Asbestos in Talc

Session C - Interpretation of Testing Data

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Moderator: Matthew Sanchez

P R O C E E D I N G S

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

questions from the audience before we move on?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

diffraction as like an initial screening tool.

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

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

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

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

Questions?

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

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

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

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

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

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

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

really depends on the individuals.

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

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

SPEAKER: It's more than I know now.

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

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

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

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

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

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

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

asbestos.

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

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

SPEAKER: It's like proving a negative.

MR. SANCHEZ: Yeah, I think --

SPEAKER: But we do it all the time --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPEAKER: So asbestos basically forms in veins?

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

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

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

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

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

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

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

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

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

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

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

But they made a comment actually --

MR. SANCHEZ: But those particles looked like asbestos.

MS. MOSSMAN: They do.

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

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

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

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

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

SPEAKER: Define meaningful amount.

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

SPEAKER: Yeah --

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

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

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

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

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

SPEAKER: Well, glass.

MR. SANCHEZ: Well, let me try to -- I'll try to define it a little better. So the term tremolite and actinolite was thrown around earlier today. The chemical in them or chemical formula for tremolite is Ca2(Mg,Fe)5Si8O22(OH)2. The way it works is within that crystal structure I can start substituting iron in for the magnesium, and nothing changes to the crystal structure, so it remains an amphibole.

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

But then the solid solution would just

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

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

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

Anyway, so that's the idea of the solid

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. SANCHEZ: No, it's --

SPEAKER: The same kind of amphiboles?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPEAKER: Sounds like a long identification process.

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

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

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

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

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

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

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

SPEAKER: Exactly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPEAKER: Right.

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

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

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

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

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

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

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

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

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

able to analyze for the chrysotile.

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

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

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

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

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

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

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

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

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

SPEAKER: Do those also produce asbestiform particles?

MR. SANCHEZ: Potentially, yes.

MS. MOSSMAN: In which types?

MR. SANCHEZ: Specifically anthophyllite would be one, anthophyllite Mg2Mg5Si8O22(OH)2. There's generally some iron in it, but there are known locations where you have very like -- no iron anthophyllites, so you could be dealing with an amphibole with, you know, less than a weight percent of iron in it, you know, just a few weight percents

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

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

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

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

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

SPEAKER: That would be different than

talc?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I'm not sure what time it is.

MS. MOSSMAN: Yeah, we're over.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

many particles you actually look at.

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

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

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

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

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

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

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

Does that help?

SPEAKER: Yes.

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

MS. MOSSMAN: We should have moved groups.

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

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

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

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

measurements, compare them to standards.

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

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

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

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

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

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

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

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

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

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

SPEAKER: Confirmation analysis.

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

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

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

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

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

MR. SANCHEZ: Oh, yeah, we --

SPEAKER: And you can also set it with a

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

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

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

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

SPEAKER: Bariatric --

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

SPEAKER: But it works. I mean, you can

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

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

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

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

couldn't.

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

SPEAKER: Correct.

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

SPEAKER: Oh, yeah.

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

information.

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

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

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

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

MS. MOSSMAN: We probably should.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the broader world, we can't answer.

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

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

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

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

MR. SANCHEZ: It's not --

SPEAKER: -- and then you take the tox

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. SANCHEZ: So to design certain

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

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

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

State of Maryland, to wit:

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

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

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

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

Jean M. Townsend

Notary Public

My Commission expires:

October 8, 2021