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Asbestos in Talc
Session C - Interpretation of Testing Data
November 28, 2018
Moderator: Matthew Sanchez

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

2 MR. SANCHEZ: So just as a matter to start
3 out with, my name is Matt Sanchez, I am pinch
4 hitting for Micky Gunter who could not make it to the
5 meeting. Brooke Mossman is the co-moderator as well
6 with this session. Since what we're dealing with is
7 primarily microscopy results and mineral
8 identification issues, I'm going to take the lead
9 because that's more my expertise than hers.

10 I'm a former student of Mickey Gunter's.
11 I have a Ph.D. in geology with an emphasis on
12 mineralogy. I currently work for a consulting firm
13 and an analytical laboratory called the RJ Lee
14 Group, I've worked there about 12 years now. So
15 we're heavily involved with testing materials for
16 asbestos, testing building materials, testing
17 industrial minerals like talcs, regardless if it's
18 going into cosmetics or other purposes. So this is
19 kind of my background there.

20 Welcome. We have some more people, that's
21 good. You missed my introduction. It's okay.

1 The goal was not from us, you know, from
2 the moderators, this was from the symposium
3 organizers. The goal they wanted to talk about was
4 established consensus on the interpretation of
5 microscopy measurements for mineral fibers in
6 cosmetics containing talc.

7 So I had a few things in my mind to start
8 out with, and then I think we can go from there with
9 questions and just see where we go with any kind of
10 confusion that may be out there that we can help
11 with.

12 The first thing I wanted to do was in all
13 the meetings this morning and all those talks,
14 nobody ever defined a mineral, which I found
15 interesting. I think as we evaluate any type of
16 data for what we're looking at here, we're looking
17 at minerals, whether we want to call them asbestos
18 or not, that's another issue.

19 When we're just dealing with the mineral
20 identification, that has to be evaluated on any of
21 the microscopy results. Does the microscopy results

1 or other test data give us enough information to
2 actually identify the mineral?

3 So to that end, a good working definition
4 of a mineral is something that's naturally
5 occurring, it has a unique crystal structure, and
6 then it's got a relatively unique chemical
7 composition.

8 So it's very important to evaluate
9 different test methods, especially microscopy
10 methods, first of all, can the instruments do it,
11 second, if the instruments can do it, were the
12 procedures in place appropriate and adequate to
13 actually do it. There's kind of two steps there.

14 And just as a matter of discussion, and
15 kind of maybe some more background here, there are
16 lot of asbestos testing labs in the United States.
17 Most of the people in these labs have -- they've
18 attended five-day training courses on how to
19 identify asbestos, that's -- that can lead to a
20 lot -- well, it gives you a larger base of people
21 that can analyze for asbestos, but it's a large base

1 of people who don't know the fundamentals of either
2 the equipment they're using or the fundamentals of
3 the materials they're even looking at. They've been
4 taught to identify five things, generally speaking.

5 So as you get into these other types of
6 materials, especially environmental samples -- or I
7 guess I'll limit myself to talc, when you're talking
8 about things that contain talc, but more than that,
9 the content -- the goal was, you know, talc in
10 cosmetics, there's all sorts of other minerals that
11 get thrown into cosmetics as well, depending on the
12 application, there's micas, there's calcium
13 carbonates, all sorts of things get used.

14 And so, you know, are those other mineral
15 additives being added in, are those being
16 appropriately screened, are they appropriately being
17 analyzed for -- so there's not misidentification. I
18 think those are all very important points when we're
19 looking at interpretation of testing data.

20 I don't know if there's any questions. I
21 can keep going all day. Does that raise any

1 questions from the audience before we move on?

2 SPEAKER: I know we always talk about
3 cosmetics, but I'm from the FDA so the drug testing
4 has been routine for the drugs.

5 MR. SANCHEZ: Well, sure, and I --

6 SPEAKER: -- one is a different set of
7 testing than we have.

8 MR. SANCHEZ: Yeah, that's a good point.

9 SPEAKER: And actually I also want to
10 broaden it to say that not what we want to -- but
11 really there are a variety of -- not just FDA
12 regulates, but that we see in commodities that may
13 be outside of the FDA's certification. Should there
14 be a uniform way to be able to assess talc in all of
15 these products and the minerals that maybe the
16 contaminants within the talc so that instead of
17 narrowing it to cosmetics, broaden it out for all
18 products that would contain talc itself?

19 MR. SANCHEZ: Yeah, I think that's a good
20 point, and part of my basis of defining what a
21 mineral was is that context. It doesn't matter what

1 the material is, if you're using the technologies
2 that we have appropriately, you can identify any
3 mineral in any type of matrix, whether it's a talc,
4 a mica, dirt outside or wherever. You know,
5 depending on what those matrices are, other minerals
6 may be present that complicate the analysis.

7 You heard of the one this morning that
8 they kept talking about, Anthophyllites in talc, but
9 there's -- in other systems, there could be other
10 things that look very similar, so you have to take
11 additional, you know, analytical steps in what is
12 standardly done by routine asbestos testing
13 laboratories.

14 SPEAKER: I think the most -- but what
15 instrumentation do they need, what do they use to do
16 their testing?

17 MR. SANCHEZ: Most of them use either PLM
18 or TEM, so most of the analytical laboratories are
19 set up to work under the AHERA Regulation, which was
20 passed back when I was young back in 1987. And the
21 AHERA is meant for -- it stands for Asbestos

1 Emergency Response Act or something, so they set up
2 a whole testing regime of, you know, PT rounds and
3 round robins all involved with that that's
4 administered through an organization of NIST called
5 NVLAC.

6 But the methods that are used are
7 primarily an EPA test method which uses PLM,
8 polarized light microscopy, so when you have the
9 bulk samples as part of that protocol, you use PLM.
10 Once you've identified asbestos in a room and
11 they've gone in and they've removed it, then they'll
12 clear -- they run the air samples using TEM to make
13 sure that there was nothing left in the air so
14 people can go back in and occupy it.

15 When you get out there with testing talc,
16 some people are only using TEM; some people are
17 using PLM; some people use a combination. And I
18 know there was a comment made earlier -- I forget
19 who made the comment, and maybe it's not important,
20 but they talked about PLM, meaning polarized light
21 microscopy, as like not being a sophisticated

1 technique, and that's not true, each of the
2 techniques are very sophisticated.

3 You know, mineralogy is a complex science.
4 You know, what you do a mineralogist is you're
5 trying to describe nature. You know, nature is
6 incredibly complex. So there's areas in mineralogy
7 that are very -- you know, you can make general
8 statements, but then when you get into some specific
9 areas, there can be a lot of disagreement.

10 One of the areas where there's general
11 agreement in mineralogy is like what do you need to
12 identify a mineral, like that -- there's general
13 agreement on what you need to identify a mineral.
14 Once you get into the realm of whether an individual
15 particle may be asbestos or not, that's much more
16 difficult to answer there at the extreme.

17 So maybe I should walk through some of
18 this. Historically in talc, especially with the
19 cosmetic grades in the '70s, there were a few things
20 that were proposed. What was eventually settled on
21 for better or for worse was using powder x-ray

1 diffraction as like an initial screening tool.

2 Does anybody know what that is or -- some
3 general idea. I'll keep it basic, I'll just do a
4 brief review. So one of the attributes of a mineral
5 is the crystal structure. So to get measurements of
6 the crystal structure, we generally use some
7 diffraction techniques. So powder x-ray diffraction
8 allows us to take measurements of the crystal
9 structures of what's in the powder.

10 So the approach in the '70s that was
11 settled on by industry, and FDA approved of it, I
12 guess, they were involved with the discussions, they
13 were using powder x-ray diffraction to screen for
14 any amphibole and serpentine minerals. So amphibole
15 is relative to amphibole asbestos; serpentine is
16 relative to chrysotile.

17 So if you're seeing either of those two
18 mineral phases from the crystal structure point of
19 view on x-ray diffraction, you would then follow
20 that test up with light microscopy, meaning
21 polarized light microscopy, in order to determine if

1 those amphiboles or that serpentine was, in fact,
2 asbestos or not.

3 Questions?

4 SPEAKER: The sensitivity of that
5 technique, what percentage of amphibole and
6 serpentine could it detect in the powder?

7 MR. SANCHEZ: And that's a good question.
8 So with XRD it really depends on the individual
9 operators and how they were running their equipment
10 and the type of equipment they would have had. The
11 standard is like the CTFA J4, and the standard said
12 you had to be at least down to a .5 percent level,
13 0.5 percent.

14 So I've seen test data from the '70s where
15 some labs were much better, maybe down to .1
16 percent, but .5 was at least the minimum standard to
17 run that procedure. And that's just inherent in the
18 instrument because even today we can't really get
19 better than that, especially in the talc matrix.
20 You can get a lot better if you can -- you know, if
21 you can dissolve 90 percent of the material and

1 weight and analyze it, you'd be much better, but
2 with something like talc, you can't do that.

3 SPEAKER: I would ask if anybody's using,
4 you know, x-ray diffraction to do this, if you get a
5 negative, you don't see it, is the line drawn there
6 and the sample is allowed to proceed?

7 MR. SANCHEZ: Yeah, so the way the method
8 is written, that CTFA method, is if you have the
9 negative XRD you can stop. But in practice it would
10 depend upon, you know, the people doing it whether
11 they did more. So I can speak from personal
12 experience that there were multiple companies in the
13 '70s that were doing much more than just XRD, that's
14 the minimal standard. I'm sure there are plenty of
15 other people that only did that, but it would be
16 specific to an entity.

17 And I said that earlier I think in my
18 comments, you know, depending on who the mining
19 company is or who the company that may be buying the
20 talc, they could be just doing the minimal
21 requirement or they could be doing much more, it

1 really depends on the individuals.

2 SPEAKER: Speaking of the mining
3 companies. From what I understand, you can fairly
4 easily tell where the deposits that are going to be
5 getting the amphibole containing deposits versus the
6 straight talc, how do they do -- is that -- are they
7 using some type of like handheld device or how are
8 they doing -- measuring those conditions when
9 they're out there in the mines, where to stop and
10 where to keep going?

11 MR. SANCHEZ: Yeah, I can't talk
12 specifics, some of the work that I do is actually
13 going to talc mines, and I'll describe what I do
14 when I go, if that helps. Again, I can't speak, I
15 don't know what company A or B would do --

16 SPEAKER: It's more than I know now.

17 MR. SANCHEZ: So as a geologist, one of
18 the things we like to do is, you know, go outside,
19 that's why we chose to do geology as opposed to
20 something else, but actually what we do when we do
21 these assessments of these mines, we go to the mine,

1 we -- depending, sometimes they're underground, most
2 of them are open pit, but we actually walk the face
3 of the mine, we walk the areas of the mine, we look
4 at the rock that they -- you know, there was a
5 comment made earlier, too, about like something
6 about blasting the talc, and I've never been to a
7 talc mine that didn't blast, so I don't know where
8 that information is coming from.

9 Most of the talc that they're mining is a
10 very compact, dense rock. I have a big piece of it
11 on my mantel, I think it's very beautiful. But they
12 are blasting, you have piles of material that are
13 loosened by blasting, you know, we climb over those
14 piles, we pick through those piles, and what we're
15 looking for is one of the -- you know, they use the
16 term common amphiboles.

17 Common amphiboles, that term is just
18 referring to -- all sorts of rocks contain
19 amphiboles, and so from a geologist's perspective
20 and mineralogist's perspective, the idea that
21 somehow just an amphibole in and of itself is

1 somehow harmful, doesn't make sense because it's
2 everywhere, we're all exposed to amphiboles. We're
3 just exposed to amphiboles of compositions that
4 don't match the regulated specified, so nobody's
5 ever looked at them, that's the kind of situation we
6 live in.

7 So there's this unknown quantity of how
8 much amphibole people may be breathing in. I've
9 tested soil samples, you know, here in D.C. outside
10 the IRS building and it contains amphiboles, right,
11 elongated amphiboles in the soil, they were not
12 asbestos, but they were amphiboles that were
13 elongated. So you know, some of these decisions are
14 important, just as that as a piece of the content.

15 SPEAKER: Along that line, talc that does
16 not contain detectable levels of amphiboles, what are
17 the methods we use whether its XRD or something
18 that's more sensitive? I gather that from
19 discussions this morning about amphibole type and
20 serpentine type minerals are the -- in this case, the
21 only source of -- potential sources for

1 asbestos.

2 So if those types of minerals were
3 demonstrated to be absent by appropriately sensitive
4 techniques and a particular limit that someone might
5 want to set, then we can say that that talc at least
6 would be reasonably clean of asbestos or whatever
7 standard we set.

8 MR. SANCHEZ: Yeah, well it's interesting
9 the language you used because that absence of
10 asbestos test, I mean, that's the language --

11 SPEAKER: It's like proving a negative.

12 MR. SANCHEZ: Yeah, I think --

13 SPEAKER: But we do it all the time --

14 MR. SANCHEZ: Well, I've seen meeting
15 minutes from the 70s of you know they have talc
16 miners and companies using talc and the FDA, and
17 it's like the FDA were the ones that imposed that
18 language early on, but all it means is within the
19 parameters of that test, nothing was detected.

20 So whenever we're testing for things,
21 there is -- we can't test to zero, right, we have to

1 live in this de minimus world to some level where we
2 find it acceptable.

3 One of the issues we have on the
4 analytical side is I can analyze a sample to any
5 level you want me to, but the levels we operate
6 under are typically for the EPA error regulations
7 one percent; for OSHA labeling laws and regulations,
8 it's .1 percent. So you can go a couple of orders
9 of magnitude beyond that, fine, but is that enough.

10 Somebody could always make the argument we
11 didn't test enough. So I think from a side of --
12 because, yeah, I mean, it's one thing -- if I don't
13 see any amphibole here of one part per million. If
14 I go down to one part per billion, will I find it?
15 I don't know, possibly, but does that matter. I
16 think that that's an important piece that is not
17 being -- I can't address that.

18 SPEAKER: What I'm looking for is, you
19 know, for -- I'm with FDA, but I'm on the
20 methodology and office of regulatory science, and
21 it's our people that are going to be doing

1 potentially some of the testing if the FDA gets into
2 this. And so I'm trying to look at, you know,
3 potential screening options.

4 And you can look at it a couple different
5 ways, you can either identify this is a problematic
6 sample, put this over here, or you can try and come
7 up with something and say, okay, this step within a
8 certain level of tolerance, let's say from the
9 morning talk, base that level of tolerance, this
10 stuff is good to go into market; this stuff for
11 whatever parameter we use, whether we're testing
12 amphiboles or serpentines or calcium or iron or
13 whatever, this is going to need more testing.

14 So you can look at either you try to
15 identify the problem stuff right off the bat or try
16 to identify the good stuff that's safe and get that
17 in the market quicker.

18 MR. SANCHEZ: Now, yeah, and I think the
19 real -- again, I've been testing talc in a
20 laboratory now for over 11 years and I've only had a
21 couple of occasions where talc came through that

1 actually contained asbestos, and both those times
2 they were imported talcs -- well, one time it was an
3 imported talc out of Northern China. There's
4 different areas in China that mine talc, some are --
5 they're very different geologically.

6 And the other one was actually out of a
7 Death Valley mine, I don't know if it's the same one
8 that Van Gosen mentioned, but those were not for
9 cosmetic purposes, they were for industrial
10 purposes. But generally the talcs that I've tested
11 from the United States from the operating mines have
12 all been clear.

13 So I think in a lot of areas of the world,
14 depending on how developed they are and how tight
15 the -- you know, the process controlling, I think
16 there's some good -- you're talking about weeding
17 out like problems, I think the question comes into
18 what's coming in out of Pakistan. Like I have no
19 personal knowledge of anything in Pakistan.
20 Twenty-five percent importation of talc from
21 Pakistan, what's in that stuff, I don't know.

1 SPEAKER: And we have -- you know, on the
2 food side we have manufacturing practices, and
3 taking that same approach, getting industry to
4 prevent the problem before it comes out and we have
5 to deal with it, that's --

6 You know, that prevention, preventative
7 control approach, things like that, solves a lot of
8 problems for the industry and for us, saving the
9 American people, you know, time and money of us
10 going out and collecting samples and testing them
11 and all that kind of stuff.

12 MR. SANCHEZ: Yeah, I know, I know.

13 SPEAKER: And charging that against the
14 general fund, and it also keeps the industry, you
15 know, fairly fluid and, you know, minimizes the need
16 for us to get in. So thinking about preventative
17 controls, that's kind of what I'm getting into and
18 that kind of also goes back to what you were talking
19 about just then about that Chinese mine and about a
20 problem, that kind of goes back to my question about
21 how do we -- talc from various mines.

1 Apparently they've got ways of delineating
2 clearly in the mines where to go and where not to.

3 MR. SANCHEZ: Yeah, well, from just the
4 mining side, so, you know, you go, you walk the
5 faces, and so the formation of amphiboles depending
6 on the deposit, could be something - a lot of
7 deposits they mine today really don't have any
8 amphibole in them, and Brad talked about the
9 Southwestern Montana mines, you know, one of the
10 issues is the --

11 So composition is only factor in what
12 controls what minerals may be present somewhere, the
13 other factors are temperature pressure conditions.
14 So when you're in talc deposits where the pressure
15 temperature conditions are very low, geologically
16 speaking, you generally don't have any amphiboles
17 because amphiboles don't form under those conditions.

18 So where you find the amphiboles, these are
19 these higher pressure temperature environments, they
20 talked about the one area in Death Valley and

21

1 you talk about, you know, Upstate New York talcs
2 where you can get quite a bit amphibole depending on
3 the deposits.

4 When you actually go into the mines
5 themselves, generally when -- most, not all --
6 again, there's always exceptions to all general
7 statements, I don't know if we all appreciate that,
8 but generally speaking, when asbestos is forming in
9 nature, it's forming as -- it's not forming as a
10 primary like mineralization with the rest of the
11 rock, it's usually forming at some bit of an
12 alteration, some secondary mineralization affect.

13 Typically those are occurring along fault
14 zones or other areas in the rock that are undergoing
15 some kind of shear or tensile strength, tensile
16 pressure type of environment. So if my hands were
17 the rock, where you -- you know, from like a fault
18 zone what you would have is you'd have rocks that
19 are slightly passed each other.

20 So as you have that fissure in the rock
21 and those rocks sliding past each other, the

1 temperatures and pressures in that localized zone is
2 very different than just the stuff a foot away
3 sometimes. So as that rock goes, the fluid flows
4 all the way in and along the fault surface, it has
5 the elements it needs and in the right conditions,
6 and you could form asbestos in those environments.

7 Other environments where the rock are just
8 pulling apart like a dilation, so as that rock pulls
9 apart, that interstitial area gets filled with
10 fluids from the surrounding rock and then it will
11 crystalize stuff out of that. So, you know, the rock
12 is pulling apart, so at that second mineralization
13 is where the asbestos is occurring those kind of
14 features.

15 So the first place you look for asbestos
16 in the mines is your looking for those fault zones,
17 you're looking for those features. And generally
18 speaking, you know, if you go up and they blast a
19 section of the mine -- I've never seen this at a
20 talc deposit, I've seen this in other just like
21 aggregate quarries around the United States -- if

1 there's an asbestos vein there, the rock breaks
2 along the asbestos vein, it's a plane of weakness.

3 So you could like walk up and there's big,
4 hairy rock sitting there. The whole rock isn't
5 hairy, it's just the surface where it broke away
6 because you actually had like an asbestos
7 formitization happening.

8 So, you know, that is a lot of what goes
9 in mines. I can't speak for every mine, but
10 ideally, you know, they're walking the faces,
11 they're evaluating, they know if there's any problem
12 areas and they're not mining that area, ideally.
13 Who knows, right. But I've been to talc mines where
14 there's actually nothing there.

15 I have been to a talc mine in South
16 America where there was one zonation in the mine, a
17 clear fault zone, clear offset at both sides of the
18 rock along the fault zone and there was asbestiform
19 everywhere, and they did not mine that area, they
20 mined -- it was five meters on each side, they waste
21 all that material.

1 And in the testing of the talcs from that
2 deposit, we never saw that material ever in the
3 talc. So it seems to me like with the testing and
4 looking at the procedures, that they were adequately
5 not including that in their mining product. But not
6 every mine would even have that, so it really
7 depends on the specific mines and their locations
8 and how they handle it on the mine side.

9 SPEAKER: So asbestos basically forms in
10 veins?

11 MR. SANCHEZ: Generally speaking, yes.
12 There are other occurrences and -- you know, some of
13 the debate of the -- and it's funny because we
14 talked -- you know, they talked about Death Valley
15 talcs and Vanderbilt -- Vanderbilt Northern New York
16 talcs, none of those talcs were used for -- none of
17 them are used today.

18 And to my knowledge, I don't think any of
19 those talcs were ever used for pharmaceutical or
20 cosmetic purposes, but I could be wrong on some of
21 the Death Valley ones, but my understanding is those

1 New York talcs were never used for the purposes of
2 the meeting today.

3 But there's a question about
4 anthophyllite, whether the anthophyllite is an
5 asbestiform kind or just regular, but when you
6 have -- this is just a nuance, and it gets
7 complicated at times, because you can have a
8 mineral, let's say, in a deposit which is amphibole
9 from like an earlier formation event, so it's a nice
10 amphibole, again, non-asbestiform.

11 But then as that rock underwent other
12 metamorphic conditions and turned into like a talc
13 deposit, the amphibole could be partially turned in
14 to talc. And the way that those alterations happen,
15 meaning the amphibole turns into talc because it was
16 subjected to a different compositional pressure
17 temperature environment where talc was the --

18 You know, the phase of the equilibrium,
19 not the amphibole, you can see the amphibole is
20 forming talc, if that process doesn't go to
21 completion, you can create some very

1 interesting-looking like pseudo amphibole talc
2 particles. And so the interpretation of those
3 things are complex, they're not that common, but
4 they do occur.

5 So a lot of that gets back into are the
6 techniques being used to identify that sufficient in
7 order to see those nuances and to understand what
8 you're dealing with. And, you know, what do you do
9 with those particles? I don't know.

10 Those talcs were used in Stanton's work,
11 they didn't cause any problems in the rats or
12 whatever Stanton was using.

13 Brooke, you talked about some of the talcs
14 from R.T. Vanderbilt in your study.

15 MS. MOSSMAN: Right. Stanton looked at a
16 number of the fibrous talcs, samples from that area,
17 and someone else who has looked at it in a different
18 species, was W. Smith, and they did the lifetime
19 studies and showed that the fibrous talcs didn't
20 have carcinogenic potential as did the asbestos
21 amphiboles in their model.

1 But they made a comment actually --

2 MR. SANCHEZ: But those particles looked
3 like asbestos.

4 MS. MOSSMAN: They do.

5 MR. SANCHEZ: The first time I looked at
6 one, I was like, oh, my God, it's asbestos
7 everywhere in this stuff.

8 SPEAKER: That gets back to what you were
9 saying this morning about the chemical composition,
10 particularly the iron -- the presence of iron.

11 MS. MOSSMAN: Right, right, that's just
12 one of the differences.

13 SPEAKER: And my other question is I want
14 to clarify something, that talc itself does not
15 contain calcium or iron.

16 MR. SANCHEZ: Not in any meaningful
17 amount, no.

18 SPEAKER: Define meaningful amount.

19 MR. SANCHEZ: Well, I mean, if I go in
20 like a soil sample I'll find lead, it doesn't mean
21 it's --

1 SPEAKER: Yeah --

2 MR. SANCHEZ: So, you know, within
3 anything you could find -- if you look hard enough,
4 you'll find something, but generally speaking --

5 SPEAKER: So a true talc deposit that you
6 wouldn't expect to find any amphiboles in, you're
7 not going to find any -- almost -- it depends on
8 what methodology you use, but almost undetectable
9 levels of iron and calcium.

10 MR. SANCHEZ: In the individual particles,
11 yeah. It's interesting, there's some -- there's
12 some -- depending on the nature of the deposit, so
13 if you're looking at talcs that are derived from
14 like ultramafic deposits, you're going to find --
15 you can find more things like chromium and stuff
16 involved with those talcs relative to other types,
17 and that just deals with what the original
18 composition of the rock was that had formed the
19 talc.

20 But that doesn't necessarily get into
21 these issues of health affects, but talc itself --

1 so they mentioned the term solid solution -- I don't
2 know -- does that mean anything to anybody?

3 SPEAKER: Well, glass.

4 MR. SANCHEZ: Well, let me try to -- I'll
5 try to define it a little better. So the term
6 tremolite and actinolite was thrown around earlier
7 today. The chemical in them or chemical formula for
8 tremolite is $\text{Ca}_2(\text{Mg},\text{Fe})_5\text{Si}_8\text{O}_{22}(\text{OH})_2$. The way it
9 works is within that crystal structure I can start
10 substituting iron in for the magnesium, and nothing
11 changes to the crystal structure, so it remains an
12 amphibole.

13 So between like tremolite and actinolite,
14 you can just keep throwing pretty much iron in there
15 and at some point mineralogists have decided that at
16 that point it becomes actinolite -- you know, on one
17 side of the line it's actinolite, on another side of
18 the line it's tremolite. So those names for those
19 two minerals are somewhat arbitrary, that's set by
20 us, I mean, humans, that's part of our nomenclature.

21 But then the solid solution would just

1 mean that we have three exchange of magnesium and
2 iron and no really change in the mineral, it still
3 remains crystal structure and amphibole.

4 Talc does not have that same process, like
5 there is no -- I can't just start substituting iron
6 in for the magnesium, the crystal structure doesn't
7 allow it, there's not enough variation and
8 flexibility for the crystal structure to do that.
9 So talc is either just pretty much primarily
10 magnesium silicate, the other -- or it's like all
11 iron, and that's another mineral called monosulfide,
12 which is a -- talc act work back in the '70s, but
13 there is no continuum between those.

14 So some mineral groups have that solid
15 solution, which makes the naming convention a little
16 more -- what's the right word -- they're just
17 arbitrary points we pick. Generally speaking in
18 mineralogy we use the 50/50 rule, with the exception
19 of the tremolite and actinolite, which is not the
20 50/50 rule for historical reasons.

21 Anyway, so that's the idea of the solid

1 solution. I forget why I was getting to solid
2 solution though. I forget why I brought that up, I
3 thought I had another point to build on. Shoot.

4 SPEAKER: One question going back to
5 presence of the iron and calcium, so do you
6 generally screen -- and we talked a little bit about
7 this before, so you do a general screen and there
8 are -- minerals, does it make sense to look also for
9 iron and calcium, and if you find iron and calcium
10 in the sample that you're doing, that that would
11 take you more towards that this is more likely going
12 to be asbestos than just -- talc?

13 MR. SANCHEZ: Not in and of itself. I
14 think the complicating factor is in any talc that
15 you look at, it's not 100 percent pure talc. So the
16 phases that you would usually -- you would generally
17 encounter, there's a bunch of them, but from a --
18 you know, how much, you encounter a mineral called
19 chlorite, it's very similar in its crystal structure
20 to talc, but typically in the iron in the rock would
21 be in the chlorite phase.

1 So if there's a chlorite component, you're
2 going to get an introduction of both aluminum and
3 iron into the system. So the measurement of just
4 like iron alone wouldn't give you a measurement
5 specific to like an amphibole or possibility of
6 amphibole.

7 SPEAKER: But would the presence of
8 aluminum help be a marker to disregard that iron
9 presence?

10 MR. SANCHEZ: Well, I mean, let me --

11 SPEAKER: If it's coming from a chlorite, like you
12 just said, is --

13 MR. SANCHEZ: Yeah, but usually the
14 amphibole itself could have iron or no iron, so you
15 don't -- without knowing what amphibole you're
16 dealing with beforehand -- so from a purely
17 unknown --

18 So if you had a deposit where you knew
19 there was an amphibole and a chlorite in there, and
20 the chlorite had general -- you had a pretty constant
21 composition of the ratio between the

1 aluminum and the iron and the chlorite, yeah, you
2 could measure iron and chlorite -- sorry, aluminum
3 and iron by the ICP methods or some other method,
4 correct that out, take your remaining irons and
5 assign it to the amphibole.

6 But you'd have to know that that would be
7 a correct assumption, and I think if you're looking
8 at unknown talcs from god knows where, I don't think
9 that gets you anywhere.

10 We have toyed with the idea in the past of
11 using calcium as a measurement for the tremolite, if
12 there was tremolite present, and that's a little
13 more useful, I think, but that only takes care of
14 the tremolitic or calcic amphibole component, but a
15 lot of talcs also -- well, all talcs will contain
16 some amount of either like calcite, which is calcium
17 carbonate, dolomite, which is calcium magnesium
18 carbonate, and possibly some magnesite, which is
19 magnesium carbonate.

20 You could remove those to get an acid, you
21 know, different acids will remove those out, so you

1 could remove those that way and then run like a
2 calcium as an upper limit of how much tremolite
3 could be there, for a calcic amphibole at least, but
4 if you really want to have specifics, unfortunately
5 you've got to look at the individual particles, and
6 that's by microscopy so --

7 SPEAKER: The type of amphiboles that form
8 at these various fracture points, is there a
9 difference when you've got a fault zone that's
10 coming -- you know, impacting or coming together
11 versus one that's going apart?

12 MR. SANCHEZ: No, it's --

13 SPEAKER: The same kind of amphiboles?

14 MR. SANCHEZ: Yes, if you're going to be
15 forming amphiboles in an environment, they're
16 generally going to be mineralogically fibrous
17 amphiboles. And you saw some of the data, and some
18 the nuances here is, you know, we talked about the
19 cave crocidolites being -- as you look at the
20 individual fibers and those bundles being much finer
21 grades than the amosites or these other types.

1 So when Ann Wiley was talking about the
2 specifics of the deposits, yeah, you could have -- I
3 mean, I've seen tremolite asbestos out in a quarry
4 which was, you know, fine as fine can be when you
5 actually start looking at the individual fiber
6 width. You can go to other places and it's a very
7 fibrous amphiboles still, but if you go look at the
8 widths of the fibers, there's a huge range.

9 So even when you have these occurrences
10 along faults, we have these fibrous materials, but
11 they're not necessarily equal, and there could be
12 multiple stages of pulling apart. Where the first
13 stage didn't create a spine of a fiber and the
14 second stage did, so you could have an imprint of
15 the original -- of the material at the center of the
16 vein being dimensionally different and it was just
17 aggregating from those outer areas.

18 But these are kind of extremes, right,
19 we're kind of talking about extreme exceptions.

20 SPEAKER: I was just wondering if the
21 different conditions at those fault zones, whether

1 it's pulling apart or coming together, you've got a
2 lot of -- when they're pulling apart, is what's
3 filling that gap, is that primarily from water
4 intrusion and bringing in minerals and --

5 MR. SANCHEZ: Well, it's literally the --
6 believe or not rocks in the earth like -- they're
7 wet, so as those gaps get opened up, it's like a
8 funnel, it's like the pressure to force the water
9 into those gaps, those waters -- and under those
10 pressures and temperatures have -- you know, they
11 have a lot of soluble elements.

12 And so when these things form, they're
13 forming from that solution based upon the
14 temperature pressure changes that are all of a
15 sudden -- you know, all of a sudden water is to dump
16 all these elements, it can no longer hold them and
17 they form different minerals. If the conditions are
18 right, you can form asbestiform.

19 Another conditions that can form is like
20 sepiolite or palygorskite, which are very fibrous,
21 look like asbestos morphologically, but their

1 crystal structure and compositionally they're
2 different. And in the health studies, there's been
3 no association of adverse health affects. I've seen
4 more sepiolite in talc mines than I've ever seen
5 asbestos.

6 SPEAKER: They were also mentioning
7 fibrous talc this morning. How does that form?

8 MR. SANCHEZ: There's all -- you know,
9 that's a -- that's a poorly defined word. In the
10 Vanderbilt deposits we talked about where you have
11 anthophyllite, in my experience -- and I haven't
12 done much -- I've never really done any work
13 directly with the Vanderbilt deposits, I have been
14 there and looked at the rock.

15 But you can go up to the rock and what
16 looks like a -- doesn't have any appearance of having
17 any fibrocity or asbestiform character, it's an
18 amphibole -- looks like an amphibole, but then you
19 can scratch it with your finger, meaning it's talc.

20 So we call that -- so talc can almost
21 completely replace that amphibole, and that

1 replacement prospect creates a very fibrous talc.
2 So in the context of the R.T. Vanderbilt talks of
3 fibrous talc, that's what it's talking about, it's a
4 replacement texture of the talc after the amphibole,
5 it creates a very funky material.

6 SPEAKER: Sounds like a
7 long identification process.

8 MR. SANCHEZ: Yeah, another thing to think
9 about talc, and this is what I more commonly see in
10 samples, talc is like a plate mineral, so if I
11 literally like sheets of like a ream of paper like
12 this, and as you crush it, it just like rips apart,
13 right, and you create all these kind of plate-like
14 particles.

15 Talc has this perfect cleavage in this
16 direction, so it just wants to break along them;
17 however, if you were to take this, turn it up on
18 edge and then look down on it, right -- so this is
19 how you typically would look at it on the microscope
20 in this orientation, very clean, if it was held up
21 on edge and then it was bent a little bit, you would

1 see the separations of those cleavage planes, and
2 that looks like -- that looks very asbestiform.

3 So fibrous talc, depending on what it
4 actually is you're looking at, could be very
5 different things, it could actually just be normal
6 talc up on edge or it could be these fibrous talcs
7 as a replacement texture from the alteration. And
8 if you're just looking at a sample without more
9 knowledge, you can't always make those distinctions.

10 And, you know, these are very detailed
11 types of analysis to do it, and really just to tell
12 that apart you would perform very precise
13 diffraction analysis by TEM and look for both phases
14 being present in the particles. And most people
15 can't -- that's not a routine analysis.

16 SPEAKER: I mean, my questions are geared
17 toward trying to identify a potential screening
18 process. So the last thing we have to do is go down
19 that very detailed type of analysis to determine
20 whether or not you've got a problem. We don't want
21 to be doing that for each sample.

1 MR. SANCHEZ: Well, you wouldn't find the
2 people to be able to do it.

3 SPEAKER: Exactly.

4 MR. SANCHEZ: Yeah, and I think from a
5 practical standpoint -- and I gave a couple
6 presentations a few years ago at SME, Society of
7 Mining Engineers meeting, about either, you know,
8 when you're using PLM or TEM to do these analysis,
9 what kind of data must be required to do be reported
10 with the results.

11 So if you look at the methods for
12 polarized light microscopy that exist, there's very
13 stringent rules of what optical properties by PLM
14 you have to measure. So you have to measure the
15 refractive index in two directions, that'll
16 differentiate talc from serpentine; that'll
17 differentiate -- mainly talc from serpentine, as the
18 system we're dealing with here. But then you get
19 into other measurements, something called bayer
20 cohesins, you look at the morphology, you look at
21 something called the extinction.

1 You know, Ann Wiley was talking about how
2 easy it is by PLM to tell talc and anthophyllite
3 apart, by in PLM, that's based upon refractive
4 indices; however, when you look at the difference in
5 the refractive indices of anthophyllite and
6 tremolite, they have the same range. But -- but
7 using -- but there's another measurement called the
8 extinction angle which you can use to differentiate
9 tremolite from anthophyllite.

10 So there's a lot of nuances to these
11 analysis based upon the minerals you're looking at
12 and what data must be recorded. And most of the
13 standard methods require all these things to be
14 reported, it's just a matter of the analysts that
15 are supposed to record all these things, do they
16 even know what it means in context of the mineral
17 identification.

18 Because there is it has this, it has this,
19 it has this, therefore, it must be it, but there's
20 some nuances in there that they -- some pitfalls if
21 you don't understand the system.

1 So from the PLM perspective, and this is
2 what we're working on in the USP Expert Panel, I
3 don't know if I disclosed I was part of that, is a
4 PLM method that requires, you know, photograph -- so
5 if you see an amphibole in the sample, you would
6 photograph it in all sorts of orientations on the
7 PLM and then in different light modes, in essence,
8 that you use on polarized light microscopy.

9 Where we'd actually take color photographs
10 to document those features; therefore, if somebody's
11 looking at that report, they can see what the
12 morphology of the particle was, they can -- and you
13 can see it clearly that by PLM again it's -- the
14 scale of PLM is such that the distinction between
15 asbestiform amphibole and non-asbestos amphibole is
16 pretty trivial in most cases.

17 So you can see whether or not it was
18 asbestiform, you can check the refractive indices
19 measurement to see if it was a reasonable conclusion
20 based upon what they called it, you can check that
21 extinction angle to make sure that it was actually a

1 tremolite versus an anthophyllite. So the idea would
2 be that the methods require much more of the backup
3 data as part of them.

4 SPEAKER: It seems like the sample
5 preparation might be critical because depending on
6 how you -- I don't know how much sample prep is
7 involved with this --

8 MR. SANCHEZ: For PLM with an already
9 ground powder, very little. You're literally just
10 taking little scoops and putting them on glass
11 slides and looking at them.

12 SPEAKER: Okay. Then, you know, they
13 talked a lot about particle size this morning, have
14 you all ever looked at a sample prep as potentially
15 a way to possibly enhance the percentage of
16 amphiboles in your sample?

17 MR. SANCHEZ: Yeah, we have, and you can.
18 And there's not -- the consequence of doing
19 something like that, there's a lot -- if you're just
20 looking for amphibole, that's fine. I have found
21 though -- because to go through like you have your

1 heavy liquid separation, for instance,
2 centrifugation, you know, washing it, centrifuging
3 it again, it's not like those are hard steps, but
4 those steps take time.

5 So let's say you take ten milligrams of
6 sample, put it in the little centrifuge vial, spin
7 it a couple times, whatever you do to get it, you
8 could just physically look at that same ten
9 milligrams and be done before you got done with your
10 prep. Does that make sense?

11 So if I'm only looking at ten milligrams,
12 I can look at ten milligrams on two to three slide
13 mounts and I would have looked at everything that I
14 could have concentrated by centrifugation.

15 SPEAKER: Well, what I'm looking is that
16 can you use that centrifugation step as a way to
17 potentially have a way of having enriched or
18 enhanced isolation of the amphibole, potentially
19 asbestos containing amphiboles, and use that as a
20 potential way to enhance your ability to properly
21 quantitate the --

1 MR. SANCHEZ: I think you're on the right
2 step there. Because in all these analysis we have,
3 there's the identification issue, then there's the
4 quantification issue.

5 SPEAKER: Right.

6 MR. SANCHEZ: In my experience using real
7 world samples of talc, I don't need to centrifuge
8 them and heavy liquid separate them to find
9 amphiboles if they're present. But in order to get
10 much more reliable quantitation of those materials,
11 doing something like a centrifugation would
12 definitely get you there, you'd be able to constrain
13 your quantitation and reduce any errors of that
14 measurement.

15 SPEAKER: So actually in our conversation
16 when I was at NIST -- Paul Brown from the FDA -- I'm
17 a toxicologist, so I'm thinking I need
18 quantification information in order to use this to
19 measure because it's important to figure out what
20 are the safe particles, what are the unsafe
21 particles.

1 That's what we're to potentially use this
2 analytical data is okay, a consumer product has this
3 much talc in it, we need to know how much fiber is in
4 there so I need to do the calculation to see is that
5 safe or not. And whatever methodology in the
6 interpretation of data is guiding that
7 quantification, I heard in this morning's session --
8 but having that sort of data for us is critical,
9 it's that quantitative aspect so that we can do that
10 daily dose calculation and risk.

11 MR. SANCHEZ: Yeah, there's a few points
12 there. Let me go -- I'll lose my points if I -- if
13 you go again, sorry. You know, the concept of
14 whether it's fibers per gram, fibers per particles,
15 I mean, it doesn't really matter, you would analyze
16 it the same way, it's just literally how you report
17 out the data.

18 But, you know, as we know, a number means
19 nothing without a comparative purpose. So right now
20 the only regulations we have to deal with are all
21 weight percents. So to move away from that, there's

1 no way to compare what you have with any existing
2 regulation.

3 So without something to -- that meaningful
4 comparison of a fiber per gram, I don't see the
5 utility in doing it, right, there's no -- yeah, you
6 get a concentration, but I can use the same data and
7 calculate out a weight percent. It's the same --
8 you would analyze it in the same fashion to get
9 either sets of data.

10 So there's really not a pro or con of
11 either one, it's just a matter of what do you have
12 to compare it with. The issue with doing -- you
13 know, if you have an unknown sample that comes in,
14 you have to screen it for chrysotile still -- or
15 chrysotile, however you say it, people always
16 correct me if I say it that way --

17 You know, you can't -- the density
18 differences between talc and chrysotile are nil,
19 there's no way to separate those two out. So if
20 you're going to separate your amphiboles or heavy
21 minerals from the talc, you're also not going to be

1 able to analyze for the chrysotile.

2 So from a routine standard of analyzing
3 these samples, to go straight to that centrifuge
4 technique eliminates your -- or only to do that
5 would eliminate your ability to test for chrysotile,
6 which is also a concern for people.

7 But I think as a -- you know, you've
8 analyzed the sample, you've identified something's
9 there, if you need better quantitative data,
10 especially if you have the amphibole component, then
11 the next step is do like a centrifugation or
12 something makes a lot of sense to get much more
13 quantitative data of what you know is already there.

14 The other thing I wanted to mention was
15 right now we're -- so, well, let's go with yours --

16 SPEAKER: Getting back to the discussion
17 about the chemical composition, to do that kind of
18 centrifugation step and look at the various layers,
19 and you could do a elemental analysis and we could
20 quantitate how much calcium, how much iron and other
21 elements are in those various layers.

1 And based upon the discussions that I
2 heard this morning, those that had calcium and iron,
3 you want to focus on counting those particles in
4 that layer because that's going to give you the best
5 opportunity to detect and quantitate any asbestiform
6 fibers in that sample. If calcium and iron are not
7 in those various layers, then the particles that are
8 in that layer aren't going to be an issue.

9 MR. SANCHEZ: Well, you could have
10 anthophyllite that has no iron, you could have
11 another mineral phase coming from that that doesn't
12 have any iron, and you'd miss it if you relied on
13 the chemical technique there. Really, unfortunately
14 we're -- I mean, the -- it's sounds like the
15 strength and weakness of microscopy.

16 Microscopy is like the only analysis that
17 allows you to see the particle and then get specific
18 information of the particle. The problems is, based
19 on time constraints you just can't look at that many
20 particles.

21

1 SPEAKER: See, that's what I'm trying to
2 get at is, you know, you do that separation, one,
3 you increase the chance you're going to find
4 something, and so that should make the microscopy
5 easier, so that's kind of what I'm looking at. And
6 the chemical analysis, so what you're saying is that
7 there are some amphibole particles that do not
8 contain calcium or iron?

9 MR. SANCHEZ: Or very little iron. No
10 calcium and very little iron.

11 SPEAKER: Do those also produce
12 asbestiform particles?

13 MR. SANCHEZ: Potentially, yes.

14 MS. MOSSMAN: In which types?

15 MR. SANCHEZ: Specifically anthophyllite
16 would be one, anthophyllite $Mg_2Mg_5Si_8O_{22}(OH)_2$.
17 There's generally some iron in it, but there are
18 known locations where you have very like -- no iron
19 anthophyllites, so you could be dealing with an
20 amphibole with, you know, less than a weight percent
21 of iron in it, you know, just a few weight percents

1 of iron there would be a very small amount of iron
2 in that type of analysis.

3 Cummingtonite is another amphibole with
4 generally the same -- has the same chemical
5 composition as anthophyllite, it's just the crystal
6 structures are different. But from a compositional
7 standpoint, they'd be -- they'd be identical.

8 SPEAKER: The refractive index of those
9 minerals versus talc, are they the same?

10 MR. SANCHEZ: The refractive indices of --
11 you could tell those apart from talc, no problem.
12 When you get into looking at the refractive indices,
13 the cummingtonite is what's called a monoclinic
14 amphibole, so if you were just looking at PLM data,
15 it would probably report out as if it was present as
16 a tremolite, if you only had the PLM data.

17 Refractive indices-wise it overlaps with
18 tremolite, it overlaps with anthophyllites, that
19 extinction angle I measured would be the same as
20 tremolite.

21 SPEAKER: That would be different than

1 talc?

2 MR. SANCHEZ: Yes, it would be different
3 than talc, that's not a problem.

4 So, I mean, right now in some samples that
5 I've been analyzing, we actually do have -- these
6 are some historic samples, but there are some
7 cummingtonite amphiboles there, not asbestiform, but
8 they're cummingtonite, but all the testing records
9 of the people that are testing these things always
10 reported out whenever they found something, as
11 actinolite. But it was only the optical data, but
12 if you actually go isolate these particles obtained
13 in the compositional information, they don't have any
14 calcium.

15 So there's a lot of -- to get back into it,
16 were the analytical methods enough to really be that
17 specific in their identification, sometimes they're
18 not, I mean, if you evaluate like older data and try
19 to -- and for me what's important is when I see like
20 discrepancies between results, I'm always trying to
21 resolve those. I'm not being like PLM in something that's

1 clearly not an asbestos amphibole, but then
2 somebody's reporting on TEM finding asbestos
3 amphiboles, like that's a discrepancy, are they just
4 counting elongated fragments of amphibole in
5 asbestos, I don't know.

6 So these are all these kind of -- you
7 know, I'm constantly trying to rectify conflicting
8 data sets, whether it's historical data reporting
9 one type of amphibole, but then actually looking at
10 older samples and it's another type of amphibole,
11 there's usually logical reasons why these -- why
12 these misidentifications occur, but it's like a
13 constant issue that I deal with.

14 SPEAKER: But amphiboles that do not
15 contain calcium or very little iron, are they
16 generally -- I know you've looked at a lot of talc,
17 are those primarily in industrial talcs, have you
18 seen any cosmetic pharmaceutical-grade talcs?

19 MR. SANCHEZ: I have not -- generally I've
20 only ever seen anthophyllite as a general rule in
21 the standard ilk talcs we were talking about. There

1 are other talc mines in the U.S. though that report
2 out anthophyllites, these have all been closed for
3 decades, so I don't think they're really that
4 germane, but the issue is that if the unknown talc
5 sources coming in, you know, it's like you've got to
6 be looking for it to make sure -- if you don't --

7 Pakistan sending us talc, I don't -- you
8 know, maybe some of the Pakistani talc is really
9 good, maybe other stuff is really crappy and really
10 bad stuff. And so without knowing more, it's like
11 you've got to be looking for all these things when
12 you encounter these unknown samples.

13 And from a laboratory, most of the talc we
14 get in, we don't know where it comes from, we just
15 get some talc sample, we don't know if it's
16 originated from Pakistan, India, China, U.S., South
17 America, Europe, we don't know. We just -- we run
18 it as a blind sample to us and report out our
19 findings.

20 Or it's not uncommon -- I'm not saying it
21 always happens, but it's not uncommon for things to

1 be blended to get to certain desirable properties
2 for these uses. A lot of times that's controlled by
3 the color, so a lot of stuff using like ceramics or
4 paints, they need a certain whiteness of the talc.

5 So if you have too much like chlorite and
6 these other minerals, the whiteness isn't where you
7 need it, so you'd blend in a much whiter talc into
8 it in enough proportions to get your talc to the
9 spec that they need pass it for.

10 So there's all sorts of reasons to blend.
11 It's always portrayed some evil dilution issue, and
12 that's not the case, it's been my experience it's
13 usually to meet some other -- some physical
14 requirement of the end user.

15 I'm not sure what time it is.

16 MS. MOSSMAN: Yeah, we're over.

17 MR. SANCHEZ: We got started about 15
18 minutes late.

19 MS. MOSSMAN: Right, and it's 2:35. I
20 guess the question that I would have is, what do we
21 want to do a group regarding recommendations.

1 And, again, this is not exactly my
2 bailiwick, so it's totally naivete, but it seems
3 that there is expertise in this room in terms of
4 either identification or what Michael was trying to
5 get at, it would be nice to have a tiered approach
6 to finding this material where you can have
7 different tiers to say, look, this is reasonable to
8 stop here, this won't be a problem. And maybe
9 that's just an idealistic solution.

10 MR. SANCHEZ: I don't think it is because
11 let me just talk back to the USP Panel, because
12 right now we're looking at the -- the real change
13 we're looking to put forward to the expert committee
14 for approval is we will be doing x-ray diffraction
15 still, because it provides much more information
16 about all the minerals present than just doing the
17 microscopy analysis alone.

18 And there's other attributes of talc that
19 people are concerned with other than just simply the
20 asbestos side. But we are going to do -- there will
21 be a mandatory microscopy methodology, and right now

1 the idea would be PLM, and I think TEM will be on
2 there as well. I don't see any reason not to do
3 them both. They both look at very different
4 fractions of the size of the particulate.

5 So one of the issues is, you know, as Ann
6 was saying, she pulled out this old body powder and
7 it's big particle sizes, so the concern of like
8 missing small stuff is very minimalized when you're
9 dealing with courser grinding talcs that are
10 typically used for body application.

11 When you get into the cosmetics, I'm not
12 sure what you all use, if they're courser or finer.
13 When you start getting to the pharmaceuticals and
14 the peels -- a lot of times they're using like what
15 they call these micronized talcs where they're
16 ground to very, very fine powders.

17 So a testing methodology for like a body
18 powder type using like XRD and PLM, I think would be
19 very sufficient, I mean, you would get the
20 information you need from that. But once you move
21 into all those micronized talcs, I think you'd have

1 to get into the realm of electron microscopy, you
2 know, to do your due diligence to rule out -- just
3 based on the particle size differences.

4 But that's the approach we're taking in
5 the USP expert panel right now, and we're also
6 working on another methodology for the
7 quantification of the asbestos or amphibole in the
8 talc sample where we're hoping right now -- we've
9 created a series of standards and we're just waiting
10 for the bureaucracy to move, which has been five
11 months, in order to get these things separated to
12 different labs and those people that are involved,
13 to do like a round robin to see how reliable it is
14 and how well that will work for these lower level
15 concentrations.

16 And we're up to pretty low levels, I think
17 the lowest fiber maybe is like 0.0004 percent. So
18 we're taking this orders of magnitude lower on this
19 particle kind of method validation. And the idea
20 there is the way the quantification will be done is
21 you would be scanning over a known amount of

1 material, so you'll weigh the amount you put on your
2 slide, and then scanning over the minimum of three
3 slides, any particle you'll see, you'll measure the
4 length and the width.

5 And then based upon other things, you can
6 calculate out its volume, apply density and you can
7 actually build a mass. So we could actually get a
8 mass by mass concentration, which by doing it by
9 that methodology, you can get a very low kind of a
10 sensitivity by doing it that way, but again, the
11 question is these low levels of homogeneity and how
12 reliable and how reproducible, I don't know.

13 But we're looking into that to try to draw
14 a way of quantifying to much lower levels so we're
15 not just left with it's less than .1 percent. I
16 mean, it could be parts per trillion, it could be
17 parts per billion, but they're being reported out as
18 less than .1 percent, so there's a lot of unknown in
19 those kind of data.

20 SPEAKER: I work for the FDA also. We're
21 kind of all over. I have 15 years in the asbestos

1 research for the last 28 years with the FDA, and one
2 of the concerns I have -- and I'll just take it one
3 go way back out the door to the practical side, this
4 gentleman here alluded to it already, we want to be
5 able to screen, we want to be able to identify
6 quickly -- correct me if I'm wrong -- and we do
7 consider -- I deal certainly -- I'm with the
8 Forensic Chemistry Center, and we deal with
9 counterfeits, you know, paper stuff like that.

10 But we handle all ports of entry, we have
11 special agents that are there, we send out --we
12 actually go from our lab, we take it and fly out to
13 these different places, use devices that we've
14 designed in our laboratory to screen these cargo
15 containers. Take one scientist who's never seen a
16 cargo container, put him in -- or her in -- and tell
17 them to sample everything in there, that's the rest
18 of their career in some cases, I mean, it really,
19 truly is.

20 So take think one of those -- well,
21 somebody says, we'll take that container and that

1 one up there, you open it up and it's front to back
2 with materials, say, okay, take that box and that
3 box, that's all you have time to do.

4 So we need something, and I don't -- I
5 agree totally about the XRD, that's got to be some
6 way that we can make that portable --

7 MR. SANCHEZ: PLM you could do -- I could
8 do PLM for you in that cargo ship right there.

9 SPEAKER: Exactly, and I'm the same way,
10 as a microscopist I couldn't endorse more the use of
11 PLM, I mean, that's my go-to, but how many places
12 outside are going to be able to have a TEM to haul
13 around with them, there's no such thing.

14 MR. SANCHEZ: Well, the TEM is very
15 impractical for these things.

16 SPEAKER: It is. I couldn't agree more.

17 MR. SANCHEZ: You know, you can make
18 calculations on sensitivities in different ways, and
19 I could make PLM look better than TEM from a
20 sensitivity perspective, but that's not the point.
21 The true sensitivity of a microscopy method is how

1 many particles you actually look at.

2 So I made the comment earlier, and by PLM
3 you're able to screen -- again, it's not a lot of
4 material, but you're still -- you know, as I said,
5 you could screen ten milligrams a sample in an hour,
6 no problem. You could not do that by TEM, there's
7 no way.

8 And then when you're actually looking at
9 the particles you're at, 2,000 X, 10 to 20,000 X by
10 TEM. Most of the particles in the talc sample are
11 too big to even analyze, so you're only ever looking
12 at the finest, the smallest of the small particles,
13 and then based on the constraints and how they have
14 to be laid out, you're not looking at very many of
15 them.

16 But then you go through these calculations
17 and these scale ups to get to these big numbers when
18 you've only ever looked at 1,000 particles total, if
19 that -- I'm just saying, I mean, 100 discrete
20 particles in a TEM grid opening, you do ten grid
21 openings, you've looked at 1,000 particles, your

1 true sensitivity was one particle out of 1,000. But
2 then you're going to try to turn that into some kind
3 of a part per million analysis.

4 SPEAKER: And you're going to spend a
5 couple days doing it.

6 MR. SANCHEZ: Well, you could, depending
7 on what you see, it could be very time consuming.
8 Where the PLM, you're physically looking at so much
9 more material, so many more particles, it's a much
10 better measurement. But again, you know, the TEM
11 can see small particles, especially if there's some
12 chrysotile present, PLM could miss chrysotile more
13 likely, that's not necessarily the case for
14 amphiboles.

15 But I think there's reason to do both, but
16 PLM looks at a lot of material and I think it's a
17 much better general instrument for analyzing for
18 asbestos or amphiboles or the things in a talc
19 sample. It's not the only answer, but I think it's
20 the most robust tool to use.

21 Does that help?

1 SPEAKER: Yes.

2 MR. SANCHEZ: I've just been kind of
3 going.

4 MS. MOSSMAN: We should have moved groups.

5 MR. SANCHEZ: Nobody's come in, so I
6 don't -- I'm waiting for someone to stop us.

7 Well, let me just back up, so the other
8 thing with the TEM though with our approach is again
9 the transparency of the data where if you're seeing
10 something, there's always going to be the image of
11 it. When you get into measuring the composition,
12 that's done by EDS, there's a readout for that, that
13 would be saved.

14 And then when you get into the diffraction
15 work, which for certain minerals is critical, the
16 anthophyllite talc issue, the sepiolite and talc
17 issue and anthophyllite differentiations, all of
18 those things are done by the crystal structures, you
19 have to do the diffraction work.

20 And measuring 5.3 per gross bases does not
21 do it, you need to manipulate the particles, make

1 measurements, compare them to standards.

2 SPEAKER: Question about the technology.

3 There are optical scanners that have been developed
4 to help do things like filth analysis, pick out
5 particles and insect parts in a batch of rice or
6 whatever. Has that kind of technology been applied
7 to scanning these SEM monographs and helped with the
8 quantitation process?

9 MR. SANCHEZ: Not necessarily that
10 technology. We've employed on numerous occasions
11 some automated SEM techniques to measure particles.
12 We were able to take an image and then obtain the
13 EDS, the chemical compositional information.

14 When we're dealing with low
15 concentrations, we get the same issue when we were
16 talking about with TEM, you can make the dispersions
17 of these powders, we go through and analyze 10,000
18 particles and we don't find any. So 10,000
19 particles isn't a lot of particles when you're
20 dealing with something that's been ground to like
21 20, 30 micron medium-sized diameter.

1 So the amount of like memory and computing
2 power to run those SEM automations to a 100,000
3 particles in order to detect something at much lower
4 concentrations is somewhat of an obstacle for us,
5 you know, the machine's tied up for ten hours, and
6 then all our computers crash when we try to like
7 summarize the data.

8 SPEAKER: Well, you could also have that
9 sort of angle with like sampling, proper sampling
10 protocols and things along those lines because, you
11 know, you can sample everything, but at some point
12 you get a case of diminishing returns, so at that
13 point you stop and then you're going to get the most
14 and best data out of it. So you can kind of
15 mitigate those issues with proper sampling.

16 MR. SANCHEZ: Yeah, again, if you're only
17 looking for amphiboles, you could do those
18 separations and help that out, but then --

19 SPEAKER: From my point of view, I'm
20 looking for that screening and if we can use
21 something, a couple methodologies, elemental analysis

1 along with, you know, some way to detect some of
2 anthophyllite amphiboles as well, if you can
3 eliminate the presence of that, then we've got an
4 initial screen.

5 And all that would do within certain
6 parameters would tell us that this talc is
7 reasonably safe and should go to be put out on the
8 market. Anything that fell outside of those
9 parameters, then you would go to --

10 MR. SANCHEZ: Do extra. Yeah, do more
11 work when you have something outside --

12 SPEAKER: Confirmation analysis.

13 MR. SANCHEZ: Yeah, and we've looked at
14 using bulk chemical composition to actually try to
15 trace -- there was a paper done by Mickey Gunter's
16 student, it was also -- Marty Rifkin gave the talk,
17 who was his undergraduate student, Marian Buzon was
18 her name, she's down at a university down in
19 Atlanta, I forget the name of it.

20 But she was getting talc samples from all
21 over the world looking at the bulk chemical

1 composition and trying to see if you could cluster
2 them and get some kind of indication of where they
3 may come from, you know, just based on the bulk
4 analysis like that.

5 I think you need to get more specific but,
6 yeah, there's all sorts of ideas, you know, how to
7 do these things. But I think -- I mean, PLM, as far
8 as just like a quick screening method is probably
9 the best based upon the data, you can do more or not
10 do more depending on how confident you are in what
11 you saw or what you didn't, if you're talking about
12 quick, you know, routine screenings.

13 SPEAKER: You can set up an EDS or WES
14 system for prep, but my experience with the EDS
15 mostly, but if you can -- rather than crashing your
16 computer looking at tens of thousands of particles,
17 you can specify, I want this particle type, I want
18 it to be iron rich to within these percentages, I
19 want --

20 MR. SANCHEZ: Oh, yeah, we --

21 SPEAKER: And you can also set it with a

1 top discriminator, once you get ten of these
2 particles or a hundred whatever, you know, stop.

3 MR. SANCHEZ: And we have played with that
4 because you can -- yeah, you can set up thresholds.
5 The issue at hand though is it still needs to stop
6 on a particle collection of data to know whether to
7 reject or accept it.

8 SPEAKER: And you can set the dwell time,
9 it's not -- with gunpowder residue, and I know this
10 for a fact, I'm on the NIST committee for that -- it
11 is done exactly the same way, you set it to particle
12 type --

13 MR. SANCHEZ: It's funny you mentioned
14 that because the company I work for, they do a lot
15 of gunshot residue and a lot of the technologies
16 they use for the automated analysis looking over the
17 bariatric material more typically --

18 SPEAKER: Bariatric --

19 MR. SANCHEZ: But it's kind of going along
20 with --

21 SPEAKER: But it works. I mean, you can

1 do a particle -- to answer your yes or no question
2 in microseconds with the new SDD detectors on these
3 things, so it is very, very fast.

4 And again, you set all your
5 discriminators, how many particles, what -- and you
6 can have it throw out everything else that comes
7 along, and you could log up to multiple mounds of
8 preparations and put it in -- like most of them in
9 the crime labs, they'll set it up before they go
10 home, and they come back the next night.

11 And then you say, well, how do I know the
12 machine really got that, each particle is identified
13 and it's up to the operator which one of those --
14 you get the new kid on the block who's just training
15 to go in there, and they have to go back to this
16 particular amount to this particular coordinate,
17 there's a particle, put the needle on it and confirm
18 that it's there. Because everything we do goes to
19 court.

20 But it could be -- this could be done that
21 way, at least I can't see a reason right now why it

1 couldn't.

2 MR. SANCHEZ: Well, the real issue is
3 the -- with the SEM alone you don't get any of the
4 crystallographic information.

5 SPEAKER: Correct.

6 MR. SANCHEZ: So any time you have a
7 longer, thinner talc particle, what is it, is it
8 talc or anthophyllite. You can't answer that
9 question with EDS alone. There's another technique,
10 and we've been trying to work on it, we've had some
11 success here and there by SEM, it's an older
12 technique, it's called electronic backscatter
13 diffraction.

14 SPEAKER: Oh, yeah.

15 MR. SANCHEZ: It's typically been used in
16 like metal analysis, we have nice polished surfaces,
17 they can determine orientation of grains, strain
18 rates and all sorts of good things by changes in the
19 crystal structures. We've had success on some
20 particles being able to use EBSD on our filter
21 preparations in talc in order to get that

1 information.

2 The issue is we don't have any -- right
3 now there's no way to have that part of the
4 automation. So you go back and you look at
5 particles and then you apply the EBSD, but it's like
6 it either works or it doesn't. But there's other
7 techniques that could be developed definitely, and I
8 think get much better as time goes on.

9 SPEAKER: EBSD wants to do with big data,
10 yeah, do this building, but it's still not there.

11 MR. SANCHEZ: Yeah, and for this type of
12 analysis, this is a pretty novel approach when you
13 get the types of particle analysis like this.

14 So I'm not sure if we should break or wait
15 for them to come. I don't know what you guys want
16 to do.

17 MS. MOSSMAN: We probably should.

18 SPEAKER: I just -- I'm also from FDA, so
19 I'm a toxicologist, and depending on whatever
20 methods biochemical chemists determine is going to
21 be the best method, is someone either on USP expert

1 panel or with this group, we need someone to
2 integrate with the toxicologists to determine that
3 whatever sensitivity you have for the analytical
4 essays, if we take our drug products or cosmetic
5 products that have the highest exposure, that we
6 need to find a sensitivity that's going to assure
7 that the amount of asbestos that the person is going
8 to be exposed to is going to be okay.

9 So I just want to put that in there
10 because I can see there were a lot of work that has
11 to be done on the analytical side, but --

12 MR. SANCHEZ: Well, that's another
13 issue --

14 SPEAKER: What's really important that we
15 need from you is a target. Because the testing has
16 to meet the regulatory expectations and
17 requirements. So what we need from you guys is a
18 limit of concern, a level of tolerance, whatever
19 terminology you want to use, give us that target,
20 and then it's up to us to come up with something to
21 meet that.

1 MR. SANCHEZ: What we're trying to do
2 right now is create a methodology with
3 quantification that takes us orders of magnitude
4 further down the chain from .1 percent where we're
5 kind of living now -- from the x-ray diffraction
6 standpoint alone.

7 A lot of people have been doing microscopy
8 analysis for a long time, but that industrial
9 standard of the USP current one is the x-ray
10 diffraction, then you follow it up with microscopy
11 if you see something. We're going to -- with the
12 benefit of microscopy which will introduce -- we'll
13 get much lower than that, but ultimately, you know,
14 you could have something in the material, but that
15 doesn't mean it generates an exposure for a
16 toxicological affect.

17 SPEAKER: So .1 might be okay, but is
18 someone working with you on the USP expert panel to
19 figure out if that's okay?

20 MR. SANCHEZ: No, we're just simply doing
21 a methodology to a reasonable level that we view

1 much below any kind of a current regulatory level
2 for quantification purposes and reporting purposes.

3 SPEAKER: So when do you get people
4 involved in that --

5 MR. SANCHEZ: I mean, frankly if you say
6 you want something at ten parts per million, we
7 can -- we'll do what we can to get a method that's
8 reliable at ten parts per million.

9 SPEAKER: It might be that .1 or 1 is
10 actually perfectly fine, we could probably figure
11 that out to an accepted --

12 MR. SANCHEZ: Well, there was work done --

13 SPEAKER: The FDA creates -- and so maybe
14 you and I can get together and I can help --

15 MR. SANCHEZ: You're Jeff. I didn't
16 know -- now I make the connection, okay. I
17 appreciate your help a few months ago. I'm sorry it
18 didn't work out. I'm just sitting on all those
19 samples. I don't know what to do with them.

20 SPEAKER: Actually, what I was going to
21 say is that that's part of the reason why there's a

1 need for a work group, to try to address some of
2 these questions that will arise as a result of this
3 meeting for the agency.

4 And not just FDA, but for all of
5 government to sit together and to try to come up
6 with what seems to be a reasonable level that we
7 should use to have some kind of consistency amongst
8 agencies to use to say that is a limit or threshold
9 that we should be using for our products, for EPA to
10 do standards for, whatever else, so that we're all
11 at least working on a consistent detection as
12 possible and we need our data to be consistent
13 because of the varied needs and products that we're
14 all looking at and how to approach it.

15 Because, you know, there's not -- not
16 every application can fit into a little mold, so
17 that's part of the discussion we need to have.

18 MR. SANCHEZ: Yeah, I think we've said
19 this in the USP meeting, it's like -- yeah, we're
20 trying to design something that would be efficient
21 and down to very low levels, whatever that means in

1 the broader world, we can't answer.

2 SPEAKER: Our focus has been to come up
3 with the best method, not to look at the toxic part,
4 but it's an important part, we need to know that.

5 SPEAKER: There's a -- in my office is if
6 you don't have to go down to -- because that's going
7 to be way over what --

8 MR. SANCHEZ: Well, the plaintiff lawyers
9 will say you never do enough.

10 SPEAKER: You even said this morning,
11 you've got to know the particles that are .1 microns
12 to five microns, I mean, that's pretty sensitive,
13 and when you need to be able to test those
14 particles, and what percentage of those particles is
15 in there that's causing cancer, so you've got be
16 able to detect those particles. And what percentage
17 of those particles is in there that's causing
18 cancer, that's what we're trying to determine, and
19 in order to do that, we're consolidating --

20 MR. SANCHEZ: It's not --

21 SPEAKER: -- and then you take the tox

1 part from that to determine, you know, if -- percent
2 of these particles, is that going to be cancer
3 causing, I don't know.

4 MR. SANCHEZ: It's a fascinating thing
5 because most of the epidemiological studies and
6 things have been associated with some of these talc
7 mines, particular the ones in Italy, I know there's
8 been ones in Vermont done, Norway -- I think there
9 was one done in Norwegian talc miners, and they
10 don't see disease, and some of those deposits do
11 contain amphiboles, not asbestos, but they do
12 contain amphiboles --

13 MS. MOSSMAN: Yeah, there's no
14 mesothelioma, although the workers get mild
15 chalcosis indicating that they're levels of exposure
16 are high, historically.

17 SPEAKER: So then it comes down to a
18 combination, and is the combination --

19 MR. SANCHEZ: Well, are there other -- are
20 there other like specific mineralogical questions
21 you guys may have that I can help with? Or I mean,

1 I can talk more detailed about methodologies, you
2 know, something like a PLM, what it can and can't
3 do, try to get some more information there.

4 SPEAKER: How quick are some of these
5 methods to actual products where they're --

6 MR. SANCHEZ: Yeah, that's a good
7 question. The biggest issue is if you're dealing
8 with some kind of a cosmetic, which has a lot of
9 like -- you know, I don't wear makeup, but there's a
10 lot of other organic things added to those, right,
11 you know, for masking purposes, a lot of those
12 things can help mask the particles and make it
13 difficult to see things like the refractive indices.

14 So whenever we're dealing with like
15 cosmetics, which these are different organic binders
16 and different colorants added in, you know, we're
17 always like ashing these things, so we're putting
18 them into low temperature ashing conditions to burn
19 them off.

20 Occasionally you'll get particles along
21 like titanium biopsy, samples along like titanium

1 dioxide, depending on how fine that is and how much
2 is in there, that could also create difficulties in
3 seeing natural particles themselves and getting
4 clean measurements from them.

5 But those are the main -- and that is this
6 pharmaceutical cosmetic grade talc and uses, I think
7 those are the main two issues that are typically
8 with the cosmetic side where they're used makeup.

9 SPEAKER: The low temp grade and if you
10 were just getting rid of the organics, and for the
11 purpose of doing it -- the low temperature ashing
12 will cause the fibers to fracture.

13 MR. SANCHEZ: Especially if you're doing
14 any --

15 SPEAKER: And they will break just as the
16 process of --

17 MR. SANCHEZ: But -- and if you're
18 actually dealing with an iron amphibole, it can
19 actually change -- it changes the oxidization state
20 of the iron and can change the refractive indices
21 measurement slightly with that change.

1 So there's a lot of papers like on heat
2 treated like amebocyte, because it looks very
3 different once you've heat treated it, and so if you
4 don't know what it looks like as it changes through
5 that process, but when you're dealing with things
6 like anthophyllite, tremolite, it's not necessarily
7 a big concern but there could be some subtle changes
8 that get made that should be accounted for.

9 It's mainly an issue with chrysotile or
10 really high iron.

11 SPEAKER: So is there a plan to come up
12 with a separate testing method?

13 MR. SANCHEZ: The USP is only
14 pharmaceutical grade talc. So we're not in the --
15 we're not thinking about end views or formulations,
16 accounting for that. So the USP guys are -- they
17 are specific in the meetings that we're only talking
18 about pharmaceutical grade talc.

19 SPEAKER: So you can control the quality
20 of the talc at the level of the drugs --

21 MR. SANCHEZ: So to design certain

1 preparation procedures would be beyond what USP
2 understands their role to be. Not that we couldn't
3 do it if we were asked to, but that's not
4 necessarily on our radar to take into account those
5 complications. They made a distinction that I don't
6 know is a real distinction in the working world.

7 I think we should go ahead and break and
8 see if we're done.

9 (Session concluded at 3:03 p.m.)

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1 State of Maryland, to wit:

2

3 I, Jean M. Townsend, a Notary Public of
4 the County of Montgomery, do hereby certify that the
5 within-named witness, personally appeared before me
6 at the time and place herein set out, and after
7 having been duly sworn by me, according to law, was
8 examined by counsel.

9 I further certify that the examination was
10 recorded stenographically by me and this transcript
11 is a true record of the proceedings.

12 I further certify that I am not of counsel
13 to any of the parties, nor in any way interested in
14 the outcome of this action.

15 As witness my hand this 28th day of
16 November, 2018.

17



18

Jean M. Townsend

19

Notary Public

20 My Commission expires:

21

October 8, 2021

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