JIFSAN SYMPOSIUM

ASBESTOS IN TALC

BREAKOUT SESSION A

TEST METHODS FOR ANALYSIS OF TALC AND MINERAL FIBERS IN COSMETICS

Conducted by Frank Ehrenfeld and Robyn Ray

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A P P E A R A N C E S

P R O C E E D I N G S

FRANK EHRENFELD: So let's see if we can -- we put together a little something here to keep the discussion going. But before I do, I thought it was appropriate that we could at least talk about a couple items that we covered this morning before I get going. However, I wanted to introduce ourselves up here.

I'm Frank Ehrenfeld. For those who do not know me, I'm the chair of ASTM D2207 in my spare time and then a laboratory director at International Asbestos Testing Labs in New Jersey.

To my left, a partner here for today, Robyn Ray; and Robyn is the special projects manager for asbestos for EMSL nationally, and she's doing a great job.

Robyn and I put this together to help our discussion today. At some point I hope to be directing traffic, meaning I hope I see multiple hands in the air so we can have some participation. But again, I want to start with a little bit -- a couple points that I heard this morning, and I thought it was interesting to perhaps reiterate.

Greg Meeker said, "Is it possible to protect public health without regulating everything?" So we have to keep that in the back of our mind as we go through the rest of the sessions this afternoon.

Also, in a side discussion with an anonymous source here today, who was wearing a hat last time I saw him in the hallway, Martin Harper indicated that the geologist used to own -- yeah -- geologist used to own the definition of asbestos. He says, "Now it has been turned over to the legal community."

In Greg Meeker's talk, he also had that -- just those few short words that also put things in perspective. "What does your lung know?" So what do your lungs know I think is an important concept to keep things into perspective.

I think I have one other that -- just one. Yeah. One other here that both Ann Wylie implied --come on in, Julie, we saved you a seat -- that Ann Wylie implied and that Martin Harper and others also mentioned today that maybe perhaps, not in this same sense, and that is that the original definition of asbestos, when it was being put together past 1975, had

to do with the mineral that we analysts -- that was intentionally formulated into the bulk building materials but that anything contaminated by materials or from a natural occurrence of asbestos maybe needs another definition---- that would help, perhaps, segregate employees, populations, and perhaps more problems that we are finding.

The last thing was a more practical concern, and that is in ASTM D2207, we have a terminology guild. That's D7712. And Steve Compton, are you in the room here today? Steve, yes. The problem children are having -- here in front, Martin. That's why you're there. (Audience laughs.) But it's easier than that. Steve will tell you that maintaining that document over the years has been -- it's taken a lot of your time. It is a difficult complication on his part. Same thing with the subcommittee. We will be sending around to the ASTM roster a survey -- three surveys over the next nine months to determine what definitions may stay or go or are popular or not popular or need to be revised, amended, or deleted.

The problem is, in these terminology

documents, we have multiple definitions for fiber, multiple definitions for asbestos, etc.; and this has, obviously, creating problems over the years as these were created, sometimes without knowledge of another subcommittee's work going forward. So I wanted to get that out there and I thought that would be a good place to start.

I think the ground rules for this short session today are, again, to think about the terms we have up here: talc, obviously; cosmetic talc; and then mineral fibers. Notice that our charge today does not use the word "asbestos" here. It uses "mineral fibers." And again, the objective that we got from JIFSAN was to establish concurrence on an analytical protocol for mineral fibers in cosmetics containing talc.

And this is where we want to know about the audience, so show of hands here. How many of you consider yourself geologists? Okay. Very good. How many of you are primarily lab analysts? Okay. How many that are related almost exclusively to the medical epidemiological, toxicological, biological side of

things? Show of hands. Okay. Good. How many of you are regulators, not work for a government agency but actually have a role in regulating something? Are you FDA? Okay.

So, obviously, the really cool kids here are the lab analysts, so -- but, no. We have a good population now of geologists, some people involved in the medical and biological side and regulators who want to hear what we have to say. We do this because we know that you'll be using those filters to help answer questions and move this along, and that's certainly what JIFSAN wants to know as well so --

You got all that down?

ROBYN RAY: Got it.

FRANK EHRENFELD: Okay. Thank you.

Here's some other things to consider. Some of these items were actually mentioned this morning, so in general, you know, we have prep and homogenization as very important steps to consider in any analytical method that Micky proposed.

How many here have prepped a cosmetic talc sample? Okay. We got it. And there's a number of

ways you can try to segregate the waxes and binders and everything that are present from the minerals that you're trying to detect. We've identified a few errors, as far as waxes and binders. Consequently, many times there's gravimetric reduction. There's ash and there's something you can remove that properly.

Identification of the minerals can be problematic, and we talked about that earlier; and we'll have a few examples, I'm sure, from you today about some of those problems using the various techniques and technologies that we have introduced, again, this morning that we will read this in here and another slide or two.

We talk about mineral habit as well, and again, many times it's not necessarily something that you run into on a practical basis.

When Ann was looking at some of those tremolite structures from that baby powder she found in her bathroom closet, it's -- as an analyst, when you're not Ann Wylie analyzing it, when you're somebody who's had a year or two of training and is looking at this stuff -- hey, let me sniff it. You've only had a year

or two with training with a light microscope. Please don't look at this stuff, right? But if you were, you need to have some sort of guidelines as to what's countable, what's not countable, regardless of its geological formation and habit or the definition of asbestos.

Where's the cosmetic you've used? And Julie nailed this one here. Is it going to be for -- is it going to be something regarding lip stick or is it going to be a powder that will tend to be more airborne? Do we look at these minerals and these products and do the methods change based upon the matrix that we're looking at? And as mentioned a couple of times earlier today, there is a lack of good reference standards. We can certainly find certain minerals, but where do we find certain minerals with the same binders and waxes and other items that might be in cosmetics, unless we actually go to the producers and ask them to share their formula.

So we threw other up here as well in case somebody had some sort of magical analytical technique that we're all missing, and again, whether that is

using the Brookhaven National Lab's Synchrotron or something; but I don't think there is a magic answer, and I think what we heard this morning, what we've heard from you as pain over the years and from the group at ASTM that is formulating these analytical amounts as well is that the -- having a suite of methods -- s-u-i-t-e -- would be certainly beneficial. There is good information. Marty expressed this as well. There's good information that we see when we're looking at a bulk material under a stereomicroscope on as a monolayer of particles on a slide with a light microscope with a experienced microscopist; and then additional information that can be gleaned by SEM, by EDS and certainly by TEM. XRD, there being the nonmicroscope technique where you're not actually able to see if it's even fibrous but at least you have the basic crystal structure and the chemistry. So all that was discussed this morning. We're going to circle back certainly to this.

Prep options. We mentioned gravimetric reduction. To what extent where you use a wet analytical prep method or a dry method. If it's a

raw material, certainly sieving to do some segregation by size. Milling -- but careful because we have all heard what milling does, and you certainly don't want to produce fibers, and you don't want to have to make sure there's material to interfere with you being able to detect that. Density separation, not only using methods such as Eric Chatfield's ISO, some of the elements of his method for ISO but even some of the heavy liquid separation for such things as vermiculite and sprayed on insulation. So there's a number of different analytical approaches to prep.

Solvent separation. Addison-Davis, I've heard mentioned, again, a few times this morning, where you are dissolving the other asbestos and other minerals to see if any of that contaminant asbestos might be in the property. Using the fluidized bed segregator that Ed, I think, is going to be selling for Christmas -- (audience laughs) -- that can also be used to help separate some of these minerals and at least, potentially, collect them and take them away.

And then data recording. Here the analytical method what's going to be important. We heard an awful

lot about morphology today. Session B, we're going to be talking about the measurement criteria and identifying and fiber counting; but morphology is certainly key.

And yet you also heard from Ann, "Don't talk to me about aspect ratio. That's -- may not be important." Okay? And yet the morphology we heard over and over again this morning, is important. Until you get back to what Greg's slide was: "Does your lung care if it's prismatic or some sort of fragment?" And then interpretation of: "What are we going to do with all that data? How are we going to deliver that data in an analytical method?"

Oh, RJ Lee is here today.

ROBYN RAY: Matt [Sanchez]'s right here. Matt.

Is Matt -- is he going to have a weight percent? You going to do a volume-type of quantitative approach? Is this analytical method going to be utilized while manufacturing professionals, people doing the exposure work, regulators? Is it going to be involved into the risk side of things or limitation?

Currently you can use some tried-and-true

light microscopy methods and the TEM gravimetric reduction methods that are out on the APA600. And if it's in there, and if you know what you're doing, you can find it. I think that's our last slide.

So with that, I wanted to sort of open it up and say: Where should we go and what are some of the other elements? And if you need me to, I'll go back to a certain slide if it means that it helps with the conversation.

So we had our hands up earlier for how many of us were lab rats and had experience with microscopy or XRD. I see one XRD expert here. Anybody else who's an XRD person?

AUDIENCE MEMBER 1: Besides me?

FRANK EHRENFELD: Yeah. Well, I'm looking at Gary, Julie, and Allen and Sean. They've all had experience, and yes, I have an XRD in my laboratory. I turn to Dr. Rozinski (ph) and say, "Go get me that data because I" --

AUDIENCE MEMBER 1: I can do that.

FRANK EHRENFELD: Yeah. I mean, for me, back in the day, I remember putting film on the inside of my

XRD.

AUDIENCE MEMBER 1: You're sure?

FRANK EHRENFELD: Yeah. Yeah. Okay. So I think these students and the people who are looking at that data now absolutely have -- they can't believe it. They were still in the dark at one point.

Martin?

MARTIN RUTSTEIN: Just an observation. When this thing with talc and cosmetics came up, my wife, Sean, said Sephora was holding them for women last year. I started --

FRANK EHRENFELD: She has a way out.

MARTIN RUTSTEIN: It's a great place to hang out with.

FRANK EHRENFELD: Have you got any --

MARTIN RUTSTEIN: I'm starting to go there and read the labels on what's in these containers. You've heard that one, mineral powder. There's no minerals in it. Everything under the sun. It's there, at least, is your starting point from all the -- I'll call it the "smart lid," sure.

FRANK EHRENFELD: Yeah. Speaking of reading

the labels, a large litigation case was avoided years ago when a floor tile manufacture wanted some new product tested and indeed there was tremolite detected; and I didn't say tremolite asbestos, but it was tremolite. However, there was a small portion of the population of tremolite -- it was in these brand-new floor tiles that was asbestiform tremolite asbestos.

A few laboratories -- in fact, Dr. Chatfield and I shared a presentation to Johnson two Johnson's ago, I think, on this. And after his fibrosity study he didn't -- was able to show that indeed about 0.1 percent of the overall material was asbestos tremolite. The flooring company said, "Oh, we'll take those back. We're going to give you another lot worth of floor tiles. The school was good to go. Everything's fine. But interestingly enough, only MSDS, shoot, from the manufacturer that, I guess, had the mineral come in, the dolomite. In the dolomite they listed, "Contains 1 percent tremolite." They were about spot on with that. There was -- a fraction of it was asbestos tremolite.

So back to technologies and methods, does anybody have the answers so we can just cut this short

and go to the bar? (Audience laughs.)

GREGORY MEEKER: No.

FRANK EHRENFELD: No.

AUDIENCE MEMBER 3: Can you go back to the slide on preparation?

FRANK EHRENFELD: Absolutely. And this may not have all the factors in prep but it's at least some.

AUDIENCE MEMBER 3: So you know, presumably we're here because there's health effects associated with this; and as a toxicologist, what is important to me is that the -- what we're looking at is as close as possible to the exposure material that causes the disease. In other words, is the pathway the same? Is the realm of exposure the same? Is the point of contact similar? Anything you do to a sample that moves it away from that dose -- the actual dose that causes the disease, moves you further from what you really want to know, and so -- and we saw that. I think Martin -- Martin's not here -- but this morning, for example, he showed that the little -- I forget what he called them -- little --

FRANK EHRENFELD: Adherences.

AUDIENCE MEMBER 3: -- little adherences to the --

FRANK EHRENFELD: The "Jimmies." The Jimmies on the long lost case.

AUDIENCE MEMBER 3: Right.

AUDIENCE MEMBER 4: What do you call them?

FRANK EHRENFELD: Jimmies.

AUDIENCE MEMBER 3: Jimmies.

FRANK EHRENFELD: Jimmies.

AUDIENCE MEMBER 3: It's a --

AUDIENCE MEMBER 4: More than one jimmies.

AUDIENCE MEMBER 3: That's a technical --

FRANK EHRENFELD: That's a geological term.

(Audience laughs.)

(Crosstalk)

AUDIENCE MEMBER 3: But it's that sort of thing that if you disturb that -- you know, if you use a technique that disturbs the sample in any way -- breaks fibers, it disperses bundles in a way that wouldn't happen biologically, if it causes Jimmies on the surface that you don't know anything about or its

effect -- then you really are moving away from what you want to know.

FRANK EHRENFELD: So two things. In an analytical lab, we want to follow a SOP or a method so that we can say we followed this; and so in purposing one, or for those methods that are already in development, to amend or revise and make sure we have them right. Are you saying -- because I want to get this right because Robyn's taking notes feverishly there -- don't do anything in prep that's going to alter the potential fiber content?

AUDIENCE MEMBER 3 : A fiber characteristic is what I -- and that might --

FRANK EHRENFELD: Okay.

AUDIENCE MEMBER 3: -- include content.

FRANK EHRENFELD: So fiber characteristic -- so don't mill it. Maybe don't do something else to create fibers.

AUDIENCE MEMBER 3: And you know -- to, you know, to clarify.

FRANK EHRENFELD: Yeah.

AUDIENCE MEMBER 4: My perspective as a

toxicologist again, I understand there might be reasons that you want to know, you know. You might want to know weight, you might want to know bulk. But in terms of what you want to know for disease characterization, the least amount of disturbance to that sample is critical; and, in order to address that, in some situations, we've turned to what's called exposure-based monitoring, where you actually pick the sample up from the breathing zone. NIOSH has done this for decades and decades.

FRANK EHRENFELD: An activity base?

AUDIENCE MEMBER 4: Activity-based monitoring. If you need a way to simulate that, the fluidized bed, which Martin, I think, also mentioned this morning --is a, you know, a close rendition of that for solid- phase sampling.

FRANK EHRENFELD: I see a few show of hands. Let's keep moving with that, but I would submit that in its purchased form, lipstick is not going to cooperate but, certainly, powder would. Steve (ph)?

STEVE: That's exactly what I was going to

ask, is how do you feel about some kind of an application so that we're collecting an air sample as opposed analyzing the bulk product.

AUDIENCE MEMBER 4: See, I think you're -- you -- again, there are situations where you want to analyze the bulk and you don't really care what the disturbance to the sample is because you want to know the weight or whatever; but I -- it's hard for me, as a toxicologist, to think of a way that you couldn't simulate the exposure. If you fix this lipstick you're concerned about, you want to collect that sample off the lips of someone who used that sample. (Audience laughs.)

AUDIENCE MEMBER 4: Is this a personal -- is this a personal reflection?

AUDIENCE MEMBER 3: It happens. It happens.

FRANK EHRENFELD: Okay. We have a number of hands up. I want to keep moving.

AUDIENCE MEMBER 5: I've done a number of contact samples, and so much of what you get has -- unless it's a straight-up talcum powder, which often isn't, has a lot of other materials in there that you

will not be able to analyze that sample unless you do something to get rid of those. I've seen where it's up to 90 percent of the materials, and there's waxes, there's cellulose, there's coloring in there. So -- and then the process of getting rid of that is going to grab microproduction. You're gonna burn the sample. Other times we can alter some sonication involved with it to try to free it up. That's going to change the nature of the fibers, but the task of the lab is often, "Tell me what's in there and how much of it is in there."So we have a different concern than you do, but there's often not a way for us to determine what's in there without altering the sample.

AUDIENCE MEMBER 3: I get that. I get that. And don't --

AUDIENCE MEMBER 5: Separation --

(Crosstalk)

AUDIENCE MEMBER 3: Let me just quickly respond to that.

FRANK EHRENFELD: Very aggressive.

AUDIENCE MEMBER 3: Let me just quickly --

FRANK EHRENFELD: Follow up to that and we're

done.

AUDIENCE MEMBER 3: -- respond to that. It's common in my world that the matrix for the poison is always a problem. It's always different. I mean, if you're looking at pure product, this is going on glyphosate, which is a big problem right now. We look at -- if you go to the hardware store and we get 15 different formulations of glyphosate, they're all different and they all have different toxicities. That's the only point I'm trying to make.

FRANK EHRENFELD: Yep. Okay. Gary.

GARY: Well, you just bring up a good point. So you're on -- let's say you're out on a cosmetic -- I'd say in a wax matrix. So the process, the formulation, the people that made that are making -- they have a process; and they're saying that, to the best of their knowledge, that product is uniformly wax coated. So it's actually almost like encapsulating even the potential problem that you're talking about. So you would always look at the material as is. That's the way I approach everything. I don't care if I got rocks, whatever. I do studies, I look at it

incrementally. That's the way I educated myself on what -- how to do things during sample preparation. If you remember the original Crayola problem, 2000-2001, they did a study. What did they do? They sat there and they got a Crayon and they went like this, and guess what? They found nothing. Why? It's in it. It's in a matrix that will not release it. Even though you would burn it off, ground measure it, reduction, (inaudible), quote, transition structures, whatever, it never was going to be released. And I thought, so it is product specific here with some cases, so you have to use common sense in how we approach things. Now, if you go back, it's the provider of the raw material of the talc --

FRANK EHRENFELD: Yeah. Go ahead and finish that up.

AUDIENCE MEMBER 3: Okay. I didn't know if Sean had a problem, but --

FRANK EHRENFELD: No. No. No. Sean does have a problem.

AUDIENCE MEMBER 5: It's not my usual problem.

AUDIENCE MEMBER 3: All right.

(Crosstalk)

AUDIENCE MEMBER 3: So there it's on -- you know, it's the producer's problem up front to do the analytical characterizations prior to the end use consumer product, okay? And I understand what you're saying.

FRANK EHRENFELD: God's given me about three or four other hands up, Greg. I'll get to you in a second. We'll do Sean next, but maybe we can also say this: Perhaps the exposure side of this is another issue and the detection, the technologies, the techniques, the prep, the homogenization that might have to be used to do what you're charged to do how much is in there -- right? -- and what is it may have to be a separate type of technique, but well noted.

Okay. Sean.

SEAN: Well, that's a good segway. The problems with your segway: We've got a product, and why do we suspect that there might be asbestos in the first place? Because it had talc in it, all right? In

testing, like you said, Andreas, thousands of cosmetics that's made in a laboratory. Because of their recent issues, do we see it when mica is the number one ingredient? Rarely, if ever. Do we see it when talc is not listed as an ingredient in those cosmetic? Rarely, if ever. The issue is asbestos in the talc, and we know that that's plausible.

So we did testing by burning a piece of those Crayola Crayons back in the day, and we found the talc was from RT Vanderbilt and it did have anthophyllite and tremolite in the Crayons, so it's in there. Now the question Chris was asking is answered by the test that you're alluding to, where you took a Crayon, rubbed it all over you, took air samples, found out if regular use is really going to be suffice. Well, that's -- I think what we need to do every time we deal with asbestos in cosmetics, just like we did with asbestos in crayons. First thing we need to establish is whether or not there are releasable --potentially releasable, countable, asbestos structures in product. So the first thing you got to do is get rid of anything that might be interfering. So there

you have your -- first make sense.

FRANK EHRENFELD: I got it. So then you go do the Karate Kid method -- wax on, wax off.

SEAN: Wax off. Only wax.

Okay. Robert.

ROBERT: Well, I just wanted to say I was involved with the OSHA regulations concerning cleavage fragments, and when you read what came out in the federal registry, OSHA said you should actually use a mineral science to define what fibers are. In whatever the lung sees, it has nothing to do with whether or not -- what the mineralogical identification of the fibers are. If the cleavage fragments were carcinogenic, they would be in a cleavage fragment standard. You don't make cleavage fragment asbestos because they cause mesothelioma. We're not going to make erionite asbestos because it causes mesothelioma.

In this question, miles continues to persist in this area but OSHA clearly did not want to regulate cleavage fragments as asbestos. They didn't say they were safe, but they didn't want them to meet asbestos standards. So I finally see the biological properties

are separate from the mineral properties. This is a cleavage fragment. It's a mineralogical definition, and then there's the biological definition of the health effects. Because the cleavage fragments, they tried really to kind of convince you they were the same as asbestos. So they were going to do it by analogy. They didn't have the respirable analytical data or you do the data that shows response to the (inaudible).

AUDIENCE MEMBER 6: Which outcome are we trying to protect from? Is it cancerous side or the noncancerous side?

ROBERT: Well, you're obviously trying to protect from both, but you should use mineral science to define what the minerals are.

AUDIENCE MEMBER 7: Yes. So if you're gonna -- if there's like a court case or something, when you go to court, the first thing you're going to have to establish is what is in the starting material and it has to be reproducible and verifiable. So then when you -- the next step is on the exposure, which is what you're talking about. That opens like endless areas of argument between multiple sides. Well, how -- does

that really simulate the exposure? You know, so the starting point is you have to have a bulk analysis and then you have to move on to the exposure.

FRANK EHRENFELD: And I think that is the -- what we are charged to help have some sort of consensus here today.

Greg.

GREGORY MEEKER: Two comments. What if the kid eats the crayon? (Audience laughs.) And then on the cleavage fragment issue, once it's identified as a cleavage fragment, it's ignored by a lot of people. And --

AUDIENCE MEMBER 2: Once it's identified as a cleavage fragments, it's ignored by a lot of people.

GREGORY MEEKER: Once someone says, "This is a population of cleavage fragments," then everyone assumes, oh, it's not a problem. We don't have to worry about it.

FRANK EHRENFELD: Right. Which, again, Greg gets back to, hey, what does my method or SOP say? If I'm a bench analyst, am I counting it, not counting it, bending it? Do I count everything? But, yeah, I

agree with you. A lot of that stuff's probably ignored.

I have one down here, then I'll get the back.

Greg, anything else to finish up that thought?

GREGORY MEEKER: Well, no. (Audience laughs.)

FRANK EHRENFELD: That gets us back to the quote that I had from you earlier, which is: "To what extent do we have to -- can we protect the public health without regulating everything?"

GREGORY MEEKER: I mean, if it's long and thin, it's probably going to behave the same way. I'm sorry. If it's the same size, same shape, it doesn't matter what you call it.

FRANK EHRENFELD: Yeah.

GREGORY MEEKER: No one has shown that, that I know of.

AUDIENCE MEMBER 2: Lee, I want to the back just to the different analytical methods and kind of coming up with this industry is a "TEM snob." "TEM's the best." I've come to realize -- the example I told over lunch, where I'm looking at Nytal, and I -- if I'm friends with anthophyllite, you're having a hard time

finding asbestiform tremolite, but then you run it by XRD, which everyone agrees it's got horrible sensitivities; it's worthless; you can't use it; and it tells you that it's about 55-60 percent tremolite, which I never saw unless I'd run it by XRD. The point I'm getting at is all these tools -- you know, PLM gives you a population. It helps you to find the population of asbestos that's in that material. Electron microscopy will show you a completely different population of fibers that's possibly in or not in that material as does XRD; and even the prep methods, you know, there's a big push right now with the heavy liquid separation which would -- talc works well for, say, iron-rich species -- tremolite or cummingtonite. It will -- it's effective for that, but you'll never find an anthophyllite that doesn't have iron in it. You're not going to find chrysotile using heavy liquid separation, so you have to go back to the EPA 600 or behind a tree to have any hopes of finding this. So I guess -- that's the only point I'm making is there's not a simple -- a lot of people say, well, you know, asbestos is just one thing. Which method is

the best? And really, depending on the -- with something like talc, it takes every tool we have in the tool box to even get close.

FRANK EHRENFELD: So can I reiterate that to say that all these tools can be used, they each have advantages, disadvantages, and it's gonna have to be matrix specific as well?

AUDIENCE MEMBER 2: I would -- to get to the right answer, all of those -- all the tools available to us need to be utilized, including things like, potentially, gravimetric reduction.

FRANK EHRENFELD: And unlike analyzing for asbestos in a ceiling tile or a floor tile, this is not going to be some 5-dollar light microscopy method. And so those that will be providing these services have to somehow differentiate themselves from those who are doing this routinely on building materials I imagine. That then gets us back to where are the reference materials.

Yes, sir.

AUDIENCE MEMBER 8: Well, I was saying that. You just said what I was going to say. I mean, as a

retired analytical chemist and toxicologist, the thing that scares me to death is Martin's talk where he says there's not very many standards even left out there. Some of them are buried out in South Africa somewhere; and you know, without standards, we can't qualify the methods we're using that drives the narrative, that takes the court action, that -- it won't stand up. So where are we going with this?

FRANK EHRENFELD: Well, this is where it gets back to either FDA or JIFSAN or somebody to say -- or USP to say, okay, manufacturers of cosmetics formulate these or get us RTI; and say, hey, RTI, we're going to provide you with a five-gallon pail of our base material; and if you could spike or blend in fractured Lone Pine tremolite at a certain percentage -- because we need to have some studies done as far as what's the recovery of certain methods based upon the size of fibers and a multitude of other variables on the analytical side.

AUDIENCE MEMBER 2: Right.

AUDIENCE MEMBER 9: A couple questions that are -- it's more of a question to the analysts. First

of all, what is the definition of cosmetic talc? And what type of products -- I mean, baby powder, lipstick. But what kind of products are we talking about?

FRANK EHRENFELD: Sean? Gary?

SEAN: Yeah. Those two should answer that question --

FRANK EHRENFELD: Okay. Yeah.

SEAN: -- as far as what defines cosmetic, yeah.

GARY: Physical, chemical, mineralogical.

SEAN: It doesn't matter.

FRANK EHRENFELD: Well, I mean --

SEAN: Question: How do we -- give us your definition because I have doubts.

FRANK EHRENFELD: A certain purity but what is that based on?

GARY: Well, there's -- they're all --

AUDIENCE MEMBER 6: They're in their new standards, probably the USP Standard is the one that we use most of the time. To turn in the quality, it's typically a certain pure --

GARY: It's also particle size to the cosmetic

--

STEVE: Physical.

GARY: I believe it's about 90 percent or greater talc -- the mineral talc.

That's two

hundred mesh or less, particle size.

FRANK EHRENFELD: Platy talc?

GARY: And they do allow certain other constituents like chlorite in talc but not above a certain limit.

AUDIENCE MEMBER 6: I can give you the definition if you want it as a reference.

AUDIENCE MEMBER 4: Yeah, I do.

AUDIENCE MEMBER 10: CTFA did issue several years ago, a definition of what cosmetic talc is.

AUDIENCE MEMBER 4: Yeah.

AUDIENCE MEMBER 10: I don't know whether that's changed over time, but --

AUDIENCE MEMBER 2: And it's not --

(Crosstalk)

AUDIENCE MEMBER 2: It doesn't -- it has nothing to say that it has to be 99 percent.

FRANK EHRENFELD: If I can have your attention, please.

AUDIENCE MEMBER 2: CTFA or the USP monograph, if you look at the attributes, there's many attributes. You look at it. You're ranging between 82 to 85 percent or better talc. The rest can be chlorite, carbonates, and other accessory minerals.

AUDIENCE MEMBER 6: Yep.

AUDIENCE MEMBER 2: CTFA is a little higher standard, probably more like 90 percent -- 92 percent, but it has nothing to do with you have got to have 99.99 percent talc to be cosmetic or pharmaceutical.

STEVE: Okay.

AUDIENCE MEMBER 2: There's physical attributes that have to be met as well --

STEVE: Right.

AUDIENCE MEMBER 2: -- which are even more important in some respects because of its properties are used in an end-use consumer.

BRAD: And platy --

FRANK EHRENFELD: Okay. Hold on. One at a time. Brad, does that answer your question or at least part of it?

BRAD: Not quite. Platy -- because if it were fibrous, it wouldn't -- or could it still qualify?

BRAD: Yeah. Playtiness, obviously gives it -- the word is liden (ph), you know --

STEVE: Lubricity .

AUDIENCE MEMBER 7: It wouldn't get very high quality talc --

BRAD: Yeah.

AUDIENCE MEMBER 7: -- if it was in what you're talking about.

AUDIENCE MEMBER 2: That's what I thought. And then what cosmetics does it end up in?

GARY: There's a lot.

AUDIENCE MEMBER 2: A lot?

AUDIENCE MEMBER 6: Industrial probably has a --

(Crosstalk)

GARY: A lot of different types.

AUDIENCE MEMBER 6: -- because of -- I

apologize -- but I mean, it's different -- but it's different monographs. We're not -- we're not (inaudible) cosmetic talc. They're the ones that would have fibrous talc.

FRANK EHRENFELD: So I'm also conscious of the time that we have right now. We're trying to make sure that we cover multiple aspects. Okay.

So thank you for your volunteering just for the group here. You get a receipt on the wait out. (Audience laughs.) Robyn's gonna have a question for Catherine.

ROBYN RAY: Yeah, just for clarification for the purposes of this discussion. Do you want the definition of the official USP Standard for talc?

AUDIENCE MEMBER 2: From USP?

ROBYN RAY: Yeah.

AUDIENCE MEMBER 2: Sure?

ROBYN RAY: Okay. I can get you that.

AUDIENCE MEMBER 2: Okay.

STEVE: That's the CTFA definition for cosmetic talc. The department --

FRANK EHRENFELD: It's probably very close to

that but --

GARY: Yep.

FRANK EHRENFELD: As we know in this industry, every word --

ROBYN RAY: Oh, believe me, USP --

FRANK EHRENFELD: -- every comma counts.

ROBYN RAY: -- every word counts.

FRANK EHRENFELD: Absolutely.

Martin?

MARTIN RUTSTEIN: Gary mentioned a few minutes ago other dangerous things in this product, in cosmetics? I Googled it. I got five hits on 10 to 12 dangerous things that cause -- things you should be aware of, bla, bla, bla. Only one of them in Australia mentioned talcum powder. They say the evidence was very weak.

The others are witches brew of organics and inorganic compounds, especially the oleander, that are problematical. So I suggest if you go looking at cosmetics, you're not going to look at the list of the stuff that they put in there. Woman have to be crazy to put this stuff on -- people have to be crazy --

ROBYN RAY: Not crazy.

MARTIN RUTSTEIN: Look how quick her --

(Audience laughs.)

MARTIN RUTSTEIN: I'm not shaming you. Please.

ROBYN RAY: Uh-huh.

MARTIN RUTSTEIN: This stuff is really a witches brew.

FRANK EHRENFELD: Okay.

AUDIENCE MEMBER 9: I think he was looking at this.

FRANK EHRENFELD: Yes.

MARTIN RUTSTEIN: Well, I'm working on it.

FRANK EHRENFELD: So I would like to turn our attention now to a couple other things, again, because of the time. And that is the analytical technique and/or technologies that would be used. We've heard about some of the prep and some of the pluses and minuses, how it could be used, how it could be limited, how it can be aggressive, or how maybe it shouldn't be that aggressive if we want to preserve what might be in

that product.

Let's talk about the technology. We saw some PLM micrographs up here today. We saw SEM, XRD Spectra; of course, TEM.

Pluses and minuses, hey, use them all. By the way, if you're going to use them all, have a disclaimer saying you didn't find anything with, you know, technique one, in order to confirm you need to also use technique two and three. Any thoughts from the group here today about the technologies and techniques?

GARY: Now, we heard a lot of this earlier about the advantages and disadvantages.

FRANK EHRENFELD: Right.

GARY: And I -- I guess I go back to what Dr. Wylie was saying, her talk about, you know, the ability of an experienced person by PLM, to pick up, evaluate a sample that way. Being a TEM guy, you know, I would also look at it by TEM, but I would not do one without the other.

FRANK EHRENFELD: Right. I agree. You can miss stuff with TEM. Martin said that, you know, you might have structures that are far greater than not

only just a field of view but multiple grid openings sometimes.

Also, if you knew that it might contain asbestos, I don't think anybody would say, "I looked at it by light microscopy. I'm done."

The other thing that Ann also indicated was, if you want to get a good reading on the width of those potential fiber structures, you have to use TEM.

GREGORY MEEKER: I think width is an important dimension that she brought up today that you can also find with PLM as well as TEM. She's tying that to what is known to be cause mesothelioma and other diseases, but the width I think is a good indicator and I think she brought up that.

FRANK EHRENFELD: And TEM would needed to discover those widths?

GREGORY MEEKER: Those thinner widths.

FRANK EHRENFELD: Yes. Okay. I have one here, and then I have two more over here. Yeah.
And this is just one question. Is there a process that allows the views -- a preferable process running

through these techniques? I mean, do you do TEM first? Do you do XRD first? Do you do PLM first?

FRANK EHRENFELD: I start with XRD, go to PLM, and then end with TEM.

GARY: So there's a decision tree involved in that?

FRANK EHRENFELD: For me, no. I do it all the same.

GARY: Same here. I do all three.

FRANK EHRENFELD: I had Sean and somebody else with a hand up. Sean.

SEAN: Yeah. Quickly, with what Ann found the tremolite in her closet, right?

FRANK EHRENFELD: Right.

SEAN: So does the room agree that if we looked at it by electron microscopy, it's possible that we could see countable asbestos structures by EM where she only saw blocky stuff by ---?

GARY: Well, as she pointed out -- she answered the question twice. By TEM, you would count that bundle. If you saw it by TEM you wouldn't try to discriminate the individual fibers in that bundle,

right?

MARTIN RUTSTEIN: I don't think that's what he asked.

SEAN: No that's not what I'm saying.

GARY: What she was saying was that you would expect to find discrete same fibers in an asbestos containing sample if you looked at it by TEM as well as PLM, but with PLM resolution, you're likely to see more of those bundles.

FRANK EHRENFELD: Sean.

SEAN: I was just saying that she found tremolite in and out in her product. Does the room agree or disagree that it's possible that there would be countable structures findable by electron microscopy in that same container?

GARY: I agree. And I think for all of those who have done that -- worked with an EM, you can go, yeah.

ROBERT: That's in every matrix, not just talc and cosmetic.

GARY: Right.

STEVE: Every single type of sampling we do

for asbestos, they're what you see by optimal microscopy is an indicator. Yeah. You might have a high percentage, but if you do it by TEM, you're going to see a lot more.

FRANK EHRENFELD: Okay. One at a time. Steve.

STEVE: And that's why in that decision tree process that we were just talking about I always start with TEM because of all the reasons that we're talking about there. That's the one that's most likely the one to find countable asbestos fibers. If I find it there, if it's positive -- and that's the question at hand -- is it there? There's no other test that's going to get overrule that.

GARY: Well, I got a clean exit then.

FRANK EHRENFELD: This is just an opportunity to have this esteemed panel. Is there a consensus on what diameter asbestos bundle can be resolved by polarized light microscopy?

GARY: Well, there's -- you can do the calculation for the limits of light and magnification.

FRANK EHRENFELD: Back before you were born,

Ian Stewart wrote a description of the inability to measure optical properties on fibers narrower than one micrometer. So you can see it, but you don't know what it is. So I think one micrometer is the boundary where you can determine the optical properties.

GARY: So there's two full questions. But you can see the 1 micrometer fiber. You just can't --

FRANK EHRENFELD: Not a 0.1.

GARY: Right. Okay.

FRANK EHRENFELD: Yeah. Okay. We have Allen and then we have Andrew.

AUDIENCE MEMBER 8: All right. I was going to say the same thing as Jim.

FRANK EHRENFELD: Okay. So then Allen and then back to you.

ALLEN: I'm trying to remember my thought here.

AUDIENCE MEMBER 10: We're both named Allen. (Audience laughs.)

ALLEN: Going back to PLM, you know, again, the value to me by PLM is, again, that example Jim just brought up with the, you know, one micrometer width.

You would expect if you had asbestos in a bulk sample looking at such a large amount of material, you would see other particles, and that goes to the population characteristics of the sample.

By TEM, I disagree if you use a founding protocol, then you see one or two fibers that meet that protocol, you have now confirmed asbestos when you deem most of this top material comes from nonasbestiform contamination. Again, going back to PLM if you have a population or even further analysis -- by TEM if you have a lot of particles, the width factors that were brought up today by TEM comes to play, and I think you can apply that and start to make some sense of what you're actually seeing.

FRANK EHRENFELD: Okay. Can we boil that down to, hey, in an analytical method in Section 16, we have to apply this -- you have to count so many particles to actually officially say that you have this hazardous fiber?

ALLEN: Well, you have to. What if you looked at it by TEM and you didn't see anything and you put it on PLM and you saw a large particles. Now you've

characterized the whole population.

FRANK EHRENFELD: Okay. Allen.

ALLEN: Okay. I guess the question I have is: Should the -- or a question maybe -- it has to do with this analytical technique. Should the FDA fund -- put out a solicitation for civil labs to develop a protocol -- I'm thinking of TEM -- such that the issues that came up in the RJ Lee Group letter that was part of the materials wouldn't arise or would solve that dilemma? And that's the question I have.

FRANK EHRENFELD: Okay.

ALLEN: Are you going to just allow that? Because if you don't have a specific technique, that's going to come up over and over and over again.

FRANK EHRENFELD: Absolutely. Let me -- let me sort of promote the ASTM way. (Audience laughs.) So Catherine -- most everybody in here is related to USP or has been on one of those panels. There's a lot of ASTM members here as well.

One of the things that ASTM has over ISO methods is that we require an inter-laboratory study to determine precision and bias and certainly

reproducibility and repeatability and confidence.

So at the end of the day, yes, Allen. If -- should some group fund a study to determine, the answer is yes, but if you heard Martin Harper, he would say, "Yeah. But can we first start with the toxicologist so that we can determine which small piece of this or that is actually maybe causing the disease before we even go there?" And yet at some point, whether it's a PLM, TEM, XRD, combination, perhaps a study per matrix needs to be involved; and maybe that's where they go to RTI and they say, "Hey, we're ending a study down the road or SRI out in California. It's going to be cosmetic talc. Can you start getting this out to reference laboratories, and FDA is paying the bill," or something, but the answer is yes. To what extent I think is the follow-up on that one.

Catherine.

CATHERINE: Yeah, Frank, just to follow up, so to put it into perspective how USP are at the meeting today, back in 2010, the CDER part of FDA submitted to USP several letters for request to strengthen specific monographs. One of those was the talc USP

monograph. At the time you recall there were several fatalities where the supply chain had been adulterated with the heparins, the glycerins. This was kind of the next phase of FDA approaching USP to put in more specific methods.

So the purview of USP is quality. It is not safety. It is not toxicology. Our goal within the panel is to come up with a method that will replace the existing method in the USP talc. So that is the scope of our work. The panel definitely can give you a lot more information in terms of, you know, the progress they have made towards getting that proposal out there; but from -- you know, from my exposure today -- pardon the pun -- I feel that we definitely need to engage all stakeholders before we put that revision proposal out in PF because I think it would be very beneficial to the panel and our expert committee to get feedback on the proposal that we will be putting in, in terms of a new method.

So I put that out there today that USP will consider some kind of a convening invitation for all stakeholders to give us comment on the proposed method

that we're putting in there. I think it's important.

FRANK EHRENFELD: Okay. I'll take one more question, then I need to slightly change the theme before we move forward. Yes.

AUDIENCE MEMBER 1: Yes. I wanted to bring up the topic you mentioned about ASTM. So before going to a test method which is going to be very specific using TEM, SEM, it could have a value that can have these steps that (inaudible) preparation of the sample if it is a -- just the material, the raw material kind of characterization versus actually in the product. So what I am hearing is that we're going on a case topic on the product containing the asbestiform or the methods for that -- the quantitative methods?

FRANK EHRENFELD: If methods that are being currently in development for ASTM, qualitative and quantitative for asbestos in talc, mineral assemblages, I think.

AUDIENCE MEMBER 3: Mineral powders?

FRANK EHRENFELD: What's that?

AUDIENCE MEMBER 3: Mineral powders?

FRANK EHRENFELD: Mineral powders. I'm sorry.

Correct. So we're working on some of these obstacles and challenges. Are you saying, hey, can you just have a prep method and then maybe can you just have a suite of methods working. Just do them all. Make sure that this method A, you say, hey, if that's not good enough, we have to use these other ones to at least eliminate all the possibilities?

AUDIENCE MEMBER 1: Yeah. So my challenge and we have almost all the (inaudible) to do all those, and we work in a nanoscience lab and we work in a nano size range not in a micro size range

FRANK EHRENFELD: Okay.

CATHERINE: Be a snob. (Audience laughs.)

AUDIENCE MEMBER 1: I have a challenge in, let's say, using an SEM or a TEM. If I quantitated my -- it is quantitative. We get excellent structural details using EES calculation analysis, but if you give me a talc product and then ask me, okay, take a gram of this, tell me how much of this asbestiform is present, this will be qualitive, not quantitive.

FRANK EHRENFELD: Right. I -- many of us here today will disagree with you. I'll give one person the

opportunity.

Sean?

SEAN: Nuts. Thank you. (Audience laughs.) We have to realize that there's some unknown problems, but this doesn't necessarily correlate to exposure. But there's a -- it gives us some sort of idea potentially. If we have a talc product that contains 7,000 countable asbestos structures per gram, it's much less likely in the same matrix as one that has 7 million asbestos structures per gram. So if we do do a quantification based on countable structures observable in the bulk material, not necessarily percentage, we are able to then know which ones are more likely to release asbestos, then we can move on to the top space where we actually simulate use. FRANK EHRENFELD: I have to move on to a slightly different theme, if it is real quick.

AUDIENCE MEMBER 4: It is quick. The structures per gram number that is used quite often in talc analysis now can be manipulated into anything you want it to be. You can find one big tremolite structure, calculate its mass and then translate that into a millions of the tiniest things you can possibly

see and then extrapolate that into structures per gram and you only saw one big structure -- not you. But I'm only saying this because I -- I saw this exactly done in a report I reviewed.

FRANK EHRENFELD: Okay. So that falls under that category we had under reporting.

AUDIENCE MEMBER 4: I know.

FRANK EHRENFELD: Right? To what extent are we going to report our data? To what extent will be qualitative or quantitative and what might be the result and in what form?

Okay. I need to get into another -- a final theme before we go forward. When the NIOSH roadmap was introduced and the elongated mineral particle concept was put out there -- now ten years ago, maybe more -- Jim Weber was present then in DC, and he purposed, slightly in the back, that it -- actually not just be EMP but be hazardous elongated mineral particles; and when they broke hemp on the board they realize that that wasn't going to fly. I. (Audience laughs.)

GREGORY MEEKER: I moved to Oregon.

FRANK EHRENFELD: That being said, we have to

make sure that we are true to our charge; and the charge here today from JIFSAN is -- if you move me back to slide one -- is for mineral fibers, right? Mineral fibers in cosmetics. So how does -- if we leave out that word "asbestos," how is that changing the complexion of anything we discussed? Meaning, hey, what about that ribbon talc? To what extent would that method capture that? What about those -- that Jim Weber or Millette -- I think Marty or somebody had a reference to the Millette 2015 --

MARTIN RUTSTEIN: Kinky Talc.

FRANK EHRENFELD: Kinky talc. Everybody perked up when somebody said "kinky." So but to what extent are these elongated mineral particles going to change the dynamic and the content of what we talk about today? Anybody? Yes.

SEAN: Let me just make a bold statement, and then I wish I was sitting closer to the door. (Audience laughs.)

CATHERINE: We'll give you a head start.

SEAN: Any elongated rock that makes its way into fiber cleavage fragment particle, it makes its

way, whether we realize or not, is going to cause inflammation. That is the initiation of a series of biochemical steps that can lead to lethal lung disease, cancer, or mesothelioma.

FRANK EHRENFELD: Okay.

SEAN: And so that's your target.

FRANK EHRENFELD: Right.

AUDIENCE MEMBER 7: Can I say --

FRANK EHRENFELD: Is it respirable? Hold on. Hold on.

SEAN: If its aspect ratio is correct, it's respirable.

AUDIENCE MEMBER 6: I guess my point is in the absence of the full mechanism, should we be reporting as much data as possible at every step? Not just what fiber -- like, okay, here's fiber retail. Here's fiber of tremolite. Then just keep recording as much data as possible so in 20 years down the line, we've gotten closer and closer. But we're losing time by not recording, I think, as much data as possible; and I think that this is the time to try to narrow that down.

FRANK EHRENFELD: Which brings us back to what

Greg's talking about earlier in your presentation. At some point -- and if you're a microscopist, you don't want to have to put that sample back in later. You want to get it all out of the way. So whatever is underneath that scope at that time, you want to count, analyze, characterize, whatever the case may be so you don't have to --

AUDIENCE MEMBER 6: You can thin out concentration any way you want, any size fiber you want.

FRANK EHRENFELD: And so then you have the data, okay? So if down the road there's a decision that, you know, ribbons of kinky talc wearing red boots are a problem, you have data to capture that. Brad.

BRAD: The good news is if you're gonna -- if we're going to stick to the discussion of talc, you're not going to find a wide variety of fibrous minerals.

AUDIENCE MEMBER 6: Okay. The actually finished product, like a lot of the talc-- a lot of the products that we've analyzed, I've seen in retail fibers left in them. There was stuff that they added to it that we're not -- they're all lost

AUDIENCE MEMBER 3: I keep thinking about rock and stuff --

FRANK EHRENFELD: Yeah. You thinking about a talc -- a talc deposit.

AUDIENCE MEMBER 3: I wouldn't put it on my face.

FRANK EHRENFELD: Instead of the talc deposit thing, cosmetic talc. Sean and a couple others, and I think we're going to try to sum up.

SEAN: Looking at a lot of these, what's the most common mineral fiber that you find in talc? Talc. All right. There's two ways it can be fibers. It can be this kinky stuff which is ribbon-y. It's more like --it exhibits its platy nature and the bends of white kinks. All right? It's still talc, and then you have blocky talc which is more often than not pseudomorphic after a fibrous parent. If it came from an tremolite or an anthophyllite parent, it looks like an anthophyllite tremolite and often can be intergrown with those mother minerals.

The other thing we see a lot when we have serpentine as a protolite is we see serpentine but more

often than not it's either antigorite or magnesium depleted chrysotile, which is actually, technically sepiolite. We see sepiolite all the time in talcs. So if we're going to look at all the known fibers that we see in talc. If we look at talc ore, it's very common to see fibrous talc -- either kinky or blocky. It's very common to see sepiolite, which has nothing to do with that thing. And then we start putting in particles we do often see -- the (inaudible) which is an interference.

FRANK EHRENFELD: I'd like to come up with a few nuggets -- bullet points here so that we can summarize this eventually. Robyn has produced a few here for us listening to the discussion. We have less alteration. The less alteration to the sample during prep, the better. Anybody vehemently disagree with that?

GARY: Yes.

FRANK EHRENFELD: Overruled. (Audience laughs.)

GARY: It's not elongated. It took Brad a long time to convince you. Now it's elongate, and it's

a fragment. It's a particular, not necessarily a fiber; and you can take a platy talc and braid it so that you get fragments parallel to the hexagonal structural framework. They're elongate. So these are particles. When we start calling them fibers or asbestiform, we're already loading the gun. I know what they are.

FRANK EHRENFELD: Right. And so to what extent would a method or an SOP either limit/censor --careful -- or allow or -- to use somebody's word --tolerate -- Martin's word -- tolerate these odd type of particle populations? Okay? And that's in the report inside as well.

So we had -- it will take more than one technique. Are we pretty much in agreement? And, yes, Steve -- Steve's like, "I'm gonna write to TEM. I'm not wasting any time and money anymore right there." And yet we also have -- yet you might miss something or you get better be on the safe side, and quite frankly, a client might want the "peon potluck" method -- don't tell anyone I said that -- but before you go to TEM, which is the terribly expensive method. So I think

that was the only word I had.

We can go right to this other method but --

GARY: Sean got hammered by the feds with a big PowerPoint because he skipped the initial methods --

(Crosstalk)

FRANK EHRENFELD: And we've all seen Sean hammered. (Audience laughs.)

The people -- no, it was unfair. It was unfair. I think what happened was that it was a Johnson conference by a really wonderful young lady standing in the corner. It's a schematic as a flowchart. (Inaudible).

FRANK EHRENFELD: Okay. So I think we're going to go with that.

ROBERT: If you go with what Robin just said and you try to characterize everything in the sample, you're going to miss a lot of the sample by only doing TEM.

ROBYN RAY: Well, that's it. My multiple techniques. I tried to characterize as much as possible through each technique so that later you can build a

better --

STEVE: One more point. The other thing is is that I guess what I heard Dr. Wylie say --and maybe other health individuals can chime in -- But it seems to me that width is the common denominator -- at least for mesothelioma, at a certain width or less it's problematic.

FRANK EHRENFELD: So that should be looked at. Let's come back to that segment. Greg.

GREGORY MEEKER: I'm not hearing SEM.

FRANK EHRENFELD: You're not hearing SEM. It's in our pantheon of technologies. If it was up there, then it's a technique that should either be explored or as an option, but perhaps none of these are individual standalone and they need to be in conjunction with another.

GREGORY MEEKER: Right. But SEM is fast. It's cheap. It's pretty. You can get very high magnifications these days.

AUDIENCE MEMBER 9: Yeah. (Inaudible) I think that ICPM can do elemental composition analysis. No, ICPMS.

FRANK EHRENFELD: So ICPMS. Possibly. That might be redundant with the XRD data and certainly under DES data for chemistry with TEM, but ICP mass spec is --

AUDIENCE MEMBER 9: Basic mass has to be quantitated. Something I can take around and then know exactly how much iron is in it. You just don't.

FRANK EHRENFELD: Just don't know if it's fiber.

GREGORY MEEKER: We do not recommend that.

FRANK EHRENFELD: Right.

GARY: Yeah, but ICPM has its --- elements.

(Crosstalk)

CATHERINE: Elements, yeah.

AUDIENCE MEMBER 9: I don't know. Something to see if it has iron or something.

FRANK EHRENFELD: Okay. Yeah.

AUDIENCE MEMBER 10: Quick question. In one of the talks they pointed out that necessity of iron being present in the fibers and correlating the biological outcome. Will any of these methods pick up how much iron is there and if it surfaced, what charge?

FRANK EHRENFELD: Wow, is that going to cost

you a lot of money after that.

AUDIENCE MEMBER 10: I know. I know but, you know. I mean, something to answer.

BRAD: I think at the end of the day, you know, the lab professionals would agree. Yeah, if you want to give me a sample that I know would have a hundred structures and I'm going to be able to take 100 different spectra and accumulate enough data where there's some sort of conference. Says, "This is good data, and I can tell you what the iron content might be," I might have to take scans of this end of that -- of that structure all the way down to this end of that structure to really get a good --

(Crosstalk)

AUDIENCE MEMBER 10: The person said the two distinguish between ferric and ferrous iron, you can't do that.

ROBYN RAY: You can't do that.

BRAD: You can't, but iron content you could.

FRANK EHRENFELD: Certainly something that we did a method would want to capture. I have Greg and then I have Jim, and then we need to do a few more

(inaudible). Go ahead.

GREGORY MEEKER: Surface with Auger are estimated. Auger.

FRANK EHRENFELD: Auger.

GREGORY MEEKER: And I'm gonna turn my pass to DR.

SEAN: That's good.

FRANK EHRENFELD: And that's -- SEM would be -- use that technique with SEM, right?

GREGORY MEEKER: Well, you can attempt scanning imagines with Auger.

FRANK EHRENFELD: Yes. Jim.

AUDIENCE MEMBER 4: I wanted to address the iron question because iron is something that Dr. Mossman has looked at in great detail, and she's a great believer that it is a primary initiator of cell responses. You talk to other pathologists, they will say, "Well, it's not really that important."

AUDIENCE MEMBER 3: I know but in toxicology free iron it does contribute to an awful lot of reactive species generations, so it's sort of like the elephant that's standing there.

GREGORY MEEKER: Well, but then is that the only method by which damage comes to the cells?

AUDIENCE MEMBER 3: No.

GREGORY MEEKER: Through free radicals.

AUDIENCE MEMBER 3: No. No. It's not the only method, but it is another method.

FRANK EHRENFELD: I had Allen. Go ahead.

ALLEN: Same analogy. Lee and I were talking last night genetic predisposition. One person has a predispositon to get mesothelioma, another doesn't. Do you ignore it, or do you quantify the iron the best you can?

AUDIENCE MEMBER 11: You (inaudible).

ALLEN: Well, yes, you look at the iron but whether or not you spend thousands of dollars on samples to determine whether or not it's FE2 or FE3--

AUDIENCE MEMBER 11: So what if he's off the (inaudible).

ALLEN: True. And all these techniques you can look at it --

FRANK EHRENFELD: Last comment, Sean, and then we need to move on. The people that just started,

cut you off.

SEAN: Just to come back into the iron thing, iron doesn't have to be part of the actual mineral in order to bring iron there. It can be biologically placed. That's why we get iron nodules on fibers, and you ask these guys -- I knew a few of them, but there's a man in the front that does a lot of them. If you look at the lung tissue, you're going to see the ferruginous bodies on almost any fiber type.

(Crosstalk)

ALLEN: Jaglets (ph) of body response (inaudible).

SEAN: Right. It's going to -- you're going to get -- yeah, the body is going to produce iron to coat. Any fiber, even silica fibers bring iron to the site which could be your toxicologic --.

GARY: Geritol.

SEAN: What?

GARY: Geritol.

FRANK EHRENFELD: Again --

(Crosstalk)

A lot of good stuff here. We want to make

sure we are just trying to formulate something here that we can put forth to the group.

So various techniques, use more than one, and we also put SEM and Auger spectroscopy on there as well. And then it's this quandary of are we going for asbestos and classical definitions in the laboratory over the years or definitions for the risk assessors for what asbestos is or definitions for the geologists and what is it for? Or are we going to go with something like EMP and what that entails? So again, we don't need to re-discuss that. I think these are some of the three main points that we discussed.

I also have written down real small to make sure we capture the larger document later, measuring for iron and being able to differentiate some of the minerals with their iron content might be important, measuring width and making sure that that data is part of the data set. It may be important. ICPMS might be added to the library of methods that we might be about to choose from.

Any other large issues that, again, fall under what we've been talking about; and I'll tell you what,

let's go through the slides again. This was our charge. We talked about -- well, we also talked about, you know, talc the deposit and perhaps talc in a cosmetic and what that implies; how it might be used; what might be holding it together or not holding it together. Reference standards, reference materials, we talked about that.

We now have a couple others that we can promote. Prep techniques, again, the general statement here which I'm clearly not altering anything; and yes, some of these techniques can be rather aggressive.

And then what are you going to do with all that data? Who's going to be the audience to you? Absolutely capture as much as possible and, you know, at some point it gets down to basic science, right? We're going to observe, measure, record document. There you go, Cline (ph). Right? You got it.

AUDIENCE MEMBER 12: The good news is that if you do mass analysis by TEM, you're doing all those careful length and width measurements. So you've got all the data to report as a mass and as structure per gram, and if you put all that data out in a report,

they can see all the widths you contend, aspect ratios, my length.

So for TEM labs -- TEM analysts here. Show of hands again. Who has done the old ASTMD5756? Right. Okay. You got to record length and width. There's a specific gravity that's thrown in there, so you can make certain calculations.

Who's done work for EPA using the old NADES -- the NADES database, right? Same thing, collect everything that you can. Throw it in there because 20 years from now, they want you to go back and look at something, and you don't want to put a sample or a grid back in that scale, right?

Is anybody else have any other final comments before we dismiss you to the bar? No, I'm sorry, to the next session. Gary.

GARY: When a structure's per gram, I think what should be presented on the denominator is the number of particles that are the nonstructures. So if you have a talc as a D50 of, let's just say, 2 micron on 5 micron, 10 micron, you should calculate a typical number; and it could be millions, and that should be

the denominator instead of what you see there is a one. Actually, your mind will see a large numerator and a one, and it says 1 gram. Your mind takes up one with possibly 10s to 100s of thousands of structures based on observing one TM structure -- calculated structures by gram. So if you think about it, it should really be represented in how many nonstructural particles are in that denominator and when you write out 10 million, 5 million with all the zeros, it's a much different perspective.

FRANK EHRENFELD: So can I summarize this thing? Put your data in context relative to what's in there?

ROBYN RAY: Yeah.

FRANK EHRENFELD: He just said, "Parts for million and parts for billions."

GARY: Right.

FRANK EHRENFELD: I had Lee. I had Greg and Shawn. Go ahead, Greg.

GREGORY MEEKER: Standards are critical and I'm not -- it's spike talc, yes; but I'm talking also about standards to analyze to see if your EDS is giving

you the right answer, okay, to see if your measurement on your image is the correct size.

FRANK EHRENFELD: Yeah.

GREGORY MEEKER: All of these things are really important, and I don't see them used enough.

FRANK EHRENFELD: Who has run out of SRM2063 to calibrate their TEMEDS? We still have a few of those glass grids left, but you know, they're carbonized and everything else.

Who's tried the Icelandic assault from USGS? Okay. Varying results? Yeah.

GREGORY MEEKER: BIR-1G is what I would recommend.

FRANK EHRENFELD: I'll be sending you an e-mail asking. Just let us know.

(Crosstalk)

GREGORY MEEKER: No, I don't -- I don't work there anymore so --

ROBYN RAY: Yeah.

FRANK EHRENFELD: That that's the Icelandic assault for you? Okay.

ROBYN RAY: Yes.

GREGORY MEEKER: Is that yes? Honey, put some in there. Yeah, RO1G is --

(Crosstalk)

FRANK EHRENFELD: Okay. I think Shawn -- Lee and Shawn, anything else?

SEAN: Go ahead.

LEE: It was just a comment on the whole fiber per gram reporting to be going back to a era where one structure could be one chrysotile .5 or a huge, you know, bundle or seven plus in a 5755 or our -- your know, Jim Millette and Steve Haze spent a -- no one has ever really successfully extrapolated the concentration like that into a risk assessment that I'm aware of, and so I've always been little cautious about that type of report.

FRANK EHRENFELD: Absolutely. Sean.

SEAN: Well, we have Steve Haze on a lot of work. He obviously did a little bit of experimental work and came up with rough categorizations. You have zero to 10,006; low to slight or none. You have 10,000 to 50,000. I don't remember the exact bracket, but he had these bins of level of severity of overall

contamination. You weren't saying this is specifically going to release this number of fibers. You just had some sort of idea in the number of asbestos structures per unit area of dust what the severity of the contamination was, and then the next step would be to go back and do, say, an aggressive air test. Well, that's the same thing that we need to do. If we have asbestos and talc, we need to say, "All right. Let's get some sort of idea how many asbestos structures there are per unit weight."

AUDIENCE MEMBER 5: We can make it (inaudible) again, so worry about the large number.

SEAN: It's the lack of SOP that concerns me.

GARY: Yeah, and that's what it comes to. The SOP is standardization, is an example of the structure per gram, and you put -- one of the problems I have is, seeing one structure, you prep your sample in such a way that you have 50 million structures per gram based on the seeing one structure. That's not a valid analysis.

FRANK EHRENFELD: It's certainly not telling the story correctly perhaps, and that's why putting it

in proper context --

GARY: And ignoring something some other technique to look at the other population. I think it's important.

FRANK EHRENFELD: Okay. I think we're done here. Julie, you have the last word.

AUDIENCE MEMBER 6: I think one thing that is really important that any method is its validation at the end of it and the way you do that is to create standards, and there is absolutely no way to create a standard with x-number of fibers. We all create standards by the weight. That's the only thing I have to say.

FRANK EHRENFELD: Okay. I want to thank you for your time today. I don't know exactly -- since we were delayed in starting on that session to start, if there's anything you think we missed, come up and let us know. Otherwise, I wanted to thank Robyn and thank you, and we'll see you at the end of the session today.

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I, KEVON CONGO, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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December 9, 2018

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CINDY FORRISTER

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