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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
1:30 p.m.

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A P P E A R A N C E S

Frank Ehrenfeld

3

Robyn Ray

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

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

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

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

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

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

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

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

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

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

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

22 The problem is, in these terminology

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

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

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

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

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

13 You got all that down?

14 ROBYN RAY: Got it.

15 FRANK EHRENFELD: Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 Oh, RJ Lee is here today.

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

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

22 Currently you can use some tried-and-true

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

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

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

14 AUDIENCE MEMBER 1: Besides me?

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

20 AUDIENCE MEMBER 1: I can do that.

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

1 XRD.

2 AUDIENCE MEMBER 1: You're sure?

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

7 Martin?

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

12 FRANK EHRENFELD: She has a way out.

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

15 FRANK EHRENFELD: Have you got any --

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

22 FRANK EHRENFELD: Yeah. Speaking of reading

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

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

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

1 and go to the bar? (Audience laughs.)

2 GREGORY MEEKER: No.

3 FRANK EHRENFELD: No.

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

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

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

1 FRANK EHRENFELD: Adherences.

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

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

6 AUDIENCE MEMBER 3: Right.

7 AUDIENCE MEMBER 4: What do you call them?

8 FRANK EHRENFELD: Jimmies.

9 AUDIENCE MEMBER 3: Jimmies.

10 FRANK EHRENFELD: Jimmies.

11 AUDIENCE MEMBER 3: It's a --

12 AUDIENCE MEMBER 4: More than one jimmies.

13 AUDIENCE MEMBER 3: That's a technical --

14 FRANK EHRENFELD: That's a geological term.

15 (Audience laughs.)

16 (Crosstalk)

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

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

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

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

14 FRANK EHRENFELD: Okay.

15 AUDIENCE MEMBER 3: -- include content.

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

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

21 FRANK EHRENFELD: Yeah.

22 AUDIENCE MEMBER 4: My perspective as a

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

10

11 FRANK EHRENFELD: An activity base?

12 AUDIENCE MEMBER 4: Activity-based monitoring.

13 If you need a way to simulate that, the fluidized bed,
14 which Martin, I think, also mentioned this morning --is
15 a, you know, a close rendition of that for solid- phase
16 sampling.

17

18 FRANK EHRENFELD: I see a few show of hands.

19 Let's keep moving with that, but I would submit that in
20 its purchased form, lipstick is not going to cooperate
21 but, certainly, powder would. Steve (ph)?

22 STEVE: That's exactly what I was going to

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

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

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

16 AUDIENCE MEMBER 3: It happens. It happens.

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

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

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

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

16 AUDIENCE MEMBER 5: Separation --
17 (Crosstalk)

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

20 FRANK EHRENFELD: Very aggressive.

21 AUDIENCE MEMBER 3: Let me just quickly --

22 FRANK EHRENFELD: Follow up to that and we're

1 done.

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

11 FRANK EHRENFELD: Yep. Okay. Gary.

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

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

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

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

19
20 FRANK EHRENFELD: No. No. No. Sean does
21 have a problem.

22

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

2 AUDIENCE MEMBER 3: All right.

3 (Crosstalk)

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

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

18 Okay. Sean.

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

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

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

1 you have your -- first make sense.

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

4 SEAN: Wax off. Only wax.

5 Okay. Robert.

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

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

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

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

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

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

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

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

7 Greg.

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

12 And --

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

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

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

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

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

4 Greg, anything else to finish up that thought?

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

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

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

14 FRANK EHRENFELD: Yeah.

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

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

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

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

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

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

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

20 Yes, sir.

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

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

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

20 AUDIENCE MEMBER 2: Right.

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

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

4 FRANK EHRENFELD: Sean? Gary?

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

7 FRANK EHRENFELD: Okay. Yeah.

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

10 GARY: Physical, chemical, mineralogical.

11 SEAN: It doesn't matter.

12 FRANK EHRENFELD: Well, I mean --

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

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

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

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

22 GARY: It's also particle size to the cosmetic

1 --

2 STEVE: Physical.

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

5 That's two

6

7 hundred mesh or less, particle size.

8 FRANK EHRENFELD: Platy talc?

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

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

14 AUDIENCE MEMBER 4: Yeah, I do.

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

17

18 AUDIENCE MEMBER 4: Yeah.

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

21 AUDIENCE MEMBER 2: And it's not --

22 (Crosstalk)

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

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

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

10 AUDIENCE MEMBER 6: Yep.

11 AUDIENCE MEMBER 2: CTFA is a little higher
12 standard, probably more like 90 percent -- 92 percent,
13 but it has nothing to do with you have got to have
14 99.99 percent talc to be cosmetic or pharmaceutical.

15 STEVE: Okay.

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

18 STEVE: Right.

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

22 BRAD: And platy --

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

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

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

8 STEVE: Lubricity .

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

11 BRAD: Yeah.

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

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

16 GARY: There's a lot.

17 AUDIENCE MEMBER 2: A lot?

18 AUDIENCE MEMBER 6: Industrial probably has a
19 --

20 (Crosstalk)

21 GARY: A lot of different types.

22 AUDIENCE MEMBER 6: -- because of -- I

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

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

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

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

15 AUDIENCE MEMBER 2: From USP?

16 ROBYN RAY: Yeah.

17 AUDIENCE MEMBER 2: Sure?

18 ROBYN RAY: Okay. I can get you that.

19 AUDIENCE MEMBER 2: Okay.

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

22 FRANK EHRENFELD: It's probably very close to

1 that but --

2 GARY: Yep.

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

5 ROBYN RAY: Oh, believe me, USP --

6 FRANK EHRENFELD: -- every comma counts.

7 ROBYN RAY: -- every word counts.

8 FRANK EHRENFELD: Absolutely.

9 Martin?

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

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

1 ROBYN RAY: Not crazy.

2 MARTIN RUTSTEIN: Look how quick her --

3 (Audience laughs.)

4 MARTIN RUTSTEIN: I'm not shaming you.

5 Please.

6 ROBYN RAY: Uh-huh.

7 MARTIN RUTSTEIN: This stuff is really a
8 witches brew.

9 FRANK EHRENFELD: Okay.

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

12

13 FRANK EHRENFELD: Yes.

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

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

1 that product.

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

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

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

13 FRANK EHRENFELD: Right.

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

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

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

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

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

9
10 GREGORY MEEKER: I think width is an important
11 dimension that she brought up today that you can also
12 find with PLM as well as TEM. She's tying that to what
13 is known to be cause mesothelioma and other diseases,
14 but the width I think is a good indicator and I think
15 she brought up that.

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

18 GREGORY MEEKER: Those thinner widths.

19 FRANK EHRENFELD: Yes. Okay. I have one here,
20 and then I have two more over here. Yeah.

21 And this is just one question. Is there a process that
22 allows the views -- a preferable process running

1 through these techniques? I mean, do you do TEM first?

2 Do you do XRD first? Do you do PLM first?

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

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

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

9 GARY: Same here. I do all three.

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

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

14 FRANK EHRENFELD: Right.

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

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

1 right?

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

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

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

10 FRANK EHRENFELD: Sean.

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

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

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

21 GARY: Right.

22 STEVE: Every single type of sampling we do

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

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

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

15 GARY: Well, I got a clean exit then.

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

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

22 FRANK EHRENFELD: Back before you were born,

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

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

8 FRANK EHRENFELD: Not a 0.1.

9 GARY: Right. Okay.

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

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

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

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

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

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

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

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

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

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

1 characterized the whole population.

2 FRANK EHRENFELD: Okay. Allen.

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

11 FRANK EHRENFELD: Okay.

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

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

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

1 reproducibility and repeatability and confidence.

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

17 Catherine.

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

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

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

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

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

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

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

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

19 AUDIENCE MEMBER 3: Mineral powders?

20 FRANK EHRENFELD: What's that?

21 AUDIENCE MEMBER 3: Mineral powders?

22 FRANK EHRENFELD: Mineral powders. I'm sorry.

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

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

12 FRANK EHRENFELD: Okay.

13 CATHERINE: Be a snob. (Audience laughs.)

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

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

1 opportunity.

2 Sean?

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

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

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

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

7 AUDIENCE MEMBER 4: I know.

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

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

21 GREGORY MEEKER: I moved to Oregon.

22 FRANK EHRENFELD: That being said, we have to

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

11 MARTIN RUTSTEIN: Kinky Talc.

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

17 SEAN: Let me just make a bold statement, and
18 then I wish I was sitting closer to the door.

19 (Audience laughs.)

20 CATHERINE: We'll give you a head start.

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

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

5 FRANK EHRENFELD: Okay.

6 SEAN: And so that's your target.

7 FRANK EHRENFELD: Right.

8 AUDIENCE MEMBER 7: Can I say --

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

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

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

22 FRANK EHRENFELD: Which brings us back to what

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

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

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

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

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

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

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

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

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

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

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

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

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

18 GARY: Yes.

19 FRANK EHRENFELD: Overruled. (Audience
20 laughs.)

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

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

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

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

1 that was the only word I had.

2 We can go right to this other method but --

3 GARY: Sean got hammered by the feds with a
4 big PowerPoint because he skipped the initial methods
5 --

6 (Crosstalk)

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

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

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

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

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

1 better --

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

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

10 GREGORY MEEKER: I'm not hearing SEM.

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

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

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

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

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

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

9 GREGORY MEEKER: We do not recommend that.

10 FRANK EHRENFELD: Right.

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

12 (Crosstalk)

13 CATHERINE: Elements, yeah.

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

16 FRANK EHRENFELD: Okay. Yeah.

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

22 FRANK EHRENFELD: Wow, is that going to cost

1 you a lot of money after that.

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

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

14 (Crosstalk)

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

18 ROBYN RAY: You can't do that.

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

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

1 (inaudible). Go ahead.

2 GREGORY MEEKER: Surface with Auger
3 are estimated. Auger.

4 FRANK EHRENFELD: Auger.

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

7 SEAN: That's good.

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

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

12 FRANK EHRENFELD: Yes. Jim.

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

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

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

3 AUDIENCE MEMBER 3: No.

4 GREGORY MEEKER: Through free radicals.

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

7 FRANK EHRENFELD: I had Allen. Go ahead.

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

13 AUDIENCE MEMBER 11: You (inaudible).

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

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

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

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

1 cut you off.

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

10 (Crosstalk)

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

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

17 GARY: Geritol.

18 SEAN: What?

19 GARY: Geritol.

20 FRANK EHRENFELD: Again --

21 (Crosstalk)

22 A lot of good stuff here. We want to make

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

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

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

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

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

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

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

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

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

3 So for TEM labs -- TEM analysts here. Show of
4 hands again. Who has done the old ASTM D5756? Right.
5 Okay. You got to record length and width. There's a
6 specific gravity that's thrown in there, so you can make
7 certain calculations.

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

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

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

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

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

14 ROBYN RAY: Yeah.

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

17 GARY: Right.

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

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

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

3 FRANK EHRENFELD: Yeah.

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

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

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

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

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

16 (Crosstalk)

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

19 ROBYN RAY: Yeah.

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

22 ROBYN RAY: Yes.

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

3 (Crosstalk)

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

6 SEAN: Go ahead.

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

16 FRANK EHRENFELD: Absolutely. Sean.

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

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

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

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

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

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

1 in proper context --

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

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

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

14 FRANK EHRENFELD: Okay. I want to thank you
15 for your time today. I don't know exactly -- since we
16 were delayed in starting on that session to start, if
17 there's anything you think we missed, come up and let
18 us know. Otherwise, I wanted to thank Robyn and thank
19 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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