
17 level, the question is, if you use this every day of the
18 year, 365, if you were to use this for 75 years, what
19 would the risk be?

20 Well, I've done the calculation. And this is
21 for chrysotile in talc, because we know something about

1 chrysotile. There are plenty of studies in which the
2 epidemio- the mortality has been determined at certain
3 levels of exposure. We calculate the cumulative
4 exposures, and we determine what the risks are. That's
5 using the linear no-threshold model, which means, for
6 every increment of exposure, there's an increment of
7 risk. Now, whether this is actually happening is
8 another story. But it is the most protective model,
9 lineal through zero.

10 Yes?

11 SPEAKER: Does that model --

12 MR. LANGER: You have to tell us your name.

13 SPEAKER: John Field, Ottawa, Canada.

14 Does that model account for -- and I realize
15 that it accounts for the amount you're exposed to, but
16 does it also account for the potential for it to
17 accumulate in your system?

18 MR. LANGER: No, of course not. It's only for
19 inhalation, and the models that we use are inhalation
20 and mesothelioma.

21 SPEAKER: No. But, I mean, is the mechanism it

1 basically gets in and chokes out the --

2 MR. LANGER: Well, there's all kinds of
3 mechanisms. Ann briefly went into this. She's
4 indicated the importance of widths. That controls
5 aerosol stability, inhalation potential, penetration
6 through the pulmonary architecture, lodging in the
7 alveolar spaces. And if you have a very narrow width
8 fiber, it penetrates from the alveolar membrane out
9 into, first, the visceral pleura and then the parietal
10 pleura, where the mesotheliomas arrive.

11 So all of these are -- these are important
12 factors. These are --

13 SPEAKER: But I guess is what I'm saying is
14 that -- I get that part. I'm just wondering, though,
15 why can the accumulation aspect -- I mean, it is
16 relevant.

17 MR. LANGER: Certainly.

18 SPEAKER: Potentially could smaller -- if a whole
19 bunch of smaller doses could essentially lead to a big
20 dose?

21 MR. LANGER: I understand that. There are certain

1 fibers in which the material accumulates, and there are
2 others where the material does not accumulate or it
3 breaks down. Chrysotile tends to break down.

4 SPEAKER: Okay.

5 MR. LANGER: This is the early stuff that
6 Chris Fogman did in 1970s.

7 SPEAKER: Okay.

8 MR. LANGER: But it's been demonstrated by other
9 techniques in other circumstances chrysotile is -- I
10 guess mineralogists will call it a labile material. It
11 is not stable in the biological environment.

12 Now, there are different components in the
13 lung so that the stability of chrysotile varies in terms
14 of where it is deposited. In some regions, it's very
15 difficult for it to get out and be mobilized.

16 Yes?

17 SPEAKER: This is Frank Ehrenfeld.

18 I want to follow up on that a little bit. I
19 think you -- I mean, you actually must have calculated
20 it on the basis of a cumulative risk over time, because
21 clearly someone who is exposed for one year is going to

1 have less risk than someone who is exposed for five
2 years or ten years at the concentration involved.

3 MR. LANGER: Yeah. We have --

4 SPEAKER: So we --

5 MR. LANGER: Sorry.

6 We calculate cumulative exposure. That would
7 be some value of fibers for whatever, fibers per cc
8 multiplied by the number of years that the individual is
9 exposed at that level.

10 SPEAKER: Right. That was your question; right?

11 SPEAKER: It does kind of address it.

12 MR. LANGER: Yes, we have a paper in press.

13 Langer, Nolan Journal of Regulatory Toxicology and
14 Pharmacology, the role of fiber type and cumulative
15 exposure in imparting mesothelioma risk, so both of
16 those factors. It's based on three mortality studies
17 out of Mount Sinai.

18 This is -- I'm sorry.

19 SPEAKER: This is Steve Wolfgang.

20 I think that .15 fiber per cc, that was
21 derived for an occupational education observation;

1 right?

2 MS. WYLIE: Yes.

3 SPEAKER: 45 years' working life, eight hours a
4 day, it was based originally on epidemiology of asbestos
5 of textile mills and that sort of thing.

6 MS. WYLIE: Crocidolite primarily?

7 SPEAKER: Right.

8 MS. WYLIE: Is that correct? Crocidolite
9 exposures primarily?

10 SPEAKER: I'm not sure.

11 MR. LANGER: Which study is that that you're --

12 MS. WYLIE: I think it's crocidolite primarily.

13 MR. LANGER: Which study is that?

14 MS. WYLIE: Regarding the risk.

15 MR. LANGER: Is that Peto's study at Rochdale?

16 SPEAKER: I can't give you a citation.

17 MR. LANGER: Okay. Yes?

18 SPEAKER: I --

19 MR. LANGER: You have to tell us your name.

20 SPEAKER: My name is Kapal Dewan, FDA.

21 Kapal Dewan.

1 MR. LANGER: That's okay for me, but he's the
2 reporter.

3 SPEAKER: My question is to be talking about the
4 topical exposure, and is there a chance it's also toxic
5 to that?

6 MR. LANGER: Well, this is a hot topic, isn't it?
7 Topical exposure?

8 SPEAKER: Yes.

9 MR. LANGER: Talc dusting the perineum and various
10 cancer in women. I don't have the foggiest feel for how
11 those particles end where they're supposed to end. I
12 don't know.

13 SPEAKER: Okay.

14 MS. WYLIE: May I comment?

15 I served on the IR panel that produced the
16 document on bottle powder; so I listened to the -- I was
17 there for two weeks, and I listened. And we never had a
18 discussion of female anatomy, and so the issue of why
19 and how it gets there is really, in my memory, I don't
20 think that that was approached. It was only the use.
21 And that there was some reference to some -- I thought

1 it was a gorilla that they held upside down -- I don't
2 know -- some bizarre thing.

3 So I think that it's -- the issue of mechanism
4 of how the talc actually gets to the ovary is unknown.

5 SPEAKER: In relation to that exposure -- any
6 other exposure over the skin, because skin in different
7 types of the body could be different. People use it
8 under the arms and many areas. Do you have any
9 information if that's been done with talc?

10 MR. LANGER: Unless it came out of a canister.

11 MS. WYLIE: I don't think so. It's -- you know,
12 70 micrometers -- and I think you can get -- I believe
13 you can get titanium dioxide of sunscreen through your
14 skin.

15 SPEAKER: Yes.

16 MS. WYLIE: Is that not correct?

17 No particles are on the order of a micron; so
18 I do think there is -- I think the vast majority of talc
19 is much too large to enter the body.

20 SPEAKER: I am just stating it the same way. How
21 do particles get -- if the size is smaller, then that

1 could be a possibility. So I'm just looking to opening
2 that discussion, that, depending upon its size and other
3 characteristics, like you said, then it's not the
4 criteria. But other criteria come into play. That's
5 what my question is. Is there any other characteristics
6 that should be --

7 MR. LANGER: I wish I could be more helpful. I
8 have no idea.

9 SPEAKER: Okay. Thank you.

10 SPEAKER: John Field again.

11 I guess -- and I know there's been some
12 controversy around this as well, but I know there were
13 excised tissues that did -- they find talc in them.

14 MS. WYLIE: I believe that's correct.

15 SPEAKER: Yes.

16 SPEAKER: Yeah. So I guess you can only argue how
17 those others get there, because if that is true, then --

18 MS. WYLIE: It doesn't mean it came up through the
19 vagina.

20 SPEAKER: No. But --

21 MS. WYLIE: No, we do not know how it got there.

1 MR. LANGER: This is a very interesting point.
2 You raise a fascinating point. Every presentation this
3 morning did not focus on talc. It focused on other
4 minerals. What about talc? Talc was found in ovarian
5 tissues. This is Henderson's study in the early 1970s.
6 What does it mean? Good point.

7 SPEAKER: The other thing -- and I'm going to play
8 the ignorant Canadian card here. I've been hearing a
9 lot of people mention the J & J lawsuits. And, I mean,
10 we're certainly not privy to any of these details.

11 Is the mechanism by which ovarian cancer is
12 occurring -- is that really being sort of mapped out to
13 asbestos impurities within the talc?

14 MR. LANGER: Well, asbestos seems like a likely
15 candidate, if it's true asbestos fiber. All of the
16 epidemiological data, all of the exposure data, all of
17 the risk analyses, risk assessments based on fiber,
18 asbestos fiber. Talc?

19 I mean, we know a great deal about asbestos.
20 We know a great deal about silica. We know a great
21 deal -- the talc -- the early talc studies are all talc

1 studies of workers who worked in tremolite talc
2 deposits. The problem was that the exposures were never
3 properly characterized.

4 You heard that this morning. People talked
5 about asbestos, whatever, without defining the nature of
6 the fiber.

7 MS. WYLIE: Yes. There's also that same IARC
8 document, and it very clearly stated that talc is not a
9 carcinogen. It very clearly states --

10 SPEAKER: Could it not -- I mean, I know some of
11 the mechanisms that were proposed is, you know, just
12 your body can't clear it and, you know, eventually it
13 creates some sort of a --

14 MS. WYLIE: There's no evidence of inflammation, I
15 understand. And I don't know why the argument would
16 hold to clay also, then. You know, I mean, you know, we
17 don't have any mechanism to know. And talc, like I say,
18 IARC says "not a carcinogen."

19 MR. LANGER: You know, Nolan is --

20 MS. WYLIE: -- for lung cancer -- lung cancer.

21 SPEAKER: Yeah.

1 MR. LANGER: Unless you smoke cigarettes.

2 MS. WYLIE: Right.

3 MR. LANGER: Nolan is engaged in a project now.

4 And those fibers have been, I suppose, put under to the
5 umbrella of asbestos minerals. That's a long time ago.

6 MS. WYLIE: That they're asbestiform?

7 MR. LANGER: Yeah. Well, they're asbestiform,
8 using it as a generic kind of morphological sense.

9 SPEAKER: So the question I have is is the data
10 for the morphological criteria for identification?

11 MR. LANGER: Oh, yes. We're going to get to that
12 right now.

13 SPEAKER: What I would like to know and understand
14 that, this morning, when we had this discussion and
15 people were talking about the nexus, so it's -- what I
16 got from that is how the sample is prepared depends --
17 and what method -- that's the key part. It sounds like
18 it's not prepared correctly and doesn't matter what
19 method you're going to use. You may get from different
20 labs data showing different results.

21 MR. LANGER: Sure.

1 SPEAKER: So what morphological criteria do you
2 think should be considered for identification?

3 MR. LANGER: Well, we're going to get into the
4 nature of this session here. I'm glad you asked that.
5 This is what the goal of this session is supposed to be:
6 to establish concurrence on morphological criteria for
7 identification of mineral fibers in the analysis of
8 cosmetics containing talc.

9 Morphology implies the visual method of
10 analysis. What are the criteria for analysis by light
11 microscopy, by electron microscopy? Are these criteria
12 the same? We have a series of questions. And at the
13 end of the discussion, we'll vote as to whether we agree
14 or disagree with it, from your own experience, from what
15 you've heard this morning, and whatever we contribute to
16 the discussion.

17 The first question is the following: Do we
18 agree that a 5-micron length particle with an aspect
19 ratio of 3 to 1 or greater, as determined by visual
20 analysis -- you can choose your own microscope -- may be
21 defined as asbestos but may also be inclusive of

1 cleavage fragments, talc fibers, and other minerals that
2 occasionally fail and yield fibrous particles?

3 Now, the definition is the federal definition
4 of asbestos. The federal definition of asbestos is one
5 of ease of microscopic analysis by light microscopy of
6 some sample. It's a standard of convenience that
7 separates nonfibrous particles, dust particles, from
8 fibers.

9 So do you agree that that could be very useful
10 in defining and determining that this material is
11 asbestos? Do you agree with that?

12 SPEAKER: I do in a sense, but my concern would be
13 is it a mineral fiber or not?

14 MR. LANGER: You mean there may be false
15 positives?

16 SPEAKER: Well, it could be something else --

17 MR. LANGER: Sure.

18 SPEAKER: -- other than a mineral fiber. We're
19 here to talk about mineral fibers.

20 MR. LANGER: You're right. Now you have
21 reservations; so you may not agree.

1 MS. WYLIE: I'll disagree. If it can't be inhaled
2 and it can't be broken out into small fibers, I don't
3 think it's sufficient.

4 SPEAKER: I would disagree with that, because you
5 can inhale particles up to 100 micrometers, as the
6 inhalable dust criteria. It doesn't go to the alveolar
7 region and probably getting into the mesothelium, which
8 was described by Dr. Mossman. But it's inhalable and
9 can end up in the lung.

10 And I think the last question is --

11 MS. WYLIE: Isn't the aerodynamic diameter 3?

12 SPEAKER: Pardon?

13 MS. WYLIE: Isn't the aerodynamic diameter of
14 getting to the lung 3?

15 SPEAKER: The reason the World Health
16 Organization, in their asbestos rule or method, has an
17 upper limit of 3 micrometers diameter is the aerodynamic
18 diameter of a fiber is to the width and, at a density of
19 that of asbestos, a 3-micron width is approximately
20 equivalent to a 10-micrometer --

21 MS. WYLIE: Micronic sphere, yes.

1 SPEAKER: So it's essentially a size that will get
2 below the bronchial entry.

3 SPEAKER: Into the alveolar?

4 SPEAKER: Right. So 3 micro- --

5 MS. WYLIE: So a 3 width, it would have to be
6 narrower than 3 microns?

7 SPEAKER: Right.

8 MS. WYLIE: But that's not what this says.

9 MR. LANGER: Well, I think that we should vote on
10 this. Do we agree that a greater than 5-micron length
11 particle with an aspect ratio of, and so on and so
12 forth, 3 to 1, as determined by some visual analysis may
13 be defined as asbestos but may also include -- it should
14 be two questions. Can you define asbestos on the basis
15 of the federal standard? If you know you're dealing
16 with asbestos in a situation, that's fine. If you're
17 looking at an isolated particle in whatever, tissue,
18 air, whatever, you can't.

19 MS. WYLIE: The original methodology that's
20 incorporated into the regulatory policy was written by
21 Liddell. I think that might be right. And in the

1 analysis and where he talks about this, he says an
2 absence of evidence to the contrary. The particles that
3 meet these definitions should be included as asbestos.
4 But if you have evidence to the contrary, then that --
5 he recognizes that's the case. So --

6 SPEAKER: I've got to believe that we're actually
7 taking ourselves down a wrong track here. You know, the
8 federal fiber definition, if you want to call it that,
9 is a definition for an index of respirable fibers on air
10 sample that could cause disease; right? And those
11 words -- "index" and "air sample" -- are very important.
12 And I just don't understand why we would want to look at
13 bulk materials and apply a definition -- a size
14 definition that is applicable to a risk assessment of
15 air samples. It just doesn't make sense to me.

16 MR. LANGER: But what you're saying is the
17 following: What you're saying is that, depending on
18 your sample, by this definition, it fails. I agree with
19 that.

20 In the United States, we have different
21 characteristics for assaying the environment. If you

1 were to work for the EPA and you were doing indoor
2 pollution studies, you wouldn't use a phase contrast
3 microscope. You would use a transmission electron
4 microscope.

5 SPEAKER: Well, yeah. I mean, there's a question
6 about that too. Because the EPA uses a transmission
7 electron microscope but uses a risk assessment based on
8 PCM fiber counts, and I have a lot of issues with that
9 position too.

10 MR. LANGER: That's very interesting. You're
11 absolutely right.

12 SPEAKER: Yeah.

13 MR. LANGER: Because the original studies -- we're
14 talking about the Mickelson update that was embraced by
15 the EPA in 1986 and revised --

16 SPEAKER: I am of the belief that, if the EPA
17 really wants to use transmission electron microscopy to
18 assess the risks of asbestos inhalation, they should do
19 it based on a risk assessment that uses TEM data.

20 MR. LANGER: I agree, but they're not going to do
21 it, of course.

1 SPEAKER: They don't have it.

2 MR. LANGER: It needs -- it takes an act of
3 Congress to change that standard.

4 MS. WYLIE: But they don't have any asbestos
5 exposures to assess it against.

6 MR. LANGER: Well, not in the United States.
7 Maybe elsewhere, yeah.

8 SPEAKER: But I don't see any reason at all why
9 the FDA has to go down the same route as the EPA and
10 just repeat, you know, these issues of the past. We --
11 you know, the FDA has the opportunity here, because it's
12 dealing with a specific material, talc, as a consumer
13 product to, you know, initiate whatever standard works
14 best for the FDA.

15 MR. LANGER: I agree with you. I agree.

16 SPEAKER: And also to add to what Martin has said,
17 for us, talc is an ingredient, but asbestos is a
18 contaminant in the ingredient. It is not the case like
19 for EPA products where asbestos may be added
20 intentionally to make a solid material.

21 MR. LANGER: Whatever, yeah.

1 SPEAKER: In the case of consumer products, such
2 as the samples, it adds it as a contaminant, not as an
3 intentional additive.

4 MR. LANGER: Yeah.

5 SPEAKER: Steve Wolfgang from FDA.

6 I think it's more akin to a naturally
7 occurring asbestos in the environment than it would be
8 to an asbestos added.

9 MR. LANGER: You're saying asbestos occurring in
10 some outcropping contributing to the environment that's
11 not an asbestos pit --

12 SPEAKER: Right.

13 MR. LANGER: -- or a mine?

14 SPEAKER: Exactly.

15 MR. LANGER: It's just present.

16 SPEAKER: Well, perhaps we should go one step
17 even, you know, closer to the kernel of this, and that
18 is to define asbestos. And since there never really has
19 been a geological definition of asbestos that's, you
20 know, accepted by everybody, the commercial and legal
21 areas have corrupted the word and turned it into

1 something for their purpose.

2 My personal definition of asbestos is anything
3 that was commercially mined and sold as asbestos, no
4 more and no less than that, which means that all of
5 those asbestos outcrops that people refer to as
6 naturally occurring asbestos would not, in my
7 definition, be asbestos. We would call them what they
8 are, nanofibrillar amphiboles or chrysotile or whatever.

9 And maybe we should just stop using the word
10 "asbestos" here and start talking about contamination of
11 talc by nanofibrillar amphiboles.

12 SPEAKER: I agree. The -- well, if you look at
13 the goals of the three sessions, we say mineral fibers.
14 We don't say asbestos.

15 MR. LANGER: Yeah. And I took issue with that
16 from the very start. Are we going to analyze mineral
17 fibers? Which talc? Structural integrals? Talc fiber?
18 Talc fiber that twists? That's easily distinguished
19 from an amphibole. All you need is a transmission
20 electron microscope and be able to do electron
21 diffraction.

1 MS. WYLIE: Just need the PLM. It's a no-brainer.

2 SPEAKER: So let me ask you this, then, just so
3 this will maybe clarify. It's just to establish
4 concurrence on morphological criteria or --

5 MR. LANGER: That is what our assignment is.

6 SPEAKER: Well, should --

7 MR. LANGER: Morphological criteria.

8 SPEAKER: -- should we propose including something
9 else?

10 MR. LANGER: I was given the assignment. It's
11 morphological criteria. If you don't think it's a way
12 to go, I agree with you. There are other diagnostics
13 that are far more specific, definitive, if you like.

14 SPEAKER: Well, all I'm thinking is what I heard
15 this from the geologist.

16 MR. LANGER: What did you hear that you liked or
17 didn't like?

18 SPEAKER: What you would expect to find in a talc
19 mine and what you need to be looking for. I thought
20 that was one of the first questions that was supposed to
21 be answered.

1 MR. LANGER: What should be --

2 SPEAKER: Types of minerals of concern in talc,
3 bullet point No. 1.

4 MR. LANGER: But that's the whole point. Those
5 talcs would never have been used as cosmetic ingredients
6 or pharmaceutical grade talcs that are used in the
7 surgical procedures.

8 SPEAKER: But didn't you say that there was mixing
9 sometimes?

10 MR. LANGER: Oh, yes. Absolutely. The cosmetic
11 grade talcs consist of mixtures. People select talcs
12 from different deposits, blend these talcs. And talcs
13 have a certain color. They allow it to be incorporated
14 with a fragrance of some kind, and the talc permits the
15 fragrance to be listed.

16 SPEAKER: I -- just speaking from our perspective
17 in Canada, what would be really incredibly useful for us
18 would be just like what we were talking a second ago, if
19 you could define what, sort of, the normal background
20 level was or how would you define like a normal
21 background. And then --

1 MR. LANGER: You mean a background level for talc?

2 SPEAKER: Sorry. No, no, no. For asbestos.

3 MR. LANGER: Oh.

4 MS. WYLIE: Asbestos or amphibole?

5 SPEAKER: Well, this is what I am getting at.

6 From our perspective it's naturally occurring, and so
7 you can't have a level of zero. Like, that's -- but
8 unless we can sort of define what a normal background
9 is -- and I know that's kind of a loaded -- then it
10 makes it very difficult for us to sort of act on things,
11 because there are two parts of this. There are trace
12 levels, and there's also the people who put it in
13 intentionally. And they're two very different...

14 MR. LANGER: All of the early studies with
15 asbestos in the environment focused on chrysotile. I
16 mean, it was a rationale thing to do. 95 percent of the
17 fibers consumed in the United States was chrysotile; so
18 people looked to chrysotile. Not only that, you
19 actually find some in the ambient air. You can look for
20 a long time and not see amphiboles.

21 MS. WYLIE: So I think we should focus more

1 future, going from here forward. I don't think we
2 should talk about what happened 30 years ago, because,
3 you know, we don't know. And it's the FDA's job right
4 now, going forward, if talc is sold under cosmetic talc,
5 how do they know it's asbestos-free? Isn't that the
6 basic issue going forward?

7 MR. LANGER: Of course.

8 MS. WYLIE: Correct, going forward.

9 And so most of the deposits that Bradley then
10 goes and shows down in California are not put in
11 cosmetics, have never, never would be, and are not put
12 there.

13 I don't think there is a background asbestos
14 level in some talc at all. There's no asbestos at all.
15 There might be a background tremolite level but not an
16 asbestos level. Asbestos occurs in very distinctive
17 geologic environments. You don't have to have it. It's
18 not distributed like magnetite as a trace element or
19 something, one fiber here and one fiber someplace else.
20 But I don't think there's -- you can talk about
21 background levels.

1 SPEAKER: Except in California.

2 MS. WYLIE: Yeah. California is weird.

3 SPEAKER: But I think the global market -- we
4 cannot limit ourselves to the discussion to your point
5 to make it very clear. I think you've got to know about
6 the mine. But I think the global market -- it would be
7 helpful for us to have a study that, yes, maybe the mine
8 maybe not be using the ones for consumer products, but
9 what about if the products are coming from all of the
10 different parts of the world? Then how do we --

11 SPEAKER: It's incredibly difficult to figure out
12 the distribute chain and know where things came from.

13 MS. WYLIE: Yeah. So we need a standard. We need
14 a dimensional standard so we can do analysis.

15 SPEAKER: That's exactly right.

16 MS. WYLIE: And I -- and, you know, toward that
17 end and to move that direction along, I think the
18 questions are do we focus only on 5 micrometers? Should
19 we start there? So should our analysis focus only on
20 particles that are longer than 5 micrometers?

21 That's what we have the occupation standard

1 for. That's what the risk assessment is based on. I'm
2 not telling you that those necessarily are the only
3 particles that may cause disease. But do we start with
4 5 micrometers for these purposes?

5 All right. And if we have 5-micrometer
6 particles, then I think we have to ask are they thin?
7 Do you have a population less than .2 or equal to .2,
8 less than .2? If the answer is yes, then I think you
9 have a fail.

10 I don't care how it's called, whether it was
11 asbestos or cleavage. If it's a reproducible and it's
12 in there, then you have a reason to say "I have some" --
13 and I don't know how much, but at least you have some
14 and you have a positive ID for the presence of asbestos.

15 SPEAKER: Going back to the 5 microns and provide
16 why 5 microns was chosen?

17 MS. WYLIE: Well, that was the occupation standard
18 put in play when this membrane filter method was
19 produced. This all goes back to the assessment of
20 occupation exposure to known asbestos. It has nothing
21 to do with anything else related.

1 SPEAKER: If you read Henry Waltman's occupational
2 hygiene review from -- I think it's 1970 or 1971 -- he
3 does touch on the choice of 5 microns at the time. And
4 it was based on results of something that was done in
5 Germany for several years prior. And I think they were
6 lobbying for 10 microns, actually, as a safe cutoff, and
7 they selected 5 to provide a safety factor.

8 MS. WYLIE: Also, reproducibility. There are
9 studies that showed that if you started counting by
10 phase contrast microscopy -- and I know there's a couple
11 of references I can give on those -- that they found
12 they had nonreproducible results. And it wasn't until
13 they began counting 5 micrometers and above that they
14 got reproducible data.

15 SPEAKER: Because there were fewer particles at
16 10 microns longer than there are 5.

17 MS. WYLIE: Right.

18 SPEAKER: But, I mean, I see a laboratory taking
19 measurements and recording lengths and widths.

20 MS. WYLIE: But you're not -- if you don't have a
21 5-micrometer particle in there, even the question is do

1 you have a problem?

2 SPEAKER: Well, as you pointed out, the number
3 sub-5-micron particles far exceed others?

4 MS. WYLIE: Yes.

5 SPEAKER: But these are related, and that's part
6 of the problem of trying to tease out a roll of actual
7 dimensions -- is that every time you have an exposure to
8 one particular size B, you have a correlated exposure
9 with another size B.

10 MS. WYLIE: They're indexed.

11 SPEAKER: So you're saying that may act as a
12 surrogate to everything that's there.

13 MS. WYLIE: Well, just for analytical purposes.
14 This is analysis. It's just a question. Do we focus
15 only on 5-micrometer particles and above?

16 SPEAKER: Does it shorten the analysis time?

17 MS. WYLIE: Well, yeah. Sure. Easily.

18 SPEAKER: Once you get -- by the way, under the
19 optical microscope, once you get below 5 micrometers, it
20 becomes harder to determine an aspect ratio of 3 to 1.
21 And when you're down around 2 micrometers under the

1 optical microscope, it's very difficult to say whether
2 it's 3 to 1.

3 MR. LANGER: What happened with the standards
4 changing from the millions of particles per cubic foot
5 to fibers per cc, and that is you went from a dust
6 standard to a fiber standard, which had limited
7 biological data to support it. But, nevertheless, that
8 occurred, and that occurred in the UK with the membrane
9 filter technique being brought over by Howard Ayers and
10 his colleagues at NIOSH. That's in the 1960s.

11 MS. WYLIE: Remember, you're not trying to
12 establish an analytical protocol that counts every fiber
13 that's dangerous or that ascends to prove -- determine
14 what's hazardous and what's not.

15 What you're looking for are hallmarks of the
16 presence of asbestos.

17 So if we start -- also, very, very short
18 particles, 1 and 2 micrometers, are very hard to
19 discriminate one from the other. You didn't really know
20 their source.

21 So if you start with 5-micrometer particles,

1 they will be present if you have asbestos. It has high
2 test strength. Long fibers persevere. 5 micrometers is
3 not very long, really. So if you start from there and
4 say "Okay. Let's only analyze those particles, and then
5 let's look for widths that conform to the most abundant
6 widths of asbestos." And if you have them, then I think
7 you would have the answer to the question.

8 SPEAKER: What do we do with a 4-micron long
9 asbestos structure that's .1 microns in diameter?

10 MS. WYLIE: They'll count it. But --

11 SPEAKER: Like, people come to me saying "Can you
12 test my product and certify that it's asbestos-free?" I
13 can't do that. You know, there's other indications.

14 SPEAKER: You cannot certify something as being
15 asbestos-free. That's ridiculous.

16 SPEAKER: Of course. But they're asking --

17 SPEAKER: If there's asbestos in the talc and you
18 find one 4-micron long fiber, then if there's any more
19 asbestos, it has a high chance of being longer than 4
20 microns.

21 MS. WYLIE: Right.

1 SPEAKER: And so at some point you will see a
2 5-micron fiber, and you say "Yes, there is asbestos."

3 If you give me a sample of talc and the only
4 thing I find in it is one 4-micron fiber, I'm not going
5 to be very worried about it.

6 SPEAKER: Right.

7 SPEAKER: I mean, statistically, that has an equal
8 chance of being zero.

9 SPEAKER: Correct. I agree.

10 SPEAKER: Even though you've seen it, which is
11 counterintuitive --

12 SPEAKER: Well, we also have to determine -- I
13 guess that's the other session -- how much do you look
14 at? How much of an area do you look at?

15 MR. LANGER: Well, you're talking about a limit of
16 detection --

17 SPEAKER: Absolutely.

18 MR. LANGER: -- and the level of fiber in some
19 sample. But they can't ask you to prove the negative.

20 SPEAKER: Oh, I agree.

21 SPEAKER: There is discussion, though, of actually

1 coming up with a number. And I've just been doing this
2 as back-of-the-envelope calculations. I know I
3 shouldn't do this. I'm not a risk assessor. I should
4 stick to my own wheelhouse.

5 But, you know, with -- as Marty pointed out
6 the word "asbestos" is fraught with, you know, emotional
7 connotation, because we all got taught that one fiber
8 can be yielded and all of the rest, and yet that is a
9 myth that's been exploded fairly recently with the
10 publication of the high risk assessment for amphibole,
11 because there they have set a reference fiber
12 concentration at which you can be exposed every day for
13 a 70-year lifetime without the risk of getting a lung
14 cancer endpoint.

15 And by "lung cancer endpoint," they mean
16 pleural thickening. And every physiologist I've ever
17 spoken to said you're not going to get mesothelioma
18 without pleural thickening.

19 So if this is a limit value that stops you
20 from getting pleural thickening -- so the fact that it's
21 a limited value that's going to stop you from getting

1 mesothelioma. Right?

2 And I've done the calculation. It's .00-

3 MS. WYLIE: Whatever.

4 SPEAKER: It's 9 times to the minus-5 per cc. And
5 if you do that calculation --

6 MR. LANGER: Is that over eight hours?

7 SPEAKER: No. 24 hours a day.

8 MR. LANGER: 24 hours a day?

9 SPEAKER: 365 days a year for a 70-year lifetime,
10 that ends up being a fiber berth of almost 6 million
11 fibers over a lifetime. And it ends up being around
12 4,000 fibers per gram of lung tissue.

13 And, you know, by the areas of publication in
14 2012, the lowest fibers of a mesothelioma patient that
15 he had in that was 110,000 fibers per gram. So it's
16 three times less than that.

17 So, I -- you know, and -- and there is a
18 point. It's in the literature that populations of
19 people that were exposed to asbestos that did not get
20 mesothelioma have less fibers in their lungs than the
21 people that do get mesothelioma.

1 MS. WYLIE: How many fibers per gram of lung was
2 that?

3 SPEAKER: Look, check my calculations.

4 MS. WYLIE: No, I'm not going to check it. Did
5 you say 100,000?

6 SPEAKER: At 2012, the lowest in the set of
7 mesothelioma patients he looked at was 110,000.

8 MS. WYLIE: 110,000. Okay.

9 SPEAKER: Correct. And I believe that there is a
10 cutoff where it's assumed that, below that level, it's
11 not very likely that you're going to get mesothelioma,
12 and above a certain level, it's likely you are.

13 And, you know, so these are calculations that
14 can be done. And then you come backtrack -- and then
15 you can look at a normal use of talcum powder, what the
16 normal concentration of dust in the air would be, the
17 time that you're using it for, the number of times you
18 use it over your lifetime, and then you can backtrack to
19 what would be the fiber concentration you would allow to
20 stay below this level. Okay?

21 And then you can work out -- that's your

1 target now. That's what you want to make sure you don't
2 exceed in any talcum product that you produce. So now
3 you've got a number.

4 And I'm telling you that the analytical people
5 among us, that's what -- we don't want to go around
6 trying to certify that this is asbestos-free, because we
7 know we can't. But we can tell you it's below a number,
8 if you tell us what number you want and here's a way to
9 do it.

10 But it -- you know, you're -- you know, you're
11 going to get those adverts, you know, like for the
12 drinking water, where the guy says "Would you like to
13 try one of these tap waters? They all contain less than
14 the amount of -- the allowable amount of lead according
15 to the EPA."

16 "Would you like one of these talcum powders?
17 They all contain less asbestos than" -- yeah. I'm
18 sorry.

19 But, you know, the fact is people have to get
20 used to this. Zero does not exist.

21 MR. LANGER: I would like to get one vote in.

1 SPEAKER: I have one question of morphological
2 function to the analysis of the counting fibers and the
3 mentions and all of that on aerosolized talc, which you
4 hear should be aerosolized under the microscope.

5 MR. LANGER: That's the way it should be done.
6 Absolutely right.

7 SPEAKER: There's information about maybe the use
8 of fluidized bed asbestos segregator, which was designed
9 as a way of determining releasable asbestos fibers from
10 things like soils, you know, as a risk assessment
11 technique. And they've tried it. And, unfortunately,
12 it just doesn't work because the talc in cosmetic
13 products is so fine that it blows up in the air too.
14 And so all it does is clog the filters up with the talc.

15 SPEAKER: But it's interesting. Because if we use
16 the airflows that Jan put together, we'd have to make
17 some adjustments based on that.

18 SPEAKER: And I did point out, but I also pointed
19 out that the original FDAS from Idaho National
20 Engineering Lab was the flow rates and such were formed
21 by calculations on movement, flow, and so on and so.

1 What they ended up with was an iteration of
2 that based on actual practical experience. And my guess
3 is, if you want to change it, you're probably going to
4 have to go through probably several iterations again
5 until you get it right.

6 So it's going to be problem.

7 SPEAKER: So, actually, our panel published the
8 Tuesday Morning articles from Goodyear from issue 40 --
9 I mean PS 40, issue 4 and the PS 43 issue 4, and we kind
10 of looked at those. We proposed the Weinstein
11 concentration method there.

12 And so -- yeah. But, anyway, I just came
13 here -- you know, one thing I agree with is to spend --
14 for our conversation, to have the comparison standard to
15 make sure -- as to the talc, to improve the asbestos
16 method, our panel is working on that. And keep an eye
17 open for our forum. And also our announcement indicates
18 we need more discussion and will support any feedback.

19 SPEAKER: Okay. Just so everybody understands
20 where we are at this point, when we wrote the letter, it
21 was at the point which we realized that the X-ray

1 diffraction was basically the no-go test.

2 MR. LANGER: That sounds pretty good. A good
3 X-ray diffraction, that's excellent.

4 SPEAKER: The X-ray diffraction, it was our
5 understanding that it was half a percent, roughly, of
6 the detection.

7 MR. LANGER: It depends on the mineral and the
8 matrix. You're right.

9 MS. WYLIE: Talc and -- chrysotile in talc.

10 SPEAKER: The back-of-the-envelope calculation,
11 how many fibers that corresponded to, caused some
12 concern.

13 MR. LANGER: I've never done the calculation. I
14 have no idea.

15 MS. WYLIE: Well, there's a lot of data on X-ray
16 and tremolite in talc. I thought it was at .1 percent.

17 SPEAKER: We believe it could be more than .1
18 percent if done by an expert who knows how to run it.

19 MS. WYLIE: Okay.

20 SPEAKER: The problem is very few laboratories and
21 pharmaceuticals have expertise in this area.

1 MS. WYLIE: And it doesn't tell you that it's
2 asbestos either.

3 SPEAKER: No, it doesn't.

4 MR. LANGER: It depends on the preparation and
5 the --

6 SPEAKER: Well, microscopy doesn't specify the
7 element and it doesn't specify diffraction, none of
8 that.

9 MS. WYLIE: You need that. If you put talc in an
10 oil that matches the indices of diffraction of talc, you
11 can find any impurity in there like that. I mean, the
12 slides I showed you, that was all talc in the
13 background. You couldn't see it, because it had the
14 same index as the oil I had. It makes it invisible.

15 But not tremolite, not amphibole, not
16 carbonate, not any of it. You can see them in these
17 very, very clearly. So PLM has got to be part of it.
18 Right.

19 SPEAKER: So by bringing us back to the question
20 of criteria, I guess the question here becomes what
21 should be the accepted criteria? What should be the

1 criteria for counting something when it's observed, say,
2 by PLM, TEM, or whatever, and what is the decision
3 point? How is the decision made as to whether that
4 material is suitable or not suitable for use?

5 MR. LANGER: I think you heard this morning the
6 plea that there are multiple instruments available and
7 that each one provides a different set of information.
8 Would you use X-ray diffraction to determine the habit
9 of a mineral? No, of course not.

10 SPEAKER: Right.

11 MR. LANGER: Form is not its strength.
12 Concentration? Well you can do well.

13 If you want to do polarized light microscopy
14 with large particles, it's fine. It's perfect, an
15 excellent instrument.

16 If you're going to have a population of fibers
17 or mineral -- elongated mineral particles that align at
18 2/10 of a micron and lower, then you need an analytical
19 electron microscope.

20 So each problem has its own set of
21 requirements -- instrumental requirements.

1 SPEAKER: Right.

2 MR. LANGER: And so if you've got a client who is
3 interested in asbestos in whatever, you can begin with a
4 light microscopy technique, polarized light microscopy.
5 Immersion oil is also proper; you can do that.

6 You could go to X-ray diffraction, get a feel
7 for how much is present of some mineral. At a 10th of a
8 micron, there is a limited amount of detection based on
9 the matrix effects. And then eventually if you detect
10 something and it might be an asbestos fiber, then you go
11 to analytical TEM.

12 Of course, no one discussed this morning the
13 time and the cost of doing analyses by analytical
14 transmission electron microscopy. Because you can have
15 an analyst spend a half a day analyzing a single
16 particle.

17 MS. WYLIE: Well, right now, they're just simply
18 counting 3 to 1 -- actually, they're 5-mic- --
19 particles that are longer than .5 micrometers and have a
20 5 to 1 aspect ratio. And it just has no bearing. It
21 has nothing to do with identifying asbestos.

1 And they -- well, the data that I showed you,
2 to me, don't show that it's in there. That's just one
3 data set. I didn't gather it. I don't know. Maybe
4 there's other data out there that I don't have.

5 But, you know, you have to have something with
6 analysis of TEM that you can be critical of. You can't
7 just say "3 to 1, longer than 5, and I find that, by
8 analysis of TEM, I have asbestos" because you're back
9 doing exactly what -- you need to show that they have
10 these particles in there, in which case, I wouldn't
11 worry about it. I would just say the talc failed.

12 MR. LANGER: Consider the Russians and the Ural
13 deposits of chrysotile. They think fiber count
14 something of a waste of time, and a lot of time. They
15 do it gravimetrically. They weigh the dust. So there's
16 an index. Our dust is running 6 percent chrysotile, and
17 they extrapolate from there and use a gravimetric assay
18 and a gravimetric health standard, whatever.

19 MS. WYLIE: If you use heavy liquids and separate
20 the talc and you look at the residue by PLM, you will
21 see that there's asbestos in there or not.

1 SPEAKER: So what if you say you're using a fluid
2 with this idea of a filter and then weighing the filter
3 afterwards of some period of time?

4 SPEAKER: Well, I sample --

5 SPEAKER: No. First off, we're not there with the
6 FDA as to technique yet. I mean, if you felt that the
7 FDA test technique had value and Julie is not convinced
8 that it does, then it would still require some time and
9 effort to evaluate it and get it right.

10 SPEAKER: I've heard it's very reproducible,
11 though.

12 SPEAKER: Hmm?

13 SPEAKER: I heard it very reproducible.

14 SPEAKER: It is. And it can go down to very low
15 levels. But the issue is, when you try to use it for
16 quantitative purposes, is that there is a recovery. You
17 don't get a hundred percent of the material in there.
18 And, in fact, for the soils that we looked at, the soils
19 that they looked at at Libby and the soils I looked for
20 erionite, the recovery was running around 1 percent.

21 SPEAKER: But for the purpose of --

1 SPEAKER: No. It's because you don't -- you don't
2 flush all of the particles out of the fluidized bed.

3 MR. LANGER: I'd like to ask you a question.

4 SPEAKER: Uh-huh.

5 MR. LANGER: I'd like to ask how much iron did you
6 find in your erionite sample?

7 SPEAKER: The -- very little. And there's a
8 problem with EDS analysis of anything that's less than
9 1 percent of the total mass. The errors with EDS are
10 huge at that level, and most people don't recognize it.
11 And they still pump out numbers to three significant
12 figures. It's just ridiculous.

13 MR. LANGER: Well, you need a handheld calculator.

14 SPEAKER: It's very easy, also, to have iron
15 amination in your EDS system, because iron is
16 everywhere.

17 We actually ran a microprobe, because that
18 ended up being better, and then we calibrated our TEM
19 EDS. We realized you have to be very, very careful.
20 It's very -- you know, it's an electron beam, for
21 heaven's sake. And zeolite is -- you heat it --

1 MR. LANGER: Easily.

2 SPEAKER: I've burned holes right through zeolite
3 particles.

4 MR. LANGER: Yeah. Easily.

5 SPEAKER: So it's not difficult. So at the end of
6 the day, being quantitative, particularly with iron, is
7 very difficult.

8 Probably a more useful assay is maybe some
9 bole, but to do that, you need a pure sample. The
10 problem is, even the purest erionite you have is
11 probably only about 85 percent pure erionite.

12 MR. LANGER: Yeah. Mixed with the mordenite
13 and --

14 SPEAKER: And what else have you got in there?
15 Probably containing iron, you know. So essentially I
16 just don't think our analytical capabilities are there.

17 MR. LANGER: Well, the bulk chemistry show a trace
18 to nil of iron. I know that many of the
19 experimentalists focus on iron as a free radical and
20 engage in a number of reactions to the behavior cycles
21 and they like iron.

1 SPEAKER: I know --

2 MR. LANGER: But there are many noniron-containing
3 materials that are biologically active, and erionite is
4 the most mesothelioma-genic material known.

5 SPEAKER: Well, I'm not certain about that.

6 MS. WYLIE: From our end.

7 SPEAKER: I'm not certain.

8 MR. LANGER: What is it that concerns you, that
9 blunts your --

10 SPEAKER: We have -- we published a paper last
11 year. The first author is Yan Marlan, if you want to
12 look it up. And it's a comparative cycle toxicity of
13 asbestos in erionite. And it appears that erionite
14 induces its toxic effect through an entirely different
15 mechanism than does asbestos.

16 MR. LANGER: Absolutely. Iron is not the sine qua
17 non. There are many other mechanisms. You're right.

18 SPEAKER: Right. And it appears that this may be
19 related to a genetic disposition of one particular group
20 of people lacking the defense mechanism that all of the
21 rest of us have.

1 MS. WYLIE: I have in my lab a drawer of erionite,
2 and I think I probably have 20 samples of erionite. And
3 the morphology is all different, and so I don't think
4 you can make generalizations about erionite. I just
5 don't.

6 MR. LANGER: They have different chemistries?

7 MS. WYLIE: They have different chemistries,
8 different morphology. It's some that may be probably
9 harmless.

10 SPEAKER: And, in fact, the chemistry of said
11 erionite also varies tremendously from particle to
12 particle based on the local ionic gradients and
13 potentials where they crystallized. And so we found
14 that you have to analyze dozens of particles even to get
15 an average. And for the exchangeable cations, we found
16 ranges from, you know, plus or minus 100 percent.

17 SPEAKER: Aren't we digressing from our goal?

18 MR. LANGER: Yes, we are digressing.

19 SPEAKER: I'm sorry.

20 MR. LANGER: But that's all the fun. Certainly.

21 SPEAKER: It is fine.

1 MR. LANGER: All right. Well, we'll never get
2 past question 1.

3 Question 2. We'll all agree that particle
4 morphology alone may in some cases exaggerate asbestos
5 by fiber count, false positives. Sure. And if you
6 don't find it, it may be a false negative, but that's
7 another story.

8 3, the third question, do we agree that
9 decreasing false positives for asbestos may be achieved
10 by the selection of an instrument that may permit the
11 analyst to observe other diagnostics that may be used to
12 distinguish among the mineral forms present?

13 If you understand that question, I would like
14 to hear from you.

15 Well, basically it says do you agree,
16 depending on the instrument you use, you're going to get
17 different results? In fact, we've just discussed that.

18 SPEAKER: Yeah.

19 MR. LANGER: Of course. It depends on the light
20 microscope, whether it's polarized light, so on and so
21 forth, and immersion oils.

1 SPEAKER: Can I ask Rob what he typically charges
2 for this package of XRD PLM on a talc sample?

3 SPEAKER: It depends on if it's one sample or many
4 or -- but it's somewhere under \$1,000 to \$1,500.

5 SPEAKER: Per sample?

6 SPEAKER: Yes.

7 SPEAKER: And so if we were interested in
8 categorizing an entire deposit or an entire mine, they
9 may have to provide you with hundreds of samples?

10 MR. LANGER: They can't -- it cannot be done. It
11 can't be done.

12 Take 1 ton of ore, a long ton at that, a
13 metric ton. How many samples do you need within that 1
14 ton to characterize it? Then you multiply that by
15 350,000 or 580,000. There aren't enough electron
16 microscopes in the world or analysts that know what
17 they're doing. That's another story.

18 MS. WYLIE: That's very important.

19 MR. LANGER: Someone with the skills and can
20 interpret the data. That is tough.

21 So all of this, when you talk about "Can you

1 characterize the deposit?" that would be ideal for all
2 of the talcs used to formulate consumer talcum product.
3 If you can do that, then you don't have to look at the
4 80 million canisters of J & J baby powder or Gold Bond
5 powder or -- and it goes on and on.

6 You have to look at market share. You have to
7 look at the number of potential samples. How many of
8 the canisters do you have to look at? This is a tough
9 problem, and it is a statistical problem. How much are
10 you going to actually look at?

11 SPEAKER: And statistics involves probability and
12 involves risks. And, you know, who's to say that a
13 canister will not get through?

14 MR. LANGER: Absolutely right.

15 MS. WYLIE: You can't analyze every canister for
16 \$1000. Come on.

17 SPEAKER: I think you've raised an important
18 point, quality assurance versus quality and control, and
19 the need for the quality assurance approach is very high
20 here.

21 MR. LANGER: Absolutely.

1 SPEAKER: So what does the QA approach look like?

2 MR. LANGER: Yeah.

3 SPEAKER: And that was discussed. Where's the
4 asbestos being mined from? So you have to start from
5 the point of origin.

6 MR. LANGER: For example, the Italian talcs.
7 We've got four analyses of Italian talc. Two are
8 negative, we think. Two are negative, and two are
9 positive for minerals. It's the same source.

10 SPEAKER: Yeah.

11 MR. LANGER: But it's like the mining industry.
12 They dropped rocks in different parts of the pit or the
13 mine. They drop rocks. Sometimes the rock is
14 juxtaposed a scene that's contaminated with whatever, an
15 unwanted fiber. They drop it, and they say "Let's bring
16 it to the mill and the mill is going to separate the
17 material. It's their problem, not ours, because we get
18 paid by the amount of rock we drop." So there's all
19 kinds of interesting issues.

20 SPEAKER: They don't like a solution, pollution.

21 MR. LANGER: Well, listen, we understand that but

1 it's a --

2 MS. WYLIE: Standard mining technique.

3 SPEAKER: Just like we have something called good
4 manufacturing practices on the drug side, and we don't
5 know if we have good mining practices.

6 MS. WYLIE: But it's standard. That's standard
7 mining. If you go into a mine and you only take the
8 highest grade of ore, say, we're mining gold, your mine
9 might last a year. If you take the highest grade of ore
10 and you mix it with a lot lower grade of ore, then your
11 mine lasts two years. And if you mix it with an even
12 lower grade and you mix it with as low a grade as
13 possible to get -- this is standard mining practice. So
14 this is not -- you're not trying to pull anything over
15 on anybody here. It's just the way that miners do it.

16 MR. LANGER: Okay. Well, we've just gone through
17 No. 3, I guess.

18 Do we agree that a decrease in false
19 positives, and so on and so forth, may be used to
20 distinguish among the mineral forms present?

21 Well, if we know the width and the size, the

1 length, and we analyze by ATM, we might be able to do
2 that.

3 Question No. 4. Do we agree, that if light
4 optical analysis is performed, that the instrument of
5 choice is the polarizing microscope, with immersion
6 oils, with a suitable range of indices of refraction?

7 You're not going to disagree with me.

8 MS. WYLIE: No, I'm not.

9 SPEAKER: I agree.

10 MR. LANGER: Good. We agree on that. It's
11 remarkable.

12 Do we agree that, if we observe a fibrous
13 particle, as defined by OSHA, a length greater than 5
14 microns, aspect ratio of 3 to 1 or greater, that the
15 presence of a continuous striation parallel to the fiber
16 length, the long axis, defines it as asbestos or more
17 likely asbestos?

18 MS. WYLIE: No.

19 MR. LANGER: I disagree with that. Yes, you're
20 right.

21 SPEAKER: I also disagree.

1 MR. LANGER: The striations. What do the
2 striations tell you? Well, you would have to do
3 something else or use a different immersion oil. Yeah.

4 MS. WYLIE: No.

5 MR. LANGER: Okay. 5, do we agree that if we
6 observe a fibrous particle, bup-ba-bup-ba-ba --

7 MS. WYLIE: 6. Go to 6.

8 MR. LANGER: Let's go to 6. Do we agree that
9 fibers with a width of about 1 micron or greater are
10 most likely cleavage fragments? Do we agree that
11 measurement of particles in a population might be useful
12 in distinguishing between asbestos and nonasbestos
13 fragments of the same mineral?

14 MS. WYLIE: Can we qualify? You could have a
15 1 micron particle of asbestos, and it's obviously a --

16 MR. LANGER: It's possible.

17 MS. WYLIE: Right. So I think if it's a single
18 crystal, then the answer would be yes.

19 SPEAKER: Well, yeah. I mean, that's the reason
20 why I'm, you know, against the air samples, because in a
21 lot of air samples these days, you may only have three

1 fibers on the air sample and if one of those is on the
2 fence, well, you know, what do you say about it?

3 The important word there is "population," and
4 I think what we need to do or we ought to do is to
5 define what is the minimum population number that we
6 need in order to be able to make this generalization as
7 to the population and not forgetting that we can have
8 mixed populations? So --

9 MR. LANGER: Sure.

10 SPEAKER: So you may have some cleavage fragments,
11 and you may have some asbestos minerals. And so, you
12 know, if you've only got two particles, you may have one
13 of each, and now what are you going to say? So what,
14 for us, is the -- what would we think is the minimum
15 number of particles that need to examine to be able to
16 make that distinction?

17 MS. WYLIE: I think you had 30 on your slide, and
18 I think --

19 SPEAKER: 30 for chemistry.

20 MS. WYLIE: If you had -- if you had 30 particles
21 that are longer than 5 micrometers, I don't think you

1 have a problem. I think you have a very clear
2 distinction on whether it's asbestos or not.

3 SPEAKER: Yeah.

4 MS. WYLIE: I really do. You know, one, that's
5 obvious, but --

6 SPEAKER: Yeah.

7 MS. WYLIE: -- you don't need that many. Asbestos
8 minerals are very uniform material. That's the nature
9 of it. If you saw the slides, I mean it's all -- it's
10 uniform. It becomes less uniform as it becomes a lower
11 quality asbestos and -- you know, but it still has its
12 characteristics.

13 SPEAKER: If you want to take a precautionary
14 approach and say that "If any of them are less than 1
15 micron width, then this indicates the possibility of
16 asbestos," then I would say the number you need is quite
17 small.

18 MS. WYLIE: But I wouldn't take the 1 micrometer
19 because that doesn't make sense of what asbestos
20 actually is.

21 SPEAKER: Well, we can argue about the precise

1 number. As I said, with the materials I created, albeit
2 artificial, only 85 was actually best separation. I
3 mean, we can argue over the precise number. But once
4 you have the number, I think, as long as you are willing
5 to say that anything less than that number is an
6 indication of asbestos, even a single particle less than
7 that number is an indication of asbestos. And we move
8 to the next level.

9 I mean that's the whole point of the D7200
10 method. It just doesn't count particles and divvy them
11 according to cleavage fragments or asbestos particles
12 and then stop. It says if you have more than so many of
13 these, you might want to go on to TEM.

14 MR. LANGER: I wouldn't --

15 MS. WYLIE: If you have enough to establish a
16 mode, I think if you have it; right? I think if you
17 have a clear mode, you have enough.

18 SPEAKER: Yeah.

19 MS. WYLIE: It could be 30. It could be 100. It
20 depends on the variance within the width measurement.

21 SPEAKER: It does. And I'm not sure that I have

1 the data immediately in my head to decide what --
2 whether it's 30 or 100. But the data is out there. You
3 know, we don't need to do further studies on this. We
4 have lots of numbers.

5 SPEAKER: The problem is there's scientific
6 definitions, but then there's also product liability and
7 legal definitions. And so will they accept a certain
8 amount of particles that we think look like asbestos but
9 may not rise to the level of being --

10 SPEAKER: What do your customers require now? An
11 actual, you know, certification from you that you have
12 looked as hard as you can and found nothing?

13 SPEAKER: We don't provide them that. They ask
14 for it, but we just give them the results down to a
15 certain detection level.

16 MR. LANGER: And that makes sense.

17 SPEAKER: And how do you define your detection
18 levels?

19 MR. LANGER: The detection limit is defined by the
20 instrument.

21 MS. WYLIE: Going back to width, Martha Warnock

1 has great -- huge studies on lung tissues of people with
2 mesothelioma, and she sent me all of her data. I have
3 all of her data.

4 MR. LANGER: Really?

5 MS. WYLIE: Yes. And the width of all of that
6 material, there were, in the hundreds and hundreds and
7 hundreds and hundreds -- I mean, huge numbers -- I think
8 I saw two particles that had a width of 2 micrometers.

9 SPEAKER: Yeah. But don't forget all of those
10 bundles broke up in the lungs.

11 MS. WYLIE: That's right. They did. That's what
12 happened.

13 SPEAKER: And they do, and I perfectly agree that
14 they do. But they may not have been fibers going in.

15 MS. WYLIE: Yeah. Yeah. They would be bundles.
16 And you could see them as bundles.

17 SPEAKER: So if I understand this, as we can --
18 the number criteria -- it's the one where they're
19 starting to come up with what's the number criteria?

20 MS. WYLIE: Yeah.

21 SPEAKER: But it's probably -- I guess, you do

1 lots of testing and have a small idea, including the
2 consumer products? We say "What should be the number
3 that you guys commonly see when you're doing a consumer
4 product, or, I guess, testing for other products -- or
5 any other products?"

6 MR. LANGER: Would you have different standards,
7 then?

8 SPEAKER: That's what I'm saying. What's the
9 number?

10 SPEAKER: I'm guessing the lab doesn't know the
11 end use of the materials that are being provided for
12 analysis.

13 SPEAKER: Well, sometimes. We get raw and
14 finished products.

15 SPEAKER: Right. But you don't always know what
16 it is. You may just get a little package.

17 SPEAKER: Anything from talc fibers to
18 non-processable tremolite.

19 MS. WYLIE: I think Martin's approach of trying to
20 go from the risk assessment has basis and establishes
21 the percentage you want analysts to focus on.

1 SPEAKER: And then we just make sure that our
2 methods can actually meet that level.

3 MS. WYLIE: Well, that's -- yeah. But that would
4 be the way I'd go. I have some data that allows you to
5 form a basis on what's tolerable.

6 SPEAKER: I think another thing is it needs to be
7 formulated so they can make compliance decisions against
8 their scrutinized procedure.

9 But what you're talking about for bulk
10 material and acceptability criteria is really kind of a
11 policy decision based on what I would call your beta
12 error. How much risk do you want to take for being
13 wrong if you say there is no asbestos when there is
14 asbestos? And that determines how many -- how far you
15 need to go. And that is a policy thing. It really
16 isn't something that science -- except maybe Martin's
17 calculation of risk can help be a guide to that policy.

18 SPEAKER: Yes.

19 MS. WYLIE: I thought so too. I thought that's a
20 real way to get at it.

21 SPEAKER: I mean, it's going to take work. I

1 mean, somebody has got to try to figure out what a, you
2 know, typical talcum dust cloud is going to be in terms
3 of concentration, how long you're likely to be in it,
4 how much -- how many particles you're likely to breathe?
5 And then, you know, figure out what percentage of those
6 particles could be asbestos and still be below the
7 standard if you use that talcum powder so many days per
8 year.

9 You know, there's work to be done. And all of
10 those assumptions, of course, can be questioned, which
11 makes it have to probably go out to public review and be
12 allowed to be questioned.

13 And it may take you 10, 15 years to get
14 through that process. I mean, I've worked on, you
15 know -- even in the scientific communities, I've worked
16 on ASTM standards where I've issued Version 16 of the
17 standard. You know, and at twice a year, that's eight
18 years. So, you know, it could take a while.

19 SPEAKER: I'd be happy if was provided information
20 that's interpretable and what are the metrics at this
21 point?

1 MS. WYLIE: We know what the limiting material
2 looks like. Yeah, we've got data. We know.

3 SPEAKER: Why did you pick that?

4 MS. WYLIE: Libby?

5 SPEAKER: Yeah.

6 MS. WYLIE: Because that's what we have --

7 SPEAKER: Because that's the only one that we have
8 a limit factor for.

9 SPEAKER: So if it's a known amphibole in the
10 environment that people are exposed to?

11 MS. WYLIE: Yeah. If there's mesothelioma
12 associated with it.

13 SPEAKER: And you can get that information right
14 out of the assessment, you know, just Google Libby
15 amphibole.

16 MS. WYLIE: And I had four analyses of Libby
17 amphiboles that were taken in very different ways by
18 different labs and analyzed, and it's the most uniform
19 material that I said I had. I couldn't believe it. I
20 couldn't believe how uniformly those percentages of each
21 of those categories of fibers were reproducible, plus or

1 minus 1.

2 SPEAKER: Right.

3 MS. WYLIE: I mean, it's amazing.

4 SPEAKER: What we need to guard against most
5 rigorously is those labs that are just willing to take
6 the money and certify zero. We know that happens with
7 asbestos fiber count in PCM. We know it happens.

8 And, you know, the only way you can guard
9 against it is by a rigorous system of participation in
10 proficiency test programs and presentation of the
11 laboratory, participation in blind PT and accreditation.
12 It's the only way.

13 MR. LANGER: You folks are welcome to sit here and
14 stay. Those of you who want to move on, by all means.
15 In fact, we're up to question 6 now, weren't we? We've
16 got a long way to go.

17 MS. WYLIE: I think we will start all over again.
18 We've got a new group, and we start all over again.

19 (Session B concluded at 3:04 P.M.)

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REPORTER'S CERTIFICATE

I, DANIEL E. WILLIAMS, RPR, certify:

That the foregoing proceedings were taken before at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony and all objections made were recorded stenographically by me and transcribed by me or under by direction;

That the foregoing is a true and correct record of all testimony given, to the best of my ability.

I further certify that I am not a relative or employee of any attorney or party, nor am I financially interested in the action.

IN WITNESS WHEREOF this 7th day of December 2018.



DANIEL E. WILLIAMS, RPR

My commission expires 08/14/22.

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