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.

COLLEGE PARK, MARYLAND

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

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

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

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

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

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

MR. LANGER: Say again?

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

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

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

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

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

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

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

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

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

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

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

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

Yes?

SPEAKER: Does that model --

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

SPEAKER: John Field, Ottawa, Canada.

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

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

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

basically gets in and chokes out the --

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

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

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

MR. LANGER: Certainly.

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

MR. LANGER: I understand that. There are certain

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

SPEAKER: Okay.

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

SPEAKER: Okay.

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

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

Yes?

SPEAKER: This is Frank Ehrenfeld.

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

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

MR. LANGER: Yeah. We have --

SPEAKER: So we --

MR. LANGER: Sorry.

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

SPEAKER: Right. That was your question; right?

SPEAKER: It does kind of address it.

MR. LANGER: Yes, we have a paper in press. Langer, Nolan Journal of Regulatory Toxicology and Pharmacology, the role of fiber type and cumulative exposure in imparting mesothelioma risk, so both of those factors. It's based on three mortality studies out of Mount Sinai.

This is -- I'm sorry.

SPEAKER: This is Steve Wolfgang.

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

right?

MS. WYLIE: Yes.

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

MS. WYLIE: Crocidolite primarily?

SPEAKER: Right.

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

SPEAKER: I'm not sure.

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

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

MR. LANGER: Which study is that?

MS. WYLIE: Regarding the risk.

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

SPEAKER: I can't give you a citation.

MR. LANGER: Okay. Yes?

SPEAKER: I --

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

SPEAKER: My name is Kapal Dewan, FDA.

Kapal Dewan.

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

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

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

SPEAKER: Yes.

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

SPEAKER: Okay.

MS. WYLIE: May I comment?

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

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

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

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

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

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

SPEAKER: Yes.

MS. WYLIE: Is that not correct?

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

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

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

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

SPEAKER: Okay. Thank you.

SPEAKER: John Field again.

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

MS. WYLIE: I believe that's correct.

SPEAKER: Yes.

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

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

SPEAKER: No. But --

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

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

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

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

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

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

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

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

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

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

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

MR. LANGER: You know, Nolan is --

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

SPEAKER: Yeah.

MR. LANGER: Unless you smoke cigarettes.

MS. WYLIE: Right.

MR. LANGER: Nolan is engaged in a project now. And those fibers have been, I suppose, put under to the umbrella of asbestos minerals. That's a long time ago.

MS. WYLIE: That they're asbestiform?

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

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

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

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

MR. LANGER: Sure.

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

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

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

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

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

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

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

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

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

SPEAKER: Well, it could be something else --

MR. LANGER: Sure.

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

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

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

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

And I think the last question is --

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

SPEAKER: Pardon?

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

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

MS. WYLIE: Micronic sphere, yes.

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

SPEAKER: Into the alveolar?

SPEAKER: Right. So 3 micro- --

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

SPEAKER: Right.

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

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

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

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

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

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

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

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

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

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

SPEAKER: Yeah.

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

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

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

SPEAKER: They don't have it.

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

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

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

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

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

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

MR. LANGER: Whatever, yeah.

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

MR. LANGER: Yeah.

SPEAKER: Steve Wolfgang from FDA.

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

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

SPEAKER: Right.

MR. LANGER: -- or a mine?

SPEAKER: Exactly.

MR. LANGER: It's just present.

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

something for their purpose.

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

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

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

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

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

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

MR. LANGER: That is what our assignment is.

SPEAKER: Well, should --

MR. LANGER: Morphological criteria.

SPEAKER: -- should we propose including something else?

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

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

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

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

MR. LANGER: What should be --

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

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

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

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

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

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

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

MR. LANGER: Oh.

MS. WYLIE: Asbestos or amphibole?

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

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

MS. WYLIE: So I think we should focus more

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

MR. LANGER: Of course.

MS. WYLIE: Correct, going forward.

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

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

SPEAKER: Except in California.

MS. WYLIE: Yeah. California is weird.

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

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

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

SPEAKER: That's exactly right.

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

That's what we have the occupation standard

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

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

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

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

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

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

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

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

MS. WYLIE: Right.

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

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

you have a problem?

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

MS. WYLIE: Yes.

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

MS. WYLIE: They're indexed.

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

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

SPEAKER: Does it shorten the analysis time?

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

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

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

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

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

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

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

So if you start with 5-micrometer particles,

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

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

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

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

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

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

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

MS. WYLIE: Right.

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

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

SPEAKER: Right.

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

SPEAKER: Correct. I agree.

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

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

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

SPEAKER: Absolutely.

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

SPEAKER: Oh, I agree.

SPEAKER: There is discussion, though, of actually

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

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

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

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

mesothelioma. Right?

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

MS. WYLIE: Whatever.

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

MR. LANGER: Is that over eight hours?

SPEAKER: No. 24 hours a day.

MR. LANGER: 24 hours a day?

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

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

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

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

SPEAKER: Look, check my calculations.

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

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

MS. WYLIE: 110,000. Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So it's going to be problem.

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

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

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

diffraction was basically the no-go test.

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

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

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

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

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

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

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

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

MS. WYLIE: Okay.

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

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

SPEAKER: No, it doesn't.

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

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

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

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

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

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

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

SPEAKER: Right.

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

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

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

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

SPEAKER: Right.

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

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

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

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

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

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

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

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

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

SPEAKER: Well, I sample --

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

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

SPEAKER: Hmm?

SPEAKER: I heard it very reproducible.

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

SPEAKER: But for the purpose of --

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

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

SPEAKER: Uh-huh.

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

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

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

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

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

MR. LANGER: Easily.

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

MR. LANGER: Yeah. Easily.

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

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

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

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

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

SPEAKER: I know --

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

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

MS. WYLIE: From our end.

SPEAKER: I'm not certain.

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

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

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

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

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

MR. LANGER: They have different chemistries?

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

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

SPEAKER: Aren't we digressing from our goal?

MR. LANGER: Yes, we are digressing.

SPEAKER: I'm sorry.

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

SPEAKER: It is fine.

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

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

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

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

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

SPEAKER: Yeah.

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

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

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

SPEAKER: Per sample?

SPEAKER: Yes.

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

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

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

MS. WYLIE: That's very important.

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

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

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

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

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

MR. LANGER: Absolutely right.

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

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

MR. LANGER: Absolutely.

SPEAKER: So what does the QA approach look like?

MR. LANGER: Yeah.

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

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

SPEAKER: Yeah.

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

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

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

it's a --

MS. WYLIE: Standard mining technique.

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

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

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

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

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

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

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

You're not going to disagree with me.

MS. WYLIE: No, I'm not.

SPEAKER: I agree.

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

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

MS. WYLIE: No.

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

SPEAKER: I also disagree.

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

MS. WYLIE: No.

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

MS. WYLIE: 6. Go to 6.

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

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

MR. LANGER: It's possible.

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

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

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

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

MR. LANGER: Sure.

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

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

SPEAKER: 30 for chemistry.

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

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

SPEAKER: Yeah.

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

SPEAKER: Yeah.

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

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

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

SPEAKER: Well, we can argue about the precise

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

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

MR. LANGER: I wouldn't --

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

SPEAKER: Yeah.

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

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

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

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

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

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

MR. LANGER: And that makes sense.

SPEAKER: And how do you define your detection levels?

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

MS. WYLIE: Going back to width, Martha Warnock

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

MR. LANGER: Really?

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

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

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

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

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

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

MS. WYLIE: Yeah.

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

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

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

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

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

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

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

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

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

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

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

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

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

SPEAKER: Yes.

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

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

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

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

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

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

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

SPEAKER: Why did you pick that?

MS. WYLIE: Libby?

SPEAKER: Yeah.

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

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

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

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

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

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

minus 1.

SPEAKER: Right.

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

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

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

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

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

(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.