U.S. FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC MEETING: TESTING METHODS FOR ASBESTOS IN TALC AND COSMETIC PRODUCTS CONTAINING TALC

Moderators: Ms. Kari Barrett
Ms. Janesia Robbs

Panelists: Dr. Kristina Hatlelid
Mr. Frank Hearl
Mr. Bradley Van Gosen
Dr. Steven Wolfgang
Dr. David Berry
Ms. Deborah Smegal
Dr. Linda Katz
Dr. Christopher Weis

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INDEX TO SPEAKERS

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P R O C E E D I N G S

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MS. KARI BARRETT: Good morning and welcome to balmy Washington in February. I want to welcome everyone today to FDA's public meeting on Testing Methods for Asbestos and Talc in Cosmetic Products Containing Talc.

My name is Kari Barrett, and I'm going to be moderating today's public meeting this morning. And then my colleague, Janesia Robbs will be joining me this afternoon as we have our public comment session. So you'll be meeting Janesia later on.

The purpose of today's public meeting is to discuss and obtain scientific information on topics related to testing methods for asbestos in talc and cosmetic products containing talc. We expect this meeting to be an important step in our continued efforts to gather information on this topic, and we thank all of you in the room and online for joining us today.

Before we jump into the program, we do have a few general announcements that I want to make. So let me run through the list.

All of you in the room should have received a folder at registration. In that, there are a number of handouts, including the agenda. There is a list of the bios. And so that's helpful because as we go through the day, we're not going to give extensive background on our speakers since you can reference that, and that will just help us move through the day a little quicker.

Also to all of the folks who are web casting in, you should also have access to the agenda, the bios, and other background information through the website.

I should note that today's meeting is being webcast. It will be recorded and posted on our website. We also will have a transcription of the proceedings today. All of that will be available. Also the PowerPoints, but give us a little time. The PowerPoints take about a week to get up and then the transcript and the recording -- the recording, I'm not sure of the exact timing, but the transcript could take up to a month. So I just want to forewarn you in that regard, but do check back to the meeting website for updates in that regard.

If we do have any media or press folks here, I hope that you have checked in with Monique Richards. Monique, can you raise your hand?

MS. RICHARDS: Good morning.

MS. KARI BARRETT: All right. There is Monique. So, if you haven't checked in and you're with media, please do.

Also, I understand we may have some congressional staff here. We have Aliza Glasner who is here to help with that. She's raising her hand in the back. You can also reach out to Monique and you can get connected with Aliza if you need to.

I would remind everyone this morning that -- a couple of things with your cell phones, please be sure that you turn them off or have them to vibrate. If you have multiple cell phones, keep them all in mind.

Also, too, if you need to have a conversation with someone, please do bring it out in the hall so it's not disruptive to the presentations. The sound in this room carries very well.

Lunch and refreshments are available in the lobby area. We mentioned earlier if you were interested in ordering lunch, there is a form, you do need to get that in this morning before 9:30.

The restrooms are located past the registration area. If you need any help in that regard, just ask the registration staff. And I do want to remind people who are offering public comment this afternoon -- we're going to talk about this later today, but do keep in mind that we are going to really be strictly adhering to the time limits that have been given. We do have, for those who are speaking, a light system, a green, yellow, red light system. And we will, again, be adhering to that. So If you have a chance this morning just to kind of revisit your talk and be sure you're within your time limits, that would be greatly appreciated.

So with that, we're going to actually now jump into the program. And it is my pleasure to introduce our first speaker, Dr. Susan Mayne, who is our director for the FDA Center for Food Safety and Applied Nutrition. And she will kick us off with some opening remarks. Dr. Mayne?

DR. SUSAN MAYNE: Thank you, Kari. And good morning, everybody. I'm really pleased to welcome you here to FDA for our public meeting that is aimed at advancing the science surrounding analytical methods, involving the testing of talc and talc-containing cosmetics for the possible presence of asbestos.

As part of our mission to protect consumers, FDA monitors the market for cosmetic products that may pose a public health risk.

In 2017, we became aware of reports of asbestos contamination in certain cosmetic products, including products marketed to children.

Currently, there is no standard definition or tests for detecting asbestos, or other potentially harmful elongated mineral particles in talc, and talc-containing consumer products, including cosmetics.

Accordingly, in the fall of 2018, FDA formed an Interagency Working Group on Asbestos in Consumer Products, which has representatives from a number of federal agencies to support development at a standardized definition and testing methods for asbestos, and other mineral particles of concern that could potentially affect consumer product safety.

Today, we are going to hear

preliminary recommendations from the Working Group members and others to further the development of a standardized definition and testing methods to improve sensitivity, consistency, and inter-laboratory concurrence of asbestos testing in talc used in cosmetic products, and of talc-containing cosmetic products.

Although, we do not intend for this meeting to produce any decisions or new positions on specific regulatory questions, we do expect this meeting to be an important step in our continued efforts to gather information, including data, to improve the consistency in terminology, analytical protocols, and data reporting for asbestos and other potentially harmful mineral particles that may be present as contaminants in talc and cosmetic products containing talc. And provide information that can be used for future discussions on health effects.

In closing, I want -- I would like to especially thank our partner federal agencies and their Subject Matter Experts for their work on this issue, along with all who helped to put this meeting together today.

We look forward to seeing the feedback that we receive on the Working Group's preliminary recommendations. Thank you.

MS. KARI BARRETT: Thank you very much, Dr. Mayne. We'll now hear from our FDA Office of Cosmetics Director and other distinguished government scientists on the issues of concern related to asbestos in talc and cosmetic products containing talc. To provide an overview of issues for talc-containing cosmetic products, we have Dr. Linda Katz, who is our Director, Office of Cosmetics and Colors for the FDA Center for Food Safety and Applied Nutrition. Dr. Katz?

(Technical difficulties.)

DR. LINDA KATZ: Thank you, Kari, and good morning, everyone. Can everyone hear me in the back? Good. Great. Thanks.

Good morning, and once again, I'd like to welcome everyone to the FDA's public meeting on testing methods for asbestos in talc and cosmetics containing talc products.

Over the next 20 minutes or so, what I'd like to do is sort of set the stage for why we are having this meeting, and for future discussion, but focusing primarily on cosmetic products.

I'll describe a little bit about FDA's regulation of cosmetic products, the uses of talc in cosmetic products. Give some historical prospective, some follow-up reports on the 2017-18 reports of asbestos in cosmetics, and some of the challenges that we're facing in establishing the most suitable method or approach for trying to identify asbestos contamination in talc.

So let me begin with FDA's authority over cosmetics. FDA regulates cosmetics under the Federal Food Drug and Cosmetic Act, where it's described -- a cosmetic is described as an article, other than soap, that's intended for cleansing, beautifying, promoting attractiveness, or altering appearance.

FDA does not have the authority to approve cosmetic products or their ingredients before they go on the marketplace, with the exception of color additives. The manufacturers are responsible for making sure that the cosmetics that they market are safe for their intended conditions of use. They may do testing, and whatever testing they decide to do is up to them. We are not specific as to how these products must be tested. They can use -- rely on similar data from products that are already on the market, or they can use available -- other available data or do their own testing.

The bottom line is that FDA's regulation of cosmetics is all post- market. That is, FDA can take appropriate action if a cosmetic is found to be adulterated or misbranded.

So what -- why is talc used in

cosmetic products. In fact, talc is used in numerous cosmetic products. We have probably reports of over 4,500 uses of talc in different kinds of cosmetics products in our own database.

It's used in products that range from baby powder, to blush, to eye shadow, to face powders. And its main purpose is really to reduce moisture, as a moisture absorber, and for aesthetic purposes. That is to provide for a slippery feel or brightness.

I've provided a link on our website to describe more about how talc is used in cosmetic products, and the products that they may be used in.

So let me shift a little bit and talk about some of the historical testing. And I'm going to go back to the 1960s to '70s, because this is basically when we began to talk about or get reports on problems with testing from a variety of laboratories in the U.S. that raise concerns about asbestos-contaminated cosmetic talc.

At that time, there were a variety of different test methods that were being used to assess for asbestos in talc-containing cosmetic products. And these include methods such as X-ray Diffraction, Polarized Light Microscopy, Transmission Electron Microscopy, thermal analysis. But the interesting part is that even though these methods may sound familiar, and they are familiar, because we're still using many of them, that the labs that were doing this testing often produced conflicting results, which, again, created problems.

The FDA realized that there was an issue and began to grapple with what would be the best approach and proposed a mandatory optical microscopy method. But at the same time, in around 1976, the cosmetic and toiletry -- Cosmetic Toiletry, Fragrance Association, CTFA, now known as the Personal Care Products Council, also began developing a new method. And that method was referred to as the CTFA Method J4-1.

The method was actually published in the "Asbestiform Amphibole Minerals in Cosmetic Talc". And this method became the standard that industry used to assess for talc that was being used in cosmetic products. That basically this is a method that uses Polarized Light Microscopy only if the X-ray Diffraction is positive.

The detection limit is low. It's greater than or equal to 0.5 percent, and it only really is useful completely for identifying amphiboles, and we will talk a little bit more about that. But that in terms of being able to identify chrysotile fibers, that its sensitivity is not really very good.

In 1994, FDA also held a workshop to address talc consumer uses and health perspectives. The proceedings were published in the Regulatory Toxicology and Pharmacology Journal in 1995. And as the title would imply, that basically, the premise was to look at the variety of different reports, the epidemiologic and toxicologic data that was available at the time related to talc.

The meeting did not concentrate or spend much time looking at asbestos. And one of the conclusions was that, probably electron microscopy was necessary to be able to assess for asbestos, but that's where this symposium stopped.

So that brings us then to from 1994 through 2008, that there were no reports of asbestos in cosmetic products that the FDA was aware of.

However, in 2009, a news report from South Korea indicated that asbestos was detected in pharmaceutical and cosmetic products traced to talc imported from China. The Korean FDA at that time ordered that products that might contain asbestos to be removed from the marketplace, and FDA, as a response related to this concern, commissioned a survey analyzing 34 talc-containing cosmetic products.

Because we did not have capabilities to do the testing ourself, we relied on a contract lab, AMA Analytical Lab who was awarded the contract. And using Polarized Light Microscopy and Transmission Electron Microscopy, they evaluated these 34 samples, and detected no asbestos in any of the raw materials, or finished makeup products that were evaluated. That information was posted on our website and is still available.

With regard to a more recent time, in July 2017 through March 2018, FDA became aware of reports of the presence of asbestos in certain cosmetic products that were marketed to children.

That, again, because FDA has still no established labs to conduct this testing, we sought the services, primarily of a contract lab to implement a suitable approach to do some testing for us that would enable the FDA to test the products of concern, to test additional products that contain talc, and to communicate findings, both with industry and consumers.

So in March 2018, the FDA entered into a technical agreement with OSHA to test products reported or suspected to contain asbestos using Polarized Light Microscopy and Scanning Electron Microscopy.

While this was ongoing, we were still awarded a contract to AMA in the fall of 2018 that AMA began to actually do some of the testing of talc-containing cosmetic products in 2019 using Polarized Light Microscopy and Transmission Electron Microscopy.

By February 2019, FDA received a report from OSHA confirming the detection of tremolite in three Claire's products, and one Justice product, which were subsequently recalled. On the latter, the Justice product, had been recalled in 2017 when the product was first suspected of containing asbestos.

Between March and October of 2019, AMA tested 50 talc-containing products. Of these, ten tested positive for asbestos and were recalled. The next slide will identify them, and they're currently identified on our website, which I've listed below.

In addition to posting them on our website, we've also had numerous safety alerts and press releases to make sure that consumers are aware when we do find asbestos in these products.

As you'll notice, there are two asterisks by two different products and these products were independently tested and analyzed, and the results were the same from two different analytical labs.

So as we've heard earlier from the opening remarks from Dr. Mayne, and that you're well aware from our Federal Register notice as well, that there are challenges in establishing the most suitable approach to test for asbestos in cosmetic products.

Part of the reason for this challenge is that there is a need for standardization. We know that there is confusing terminology. Not everybody interprets the fibers in the same way. The data from different labs suffer from a lack of procedural standardization, and some degree of subjectivity. That the reports of findings, that is how -- specifically how fibers are characterized, counted, and expressed, in quantitative and statistical terms is also not standardized. And there is no appropriate reference material.

In addition, the FDA realized that we need to go ahead and to think about how to develop these approaches. So as you've heard, we've formed an Interagency Work Group that I will talk more about as we go further, but to try to deal with some of these issues, and to develop suitable analytical approaches to look at ways to develop a definition of asbestos, to reference the properties, including appearance of commercial types of asbestos used in finished products, to evaluate counting criteria for the asbestos fibers, to realize -- to look for a suitable reference and sample of preparation and test methods.

Further, that the importance is that we realize that we need to have individuals with experience in these complex methods to help to detect, characterize asbestos and talc, and talc-containing products.

The proposed approaches need to have adequate sensitivity to detect asbestos at levels at which it might be present in talc and talc-containing cosmetics. And that the proposed approaches need to be able to be used in a wide range of products, not just cosmetics.

So that FDA has been involved in not just the Interagency Work Group, but in a variety of different places as a stakeholder to try to advance the science.

In 2010, FDA proposed the formation

of the Talc USP Expert Panel, which was charged with developing suitable methods for asbestos testing of raw material for drugs.

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) Scientific and Technical Symposium, which was held in November of 2018, was an attempt to address the need for standardization of definitions and methods necessary to detect asbestos in talc-containing products.

And we will hear more from the Interagency Work Group on asbestos in Consumer Products today, but this was formed in the fall of 2018 as a federal government-wide with eight different partner agencies to be able to address and grapple with some of the issues to try to further look at definitions and methods that might be useful to help us to detect asbestos in cosmetic and other products that the FDA -- that the government regulates.

In going forward, we realize that

approaches are needed to be evaluated to understand the sources of variation in order to enable refinement of methods. Improve repeatability, reproducibility of the tests to create definitions, and eventually to publish a standard method.

We realize that further discussion is needed regarding interlaboratory studies and broader scientific participation from the community itself of experts.

So with these parting thoughts, I will end so that we can hear from the experts of the Interagency Work Group as we go forward for the day, and I thank you.

MS. KARI BARRETT: Thank you, Dr. Katz. Okay. We will now like to invite Bradley Van Gosen who is a research geologist, United States Geological Survey, to address the Mineral Fibers of Potential Concern in Talc Geology and Mineralogy. Thank you.

MR. BRADLEY VAN GOSEN: Thank you.

My presentation will be an overview of the geology and mineralogy of large talc deposits.

I will describe the mineral fibers that can be naturally intergrown with talc and show that their presence or absence is based on the mineral deposit type, that is the geologic conditions that form the talc deposit.

First, for context, I thought I'd provide some background on the scale of the U.S. talc production in markets. This is data compiled annually by our USGS National Minerals Information Center.

So during -- in 2018, total domestic sales and export from domestic operations of talc by U.S. producers was estimated to be about 540,000 metric tons, with a value of about $117 million. So again, during 2018, talc produced and sold in the U.S. was used mainly in ceramics, paint, paper, and a lesser amount in plastics, rubber, and roofing. And you can see that cosmetics represent a relatively small amount of the talc uses in the talc market.

Talc is one of the few mineral commodities that we produce more of domestically than we import. For example, in 2017, 540,000 metric tons were produced in the U.S., while we imported about 354,000 metric tons. And this import number represents the amount of talc imported as crushed ore, and does not account for talc that has already arrived in a product such as a cosmetic, because this type of data is not reported.

Including imported talc and domestic production, the U.S. end uses in decreasing order by talc tonnage include plastics, ceramics, paint, paper, roofing, rubber, and again, cosmetics is a relatively small amount of the talc market.

Talc is a magnesium silicate mineral, used as number 1 on the MOH hardness scale as the example of the softest mineral.

Talc is usually platy -- a sheet silicate, but as I'll show, fibrous varieties of talc can occur. There are weak bonds between the layers of talc, so they easily slide past each other, which gives talc its greasy and slippery feel, and it's very low hardness. Well-developed crystals of talc that are invisible to the naked eye extremely rare. Rock that is described as talc and is the least bit hard means it also contains other minerals such as quartz or calcite.

In regards -- whoops, did I skip -- in regards to the regulated asbestos minerals in relationship to talc, -- the amphiboles that are relevant are the asbestiform varieties of anthophyllite, actinolite, and tremolite. And crocidolite, as I'll explain a little later, the asbestiform of amphibole called riebeckite is commercially called crocidolite. And the asbestiform of the cummingtonite-grunerite series is referred to as amosite. So these are not relevant to the talc deposits, because they do not form in the same environment.

You'll notice that talc and anthophyllite asbestos are similar -- are -- these are out of order. I'm afraid these slides are out of order, I'm sorry.

Talc and anthophyllite form in the same -- can form in the same geologic environment. You'll see that magnesium, silica, and water are the essential ingredients to form both talc and the asbestos minerals.

So it's not unusual geochemically if these form together. The amphiboles are -- can vary in their shape and morphology. The most -- even within a single deposit. These are examples of tremolite particles within a single talc deposit of the Death Valley area.

This variation and amphibole shape is not specific to talc deposits, but can occur in all deposits of asbestos. The most common forms of amphiboles are the blocky to prismatic forms. The asbestiform varieties are much less common. Acicular, the example in the lower left is another word for needle-like.

And note that the disaggregation of a fiber bundle, such as this example on the lower right, can result in the release of an isolated, thin, elongate mineral particle that could be similar to the acicular needle-like example.

These are more examples of asbestiform amphiboles. These are asbestiform tremolite. With light pressure, these fiber bundles will disaggregate and the individual fibers will be released and scattered.

Another nuance about amphiboles. Minerals break, cleave, and separate preferentially along planes that are due to their internal crystal structure. The predominant plane in which a mineral species will most readily break is called the mineral's cleavage.

The cleavage for amphiboles is preferentially along their long axis, forming elongate minerals such as this example of actinolite in the upper left. For amphiboles, the elongate particles that are produced are often referred to as cleavage fragments.

With further pressure, these cleavage fragments can break into thinner and thinner elongate particles, such as the ones I've circled in the upper left. The arrow indicating small particles cleaving off in the lower left, and in the upper right, another example that is most likely a cleavage fragment.

When an amphibole bearing rock, including talc is pulverized, micronized, and put into a product, it can be difficult to determine whether a very small, thin, elongate amphibole particle that you observe, even under high magnification, whether it represents a cleavage fragment or instead is a fiber that was once part of a fiber bundle. And just to complicate matters, some amphibole particles, such as this example in the lower right, can display characteristics of both fibers and cleavage fragments.

The same geologic processes that form talc can also form amphiboles, sometimes including the asbestiform varieties of the amphiboles. In at least one deposit-type talc, ores can be spatially associated with chrysotile, as I'll show.

The general process involved in forming both talc and asbestos is called metasomatism, which is the dissolution and deposition of a new mineral that grows in and replaces the body of a pre-existing mineral or a mineral aggregate.

Talc and the asbestos minerals replace pre-existing minerals. To form talc by metasomatism, the process can be driven by regional metamorphism, which is driven by plate tectonics. By contact metamorphism, the intrusion of a magma into a pre-existing magnesium-rich rock, or the circulation of hydrothermal fluids which are heated by a magma in which the fluids react with and replacement of magnesium-rich rock.

In each of these processes, you need a magnesium-rich host rock, which is either a dolostone magnesium-rich carbonate rock or an ultramafic rock, which are magnesium-rich metamorphic rocks. And I'll show examples of these types of processes and geologic settings in a moment.

Regional metamorphism of dolostone's magnesium-rich carbonate rocks, again, can form large talc bodies. The best examples occur in upstate New York. Compression and shortening of the earth's crust across the region due to plate tectonics produced high heat and pressure that metasomatized thick layers of magnesium rich marble, a dolomitic marble.

The heated fluids under pressure moves silica into the dolostone marble and form large deposits of the amphiboles, tremolite, and anthophyllite.

Platy fibrous talc formed amongst the tremolite and anthophyllite as the pressure released in the region and the fluids began to cool. These are the mineral reactions that occurred in these systems. First, under high heat and pressure, dolomite in the presence of silica and heated waters formed large bodies of tremolite replacing part of the dolomite marble.

Much of this tremolite then converted to anthophyllite, another amphibole as temperature and pressure dropped in the system. And as pressure and temperatures lowered even more in the system, much, perhaps, most of the anthophyllite was replaced by talc, forming a fibrous talc intermixed with platy talc and tremolite.

This is fibrous talc -- whoops, sorry. This is fibrous talc accompanied by platy talc in one of the deposits in which talc has replaced pre-existing fibrous anthophyllite. The talc deposits of upstate New York are classic examples of fibrous talc, and these were used in the manufacture of paints, ceramics, and plastic molding compounds, but not suited for cosmetics.

In these same deposits, mineral fibers sometimes referred to as transitional fibers were formed. And these particles, pre-existing anthophyllite was partially replaced by talc. Forming elongate mineral particles partially composed of talc and partly of anthophyllite.

Our next type of talc deposit that contained fibrous amphiboles are formed by contact metamorphism, in which the magma intruded into a magnesium-rich rock, a dolostone once again. There are dozens of examples of these types of talc deposits in the Death Valley Region, which are now abandoned such as this abandoned talc mine within Death Valley National Park.

The Death Valley talcs were used mainly in the manufacture of ceramic wall tiles and in paints.

This view shows the relationship well. A pre-existing cherty dolomite, a silica magnesium rich carbonate was intruded by the magma represented by the gabbro sill. This reaction caused by the heat of the magma, and its heating of the waters in this sytem formed a talc tremolite rock, which became the talc ore body.

This is a schematic cross section of a typical Death Valley talc deposit, modified from Lauren Wright's excellent descriptive report on the talc deposits of the Death Valley region.

As I just described, magma intruded into the cherty dolomite which provided silica and magnesium. The magma-heated fluids in the system drove the reaction that added silica to the dolomite, forming layered rocks composed of talc, tremolite, calcite, dolomite, and quartz. And these are the -- these talc tremolite deposits were the deposits that were mined in the past across the region.

This is a closer view of the type of talc deposit that was formed in the Death Valley type deposits. You can put your finger on the contact between the gabbro, which was the invading magma. And your reaction to them that became the layered talc tremolite rock.

From samples of these deposits that I collected for more than a dozen of the Death Valley talc mines, using a scanning electron microscope, we usually found many examples of asbestiform tremolite intimately intergrown with platy talc. When crushed or even lightly handled, these tremolite bodies disaggregate and the individual elongate tremolite particles will disperse.

This is another example of the relationship between a tremolite fiber bundle, and the Death Valley talc and an elongate particle that's separated from a bundle. So these are images of a mineral dust dabbed from the inside of the plastic sample bag which was easily disaggregated just by a light handling.

So even under high magnification, it may not be clear that in an individual elongate particle within a dust or in a milled product were the result of an asbestos bundle that was crushed, or instead began as a thin, elongate cleavage fragment.

Our next deposit type geologic environment that can form talc deposits of commercial size are the result of regional metamorphism of ultramafic rocks. Ultramafic rocks are magnesium/iron-rich rocks that can either be igneous or metamorphic in origin.

During regional metamorphism, again, during plate tectonics across the region, shortening and squeezing of the crust can force silica-rich fluids into the ultramafic rocks, and form a rock type called serpentinite, which usually has the gray green appearance as you see here.

Serpentinite can contain chrysotile and amphophile asbestos, and in some settings can contain talc deposits. The very presence of serpentinite indicates that the chemical components needed to form asbestos are present.

This diagram is a very generalized depiction of a talc deposit formed by regional metamorphism of ultramafic rocks. And these examples occur in Vermont. The most thorough published discussion of the reaction zones displayed by a Vermont-style talc deposit is a paper by Rick Sanford in 1982, which represents his -- a synthesis of his Harvard Ph.D. study. His diagram, which I've simplified here, shows what Rick observed in a typical ultramafic-associated talc deposit in Vermont.

These types of deposits in Vermont were once sources for cosmetic-grade talcs. The talcs from this type of deposit are described as high purity, thus with high talc content and very little other minerals such as quartz or clay or calcite.

Rick determined that between the ultramafic rock shown on the left and the country rock on the far right, that there are a series of distinct zones formed by metasomatism due to the movement of waters through the pores during regional metamorphism. Rick can determine these involved temperatures in the range of 590 to 645 degrees centigrade, and pressures of seven and a half to eight and a half kilovars. This occurred during the Acadian orogeny, which was about 430 to 390 million years ago affecting the northern Appalachian Mountains.

Sorry. On the left, we have the serpentinite body, the magnesium source which can certainly contain locally chrysotile and fibrous and non-fibrous tremolite, actinolite, and anthophyllite. Inward is a talc carbonate zone, a low purity talc zone because it contains magnesite, a magnesium carbonate, and dolomite and calcite and evidence of talc replacing anthophyllite.

The central zone is the high purity talc zone, the talc ore body, with small amounts of other minerals such as quartz and clays.

Whether it can contain small amounts of anthophyllite, actinolite, or tremolite or chrysotile has been at the center of the debate.

Unfortunately, Rick did not have the benefit of an electron microscope, only a polarized microscope. And it appears that he could not examine the mineralogy of the talc ores at very high magnification. Nor have I found a peer-reviewed publication that has detailed the mineralogy of the high purity talc zones in these type of deposits as they occurred in the ground, only after the talc has been mined, ground, and processed.

So I'll suggest that a very detailed mineralogy examination of the talc ores from this deposit types, taken from samples at the mine site, is a study that should be undertaken.

On the right is a zone of actinolite chloride rock. An amphibole clay combination with abundant actinolite that has not been described as asbestiform and talc replacing actinolite and, perhaps, tremolite.

Moving further outward to the altered country rock in which the metamorphic texture remains with stubby amphiboles. And finally, the country rock, and the iron silica-rich gneiss metamorphic rock, which was the source for the silica in this complex reaction.

Our last talc forming system that can form large talc deposits is by the circulation of heated fluids called hydrothermal fluids that react with and replace dolostones once again.

The heat in these geologic systems is supplied by magma that rose through the crusts, but did not ultimately come in contact with the dolostone.

So heated fluid circulated upwards through faults and fractures, and reached an overlying dolostone marble, and replaced large areas of the dolostone with talc deposits.

The heat and pressure conditions were high enough to form talc, but did not reach the higher temperature pressure conditions needed to form amphiboles or chrysotile. Instead, dolomite simply converted to talc and the amphiboles, Alton ore or serpentine were created in these types of deposits.

This is a very simplified depiction of the geologic system that I just described. Magma rose through the crust expelling heated fluids that followed faults and fractures upwards into a dolostone unit, magnesium-rich marble.

The fluid gathered silica in the overlying units and likely also mixed with brown waters on the way. And the result was large talc deposits replacing the marble, bordered by envelopes with quartz, calcite, and dolomite.

The talc forming conditions, the depth and temperature conditions that formed these talcs were less than half of the temperature/ pressure conditions that I just showed that formed chrysotile and amphiboles in a regional metamorphism or a contact metamorphism setting.

This is the Yellowstone talc mine of Imerys in southwestern Montana. It's the largest known talc body in the U.S., and largest producer of talc in the U.S.

This large talc body formed by the process that I just described, because the heat source was at depth, the temperatures and pressures required to form amphiboles or serpentine were not reached. So this talc deposit and others like it in the region lack amphiboles or chrysotile.

However, much of the deposit and others like it in the region contain some grit, quartz, calcite, and dolomite, which can reduce the smoothness of the talc. And parts of the ore body contain iron oxide and graphite, which reduces its white brightness, which would be required for cosmetics.

So while considered to be a high purity talc, because it is at least 90 percent talc, only pockets of the deposit are considered suitable as cosmetic talc, mainly because of its darker color.

This talc is used for manufacturing paper, paints, coatings, plastics, rubber, ceramics, and agricultural products. So it has wide, diverse applications.

The points that I've hopefully made in my presentation, as I'll suggest that geologic conditions that form the talc body controlled whether their intergrown mineral fibers can or cannot exist.

Gel consistencies exist between the deposit types to form talc ore bodies that contain mineral fibers. However, all talc deposits can have some internal variations was just the nature of mineral deposits.

All talc ores used in products require detailed mineralogical studies so that we can fully characterize them and further understand them.

And one last point, I'll suggest

that it would be much easier to determine the amphophile and chrysotile content of a talc that was used in a commercial product, including cosmetics, if the mineralogy was examined from samples that were collected in place at the mine site before the talc rock had been mined, pulverized, micronized, and then mixed into a product where the mineral particles now, including fibers are now extremely small and scattered, and are difficult to observe or to analyze. Thank you.

MS. KARI BARRETT: Now, we'll turn to Dr. Christopher Weis, the toxicology liaison and senior advisor in the Office of the Director at the National Institute of Environmental Health Sciences.

Dr. Weis will walk us through mineral fibers and the lung exposure and toxicity. Dr. Weis?

DR. CHRISTOPHER WEIS: Welcome. And thanks to FDA and the IWGACP, the Interagency

Working Group, for inviting me here today.

I'd like to take a few minutes and discuss some basic aspects of fiber exposure and toxicity to set the stage for some of today's discussions.

But first, NIEHS, the National Institute for Environmental Health Sciences is one of the 27 institutes of the National Institutes of Health. NIH is also home to the National Toxicology Program.

The National Toxicology Program reports directly to the Secretary of Health and Human Services. So it's somewhat separate from our institute in that respect. It's important to note that NIH is not a regulatory agency. We primarily conduct and fund health research throughout the United States and the world, often in collaboration with our partners at HHS.

Over the next several minutes, I'd like to give you some background regarding our thoughts about the exposure and toxicity of the elongate mineral particles. I'll refer to these sometimes as EMPs, and these include asbestos.

Then, I'd like to take you on a trip deep within the lung, where exposure to EMPs is most important. And where most of the biological damage due to EMP exposures occurs.

Finally, I'll provide some data from my experience, and that of others who demonstrates the public health need for much better information about EMP exposures. Some of the topics that I'd like to discuss include lung anatomy and the physiology as they relate to exposure and toxicity of EMPs.

Then, I'd like to take -- to explain a simple -- in simple toxicological terms how EMPs initiate progressive inflammation that leads to lung disease.

Finally, I'll show you some examples of how EMPs that are below the resolution of light microscopy contribute to exposure. And why the characterization of all EMPs are vital for an understanding of disease.

Once inhaled, exposure to asbestos is in large part driven by the anatomy of the lungs. So I want to step through that with you briefly. Fibrous particles enter the lung through the trachea on a laminar air flow. The length-to-width ratio, or the aspect ratio of fibers, determines their aerodynamics characteristics as they fly through the passageways of the primary, secondary, and tertiary branches of the respiratory tree shown here.

This is why measurement of fiber size and shape is so important to the path of physiology of EMP exposure. Particles that impact on the surface of the upper reaches of the respiratory tract prior to reaching the alveoli of the lung, can be removed by mucous-coated cilia or little hairs on the surface of the trachea or bronchus that push them up to the esophagus then they're swallowed into the digestive tract.

However, at the level of the terminal bronchials and alveoli on the very far right of this picture of the lung, there are no cilia to assist removing these particles. The lung must rely on the cells called macrophages to remove the particles to the lymph system where they are eventually excreted into the urine. I want to zoom in a little bit closer.

This is a closer look at the alveoli clusters. There are about 600 million alveoli in a typical human lung. You can see in this picture that the alveolus cluster is surrounded by vessels.

In addition to arterioles and venules, the cluster is closely surrounded by lymphatic vessels shown in this figure in green. It's through the lymph vessels that waste products are removed from the alveoli and transferred to the kidneys for filtration and excretion.

Damage caused by the EMP is not

limited to the lung as they can be transported through the lymph to remote regions of the body.

Here we see a scanning electron micrograph of these alveolar clusters. The surface area at the alveoli in the human lung is huge, possibly covering as much area as half of a football field or more.

This cartoon represents a typical alveolus. I'd like you to take -- I'd like you to take note of a couple of interesting aspects of the physiology here. One, note that the thickness of the alveolar membrane is only about 0.2 microns. That's approximately 5,000 times thinner than a human hair.

This membrane across which gas exchange must take place is extremely thin. The membrane is very fragile to allow gas exchange to efficiently occur, so it's very susceptible to inhaled particles and other toxicants.

The other thing that I want to point out, and which we'll talk about on the next few slides, is the alveolar macrophage, this subtle color green here down in the lower right. The macrophages are a type of monocyte or a white blood cell that course through the body identifying and removing foreign material, and recycling old diseased or dead cells. They do this by engulfing these particles, treating them with acids and hydrolytic enzymes that reside within the macrophage cell.

As we'll see in a minute, macrophage cells are very important to the toxicology of EMPs.

This photograph shows an alveolar macrophage using its pseudopods to identify particles in the environment of a lung. The macrophage must accurately identify and orchestrate the removal of foreign materials from the alveoli and the terminal bronchioles.

All EMP, regard -- all EMP, regardless of their mineral makeup or size, are clearly foreign and potential targets for these macrophage. The green particle here -- the green particles here are bacteria and the red circular object is a red blood cell for scale. The macrophage uses surface ligands, as well as other characteristics to identify target particles that will be engulfed, and recycled through the lymph ducts and eventually excreted in the urine.

With the advent of nanotechnologies, and the potential for inhalation of these materials by workers and the public, much research has proceeded to understand potential exposures to these new substances, and find methods to mitigate or eliminate the inhalation hazards.

One advantage of this research is the ability of scientists and engineers to manufacture consistently-sized particles and analyze the toxicity to these uniform-sized populations of biopersistent engineered particles.

Here we see a variety of different shaped particles, some obviously manufactured, others naturally occurring, such as the panel on the lower right. All are potential targets for removal by the macrophage cells if they were to be inhaled.

In this scanning electron microscope photo, a pulmonary alveolar macrophage cell is attempting to engulf and ingest several elongate mineral particles at once. The macrophage has become frustrated by the inability to engulf these EMPs. This frustration, the incomplete ingestion of biopersistent particles, causes the release of cytokines, or cell signals, such as interleukin-1 beta, proteolytic enzymes, and reactive oxygen species from the frustrated macrophage.

These cytokines initiate an adverse outcome pathway that begins the process of inflammation, fibrosis, and progressive pathogenesis. All biopersistent EMP have the potential to initiate this inflammatory cascade of events.

This work by Ji et al. -- and one of the authors, by the way, is with us in the audience today, and we may hear from him later this afternoon -- was funded by NIEHS, and depicts the use of engineered elongate mineral particles to measure the release of cytokines as a function of aspect ratio or length-to-width ratio labeled AR on the right side of the graph here.

The researchers were able to use short manufactured particles on the order of two microns in length, and well below the level commonly recorded by most laboratories. And look at the release of the cytokine interleukin-1 beta when these cells were challenged.

What we see here is that short, biopersistent particles with higher aspect ratios cause greater interleukin-1 beta release.

Dr. Paul Howard will give us several examples of this later today. Stimulated release of cytokines, proteolytic enzymes, and the production of reactive oxygen species is clearly an adverse outcome pathway associated with the inflammatory processes in disease progression. All EMP have the ability to trigger this adverse outcome pathway.

Inflammation such as this can cause a variety of diseases. These are some of the apical diseases associated with cytokine release and inflammation. Pleural effusions, the pleura is a delicate membrane that lines the surface of the lung cavity. These effusions are the earliest and most common effect of EMP exposure and are usually seen 10 to 20 years after even minimal exposure.

Pleural plaques and diffuse pleural thickening. These lesions when examined at autopsy usually contain many EMP.

Pulmonary fibrosis. This is a bilateral interstitial fibrosis frequently associated with diffuse pleural thickening.

And malignant mesothelioma. This very lethal disease usually arises in the pleural and the peritoneum, but sometimes the pericardium, the larynx, and the kidney. It's strongly associated with a cumulative burden of EMP exposure, and has a latency of 35 to 40 years. This disease is aggressive, most die within one year of diagnosis.

And bronchogenic carcinoma, develops in 20 to 25 percent of asbestos workers, or others who are chronically exposed to EMPs, usually after 10 to 30 years of latency, and the prognosis is poor. Amphiboles are 10 to 50 times more potent than chrysotile as an inducer. And smoking, coupled with EMP exposure, greatly magnifies the risk.

This and the following slide shows some of the consequences of chronic inflammation due to EMPs. These apical diseases are progressive. All can be fatal. The left two panels show asbestos bodies viewed under light microscopy following autopsy. The upper right photo shows severe diffuse pleural thickening and bilateral fibrosis. The bottom right photo is the diaphragmatic view of the lungs of an individual who died with pleural plaques.

So to summarize what we've seen, inhaled particles accumulate in the lung. The smallest particles, with higher aspect ratios, travel more deeply into the lung. Clearance from lower airways, if it happens at all, can take decades, 20 years for amphiboles, 10 years for chrysotile.

Oops, I'm sorry, here we go. I skipped a slide, sorry.

So to summarize what we've seen, inhaled EMP accumulate in the lung. Macrophages engulfed trapped particulates and then travel to the lymphatic system. The frustrated phagocytosis causes inflammation and can initiate fibrosis. Many biopersistent particles activate an inflammatory response, initiating collagen deposition, granulomas, scarring, fibrosis, interstitial lung disease, and cell mutation.

EMP-related respiratory diseases are initiated by chronic inflammation, and typically develop over a long period of time.

Next, I'd like to show you some data collected by myself and others that causes concern about incomplete characterization of EMPs in the environment.

This scanning electron micrograph was taken by the USGS, the United States Geological Survey, at their new mineralogy lab in Colorado where Brad works. It shows a bundle of Libby amphibole EMPs observed in a residential soil sample that was originally recorded as non-detect, using analysis by Polarized Light Microscopy.

This type of EMP was originally labeled as cleavage fragments by industry consultants working on the site. As such, they would not normally have been counted or even considered in the exposure equation.

Bundles similar to this can be inhaled and might be expected to disaggregate into hundreds of individual EMPs. This mischaracterization by light microscopy was common during the early stages of the Libby response. And as the science advisor for the response, I requested that we turn to more powerful analytical techniques.

This disaggregation of EMP can occur even after inhalation. This work by the late Dr. Phil Cook demonstrates that the disaggregation process actually occurs within the lungs.

In this series of experiments, Dr. Cook provided a single dose of EMPs to a population of experimental animals, then followed them for the next two years. What he found was that the number of individual EMPs increased over the course of his observations. This clearly demonstrates that bendable fibers can disaggregate even after they're inhaled.

Under certain analytical protocols, it's common convention when addressing exposure to EMP, that the microscopist exclude fibers less than five microns in length. While this practice may have been useful for screening occupational exposures, it places an undue burden on the analysts, and limits the information that toxicologists and epidemiologists critically need to understand the pathology and pathological effects of the overall dose.

This graphic -- this graphic shows the length distribution of EMPs collected during the federal response action in Libby, Montana. During that action, the EPA collected and counted all fiber sizes visible by electron microscopy. This frequency distribution graph shows the cumulative length fibers counted in more than 29,000 Libby air samples. Nearly half of the fibers were found to be less than five microns in length. So nearly half the EMP exposure in Libby would have been excluded from reporting under conventional laboratory reporting methods.

Here are a couple of fiber length distributions of tremolite EMP collected from two cosmetic talc samples. Yet again, we see this dominance of short EMPs that are not usually counted. EMPs to the left of the red mark in both panels are shorter than five microns in length, and would not conventionally have been included in the laboratory report.

As a toxicologist, this is unacceptable. We must fully characterize EMP exposures in order to understand the full spectrum of their health implications.

This work by Dr. Les Stayner and his colleges at the University of Illinois in Chicago, shows the full fibrous size distribution of occupational exposures to chrysotile workers. Here, once again, we see the same phenomenon. The author has found that TEM-based cumulative exposure estimates provided stronger predictions of asbestosis and lung cancer mortality than light microscopy-based estimates.

The boxes shaded gray at the tops, even though they represent most of the exposure to these workers, were not originally counted. Stayner's team reanalyzed the data using a transmission electron microscope to obtain a full characterization of the fibrous sized distribution.

Again, we see that short fibers, those not conventionally counted, dominate the worker's exposure.

I'd just like to read you the statement that Dr. Stayner made regarding his observations.

"Fibers shorter than five microns have traditionally not been counted by methods used for regulatory standards for asbestos, because these methods were developed to provide a reproducible index of fiber exposures."

"The findings from our analysis [Stayner's analysis] show that cumulative exposures to all fibrous indices, including fibers less than five microns in length were highly statistically significant predictors of lung cancer or asbestosis mortality."

This is my last slide, and it's really a wish list for the types of information that I think we need to be able to better understand how EMPs cause toxicity, disabilities, and death in well over 10,000 Americans each year.

Length and width. Fibers should be characterized completely for all lengths and all widths. Biopersistence in biological tissue is critical. You've seen how the macrophage struggles with biopersistent particles. The surface area of these particles, we believe, has much to do with the recognition by macrophages, and should be characterized and measured in the best ways that we can.

Mineral type and habit are, yes, very important. Surface reactivity and surface charge. We know that many mineral fibers carry an electric charge, and if there is a way to measure that, that should be done.

Thank you very much, and thanks

again to FDA and the Interagency Working Group for letting me speak today.

MS. KARI BARRETT: So I do see we are ahead of schedule. I think what we'll do is we will go ahead and take our break, and we'll start up again at 10:10. So we'll come back at 10:10 and go to our next session.

(Short recess taken.)

MS. KARI BARRETT: It looks like we're ready to begin. So now we're going to hear from a panel of FDA speakers who are all involved in the Interagency Working Group on asbestos and consumer products, also known as the IWGACP. So it's an acronym you'll get used to.

To start, we have Debbie Smegal, who is our associate director, Office of Cosmetics and Colors, FDA Center for Food Safety and Applied Nutrition. And she's going to give a work group overview. Debbie?

MS. DEBORAH SMEGAL: Good morning, I'm Deborah Smegal, Chair of the Interagency Work

Group on Asbestos in Consumer Products this past year, and I will be giving an overview of the Work Group.

So the IWGACP was formed in the fall of 2018 to support the development of standardized testing methods for asbestos and other mineral particles of health concern that could potentially affect consumer product safety.

The purpose of the Work Group was to coordinate an effort amongst various U.S. Federal Agencies, to develop recommendations on key topics related to asbestos testing methodologies, and to harmonize criteria for data interpretation regarding the presence of asbestos and other potentially harmful elongate mineral particles (or EMPs) as contaminants in regulated consumer products containing talc. And this includes cosmetics, foods, dietary supplements, drugs, medical devices, ceramics, and art supplies.

When we refer to consumer products, we are referring to products used by consumers, which are regulated by a variety of federal agencies. This includes, but is not limited to, consumer products defined under the Consumer Product Safety Act.

The focus of the Work Group is on cosmetic- and pharmaceutical-grade talc, and NOT industrial-grade talc.

While the charge to the IWGACP was to assess consumer products more broadly, the focus of today's meeting is specifically on cosmetic products containing talc.

The Work Group consists currently of 38 Subject Matter Experts from eight federal agencies shown on this slide. That includes the Food and Drug Administration. The National Institute of Occupational Safety and Health. The National Institutes of Health/ National Institute of Environmental Health Sciences. The Occupational Safety and Health Administration. The Environmental Protection Agency. The Consumer

Product Safety Commission, the U.S. Geological Survey, and the National Institute of Standards and Technology.

The participating federal agencies have expertise in asbestos testing and/or asbestos-related issues, such as from a health perspective -- where you heard from Chris earlier this morning -- or they regulate some of the consumer products that contain talc as an ingredient.

In the fall of 2018, the FDA and other federal government agency representatives attended a scientific and technical symposium held by the Joint Institute for Food Safety and Applied Nutrition, otherwise known as JIFSAN, at the University of Maryland that was designed to provide a forum for experts in asbestos mineral analysis, academicians, and government officials to share their knowledge and technical expertise in

testing methods for analysis of talc, developing criterion used for fiber identification, and interpreting data.

The IWGACP efforts considered the scientific and technical information shared at the JIFSAN symposium that focused on analytical challenges, such as those shown on the slide, including analytical methods, identification of mineral fibers using physiochemical characteristics, definition of terms, quantification of mineral fibers, and reporting and interpretation of analytical data. The symposium -- the JIFSAN symposium -- did not address health implications, which should be considered in deciding how to view and interpret data.

Now, I'm going to show some of the questions that were discussed at the JIFSAN symposium that were also considered as a starting point for the IWGACP in developing a draft white paper.

Question one was, considering the characteristics of fibers, including length, width, aspect ratio, morphology, what criteria should be used in assessing if talc or a talc-containing product tests positive for asbestos fibers?

Two, what general techniques and published test methods should be considered for the identification of asbestos fibers in talc-containing products? For example, methods for sample preparation, as well as instrumentation needed to make an assessment.

Three, how are the terms asbestiform and cleavage fragment relevant to categorized population of fibers detected in the testing of talc?

Four, which unit of quantitation, for example, percent weight or number of fibers, and what measurement criteria should be used to express the amounts of asbestos in talc and talc-containing products?

And five, what standards should be developed for use to assess the presence of asbestos in talc-containing products? And this can also include reference materials, as well as methodology.

This slide presents an overview of the Work Group. Our first task was to develop a charter that established the operating principles, roles and responsibilities of the Work Group participants. And the focus areas for the IWGACP to leverage the scientific expertise and resources across the federal agencies.

Our scope was to deliver recommendations for suitable, analytical approaches, and terminology that can be applied to detect and characterize mineral fibers that naturally occur in talc used to manufacture consumer products focusing on cosmetics.

The scope of products is limited to those containing talc as an ingredient. And as I mentioned earlier, we focused on cosmetic- and pharmaceutical-grade talc, and not industrial-grade talc.

The IWGACP held ten monthly meetings

from February to December of 2019. And we also formed three Subgroups to address the most pressing questions regarding testing. Other questions that follow logically were deferred to a later date.

Collectively, the three Subgroups met more than 31 times, and this was in addition to the entire work group meeting monthly.

So there was a significant level of effort expended in this past year by the Work Group, just to get to today's meeting.

And of course, the goal was to have today's meeting where we could present our preliminary recommendations on testing methods for asbestos in talc, and consumer products containing talc. This information is also available in our Executive Summary that is available as part of the background materials as posted on the meeting web page.

And our goal is to develop a white paper with the final recommendations after this meeting.

So ideally, the white paper will contain recommendations that will seek to resolve inconsistency, and analytical methods and data interpretation of asbestos and other EMPs of health concern in talc and talc-containing products. To identify a testing approach and definitions of EMPs that may be found in talc intended for manufacturing FDA-regulated products, as well as other consumer products. And to build consensus on the recommendations for analytical methods, and acceptance criteria that can be utilized by regulatory agencies to prevent exposure to potentially hazardous EMPs.

So as I said, we formed three subgroups due to the size of the Work Group, which was initially over 50 participants. And because of the complexity of the issues, and the timeline for drafting a white paper and holding this public meeting to get stakeholder input.

Subgroup formation was decided based

on the expertise and interest of each member, and having at least one representative per federal agency.

Membership in Subgroups was on a voluntary basis. The Subgroups met on an as-needed basis, and were led by a Subgroup chair to discuss and develop their respective Subgroup work products.

The Subgroup chairs also volunteered to lead the technical discussion and deliberations of the subject matter experts. Subgroup 1 focused on terminology and definitions of mineral fibers of concern in talc.

Subgroup 2 focused on the analytical methods for detecting mineral fibers in talc and talc-containing consumer products. While Subgroup 3 focused on data reporting and analysis with specifics related to the content and format of the analytical reports.

Each subgroup was provided a problem statement and a series of charge questions that built upon the questions discussed at the JIFSAN symposium.

In addition, we had several ad hoc groups that met to discuss unresolved issues in greater detail. And we encourage dialogue amongst the subject matter experts of the work group.

So this slide, I'm going to show the original goal for each subgroup, some of which may have evolved during the year of deliberations.

So Subgroup 1 considered the goal to establish consensus on terminology and definitions of mineral fibers of health concern in talc, and talc-containing consumer products. And they deliberated on several charge -- on several charge questions to help focus their discussions.

Subgroup 2 -- their goal was to develop a robust, analytical protocol for detecting asbestos and other EMPs of health concern in talc and consumer products containing talc.

They deliberated on a long list of

charge questions, including nine questions that were discussed at the JIFSAN symposium.

Subgroup 3 focused on developing recommended laboratory reporting standards for content and format of analytical reports. Their goal was to establish concurrence on physiochemical attributes and criteria for identification, and counting of mineral fibers of concern during analysis of consumer products containing talc.

This Subgroup also had a series of charge questions to consider. The charge to each subgroup was very ambitious, and not all of the questions were fully resolved during the ten months of deliberation in 2019. However, we anticipate that the discussions will continue after this public meeting, as we work to finalize the white paper.

So next you will hear from our Subject Matter Experts on preliminary recommendations from the IWGACP.

Dr. Paul Howard, who is the rapporteur of Subgroup 1, and the Chair of Subgroup 2, and Senior Advisor in the Office of Regulatory Affairs at FDA, will present a summary of both Subgroup 1 and Subgroup 2's deliberations to date on the topics of mineral fiber terminology and definitions, and analytical methods. Unfortunately, the Subgroup 1 chair from OSHA was unable to attend today's meeting.

Then, Dr. Steve Wolfgang, who is the Chair of Subgroup 3, and a Subject Matter Expert and Consumer Safety Officer in the Office of Cosmetic and Colors at FDA will present a summary of the questions and recommendations of Subgroup 3 that focus on developing recommended laboratory reporting standards.

In addition, Steve will present a summary of research needs, and a recap of the IWGACP preliminary recommendations. This concludes my overview of the Interagency Work Group on Asbestos and Consumer Products. Thank you for your attention.

MS. KARI BARRETT: I really don't have anything to add beyond what Debbie has already said in her talk. But I will note next is Dr. Paul Howard, Science Advisor, Office of Regulatory Science, FDA Office of Regulatory Affairs.

DR. PAUL HOWARD: Thank you, Kari and thank you, Debbie for introductions and details about the organization of this working group.

I will -- I'm Paul Howard, and I'll be presenting the preliminary recommendations from subgroup one subject matter experts regarding terminology and definitions of mineral fibers of concern in talc.

As pointed out, Don Halterman who is the outstanding Chair of Subgroup 1 was unable to be with us today. I'm just getting over the flu, so please forgive me for coughing.

These preliminary recommendations

recommends are from individual scientists functioning as Subject Matter Experts in their respective scientific fields participating in a work group striving for consensus recommendations, and do not necessarily reflect the opinion or policies of their agencies, or represent proposed changes to any regulation of the U.S. Government.

In addition, the following that I will go over are preliminary recommendations from the working group Subgroup 1 Subject Matter Experts regarding terminology and definitions to use in addressing the levels of asbestos in talc-containing consumer products, including cosmetics.

The deliberations of the Subgroup and Working Group focused on terms and definitions required for consistent identification and measuring of minerals in consumer products.

Well, the goal of the Working Group Subgroup 1 was to establish consensus on terminology and definitions for mineral fibers of concern in talc and talc-containing consumer products. So in other words, the goal was to define consistent language of what should be analyzed in talc and talc-containing consumer products.

Furthermore, the Subject Matter Experts did not rely entirely on current definitions and counting criteria when considering how to address the current issue of the possibility of asbestos in talc used in consumer products.

Today's meeting will focus more specifically on cosmetic products than any other product.

As a quick review of the talk that was given by Brad Van Gosen of the U.S. Geological Survey, greater than 90 percent of the earth's crust is composed of silicates. These minerals are classified into seven groups depending on the chemical content and mineral structure. We will not delve into each group and the minerals contained in those groups, except to say that the asbestiform minerals anthophyllite, amosite, tremolite, actinolite, and crocidolite are members of the amphibole group in the double chain ino-silicates.

Chrysotile is a serpentine mineral of the phyllosilicates. And in the same phyllosilicate group, you will find the desired mineral products, talc, vermiculite, kaolinite, and others. The formation of these minerals, the ones that are desired, such as talc and vermiculite, and also the ones that are not necessarily desired, the chrysotile and the amphiboles, was eloquently described earlier by Brad Van Gosen. And we should consider that non-asbestiform minerals and asbestiform minerals may form in close proximity in the earth's crust.

An example of the growth of minerals into non-asbestiform or asbestiform space shown on this slide are examples of non-asbestiform grunerite-cummingtonite, as shown on the left here, and amosite, which is the commercial term for the asbestiform mineral grunerite-cummingtonite. So the same minerals can result in two different formations: asbestiform and non-asbestiform fibers.

The Working Group -- the Subgroup 1 of the Working Group considered many publications and agreed with the recommendations and rationale provided in the peer-reviewed NIOSH Current Intelligence Bulletin 62 that's titled "Asbestos Fibers and Other Elongate Mineral Particles State of the Science and Roadmap for Research". This HHS publication was released in the year 2011.

The reasons Subgroup 1 recommended adoption of some of the definitions and terminology in the NIOSH Bulletin 62 were are as follows: First, it's a peer-reviewed document and a coherent document developed by Subject Matter Experts.

Second, this document has stood the

test of time for over eight years as an excellent guidance document.

Thirdly, this document was developed as a consensus and reference guideline for NIOSH, which is a leading U.S. Government Research Agency.

Subgroup 1 of the Working Group agreed with the recommendation in the NIOSH Current Bulletin 62 regarding adoption of the term, elongate mineral particle, or EMP that is defined as any mineral particle with a minimum aspect ratio that is linked with a ratio of 3 to 1.

EMP is a broad term encompassing both asbestiform and non-asbestiform particles, habits. Having dimensions that may result in being respirable and biologically persistent.

Within this definition, asbestos minerals that have aspect ratios of 3 to 1 or greater, are a subset of EMP, and should be counted and identified as asbestos.

As a reminder, the six regulated asbestos fibers described in Brad Van Gosen's presentation are a subset of elongate mineral particles.

Subgroup 1 recommends the recording and reporting of EMPs with lengths greater than one-half micrometer or micron in length. This lower limit of length is shorter than other recommendations for recording and reporting, where other recommendations are to record and report, only particles greater than five micrometers in length for asbestos counting.

Subgroup 1 also recommends there not be a maximum length for recording and reporting EMPs. Countable EMPs defined in NIOSH Bulletin 62, is a particle that meets specified dimensional criteria for it to be counted according to established protocol.

Thus any EMP, according to Subgroup 1's recommendation, any EMP that is greater than one-half micron in length, should be recorded and reported by an analyst.

Well, there are several reasons why Subgroup 1 is recommending EMPs be defined, not only as a particle with an aspect ratio of 3 to 1, but that countable particles should also be those that exceeds one half micrometer in length.

The first justification for this recommendation is that it's consistent with the counting rules fibers established by the global standard for transmission electron microscope sampling and analysis, that is ISO 10312:2019 edition.

The second justification for recommending recording and reporting of EMPs greater than one-half micron in length, is based upon published reports that indicate particles less than five micrometers may pose a health concern.

Now, we do not have time today to cover all of the publications that support this position. However, we will look briefly at the conclusions of a few representative publications that were identified by Working Group and Subgroup 1, and are listed in the executive summary.

Well, in addition to the work of Stayner & Associates in 2008 that were cited and discussed by Chris Weis in his presentation, we cite other examples of studies that support the justification for counting EMPs greater than one half micrometer in length, and this includes the work of Suzuki and Yuen at Mount Sinai School of Medicine in New York City from 2002.

The authors obtained tissues from 168 patients that had mesothelioma, and used high resolution transmission electron microscopy to determine the asbestos particle type, the number, and dimensions in lung and mesothelial tissues.

Now, remember, asbestos exposure has been linked with pleural effusions, pleural plaque and diffuse pleural thickening, asbestosis, malignant mesothelioma, and bronchogenic carcinoma in the lungs as Chris Weis pointed out in his presentation.

Suzuki and Yuen detected and examined approximately 10,500 asbestos fibers by high resolution transmission electron microscopy in specimens of the lung, pleural plaques, or mesothelioma tumor tissue from these 168 patients.

The data from their Table 4 of their study, as shown in this slide, where the authors segregated their data into asbestos mineral type, as far as amosite, chrysotile, and crocidolite. And on the next slide, that I will show, were the tremolite and one of the others.

They also segregated it by fibers from the different tissue types. So they looked at, in lung tissue, what -- counted how many amosite were found, plaque tissue, how much amosite was found, and tumor tissue how much was found, and segregated their data in this way.

The yellow highlights that are placed on this slide point out some things that I want to draw your attention to. First is GM, which is geometric mean of the particles that they detected. It's highlighted in this column. And then also GSD is the standard deviation of the geometric mean, which is shown and I'll highlight here for amosite particles.

Let me draw your attention to the amosite that was detected in the lung tissue, which had a geometric mean of 5.08 microns, and a standard deviation of 3.12 microns, with the smallest particle that they detected being 0.2 microns in length, and the longest being 82.4 microns in length.

Now, we don't have time to really thoroughly examine this data. However, what is noticeable is a trim in the asbestos mineral sizes that were detected in these human organ tissues. The amosite particles in the lung, the plaques or the tumor tissue averaged 5, plus or minus 3, 2.4 plus minus 3.6 or 4.6 plus or minus 3.5 microns in length.

So based on this, a significant

number of the particles that were detected in the human tissues were greater than five microns, and a significant number were less than five microns in length.

The chrysotile asbestos, which we'll look at next, is considerably smaller in size, the ones that were detected in these tissues, with geometric means around 0.4 microns, with a large standard deviation, indicating that a large number of them distributed about that same, although a considerable number of those were below five microns in length.

The same is shown for the crocidolite that was looked at, and we'll just focus on the crocidolite in the lung tissue, that the geometric mean of the particles was 4.6 microns with significant distribution both above five microns and below five microns in these human tissues.

Continuing with Table 4, with Suzuki and Yuen tremolite and anthophyllite asbestos particles that were detected in the human lung tissue had somewhat similar distributions. In the lung tissue, around 5.8, plus or minus 2.75 microns. In the tumor tissue smaller, but still with a pretty good distribution. And for the anthophyllite, also a distribution around five microns.

The significant conclusion from this table in this study is that you have a distribution both above and below five microns in human tissue taken from patients suffering from mesothelioma disease.

Suzuki and Yuen summarized the size of asbestos particles detected in all tissues from the 168 patients, whose data is shown in their Table 5A, which is on this slide. Now, with the exception of the chrysotile asbestos, approximately one half of the asbestos particles that are detected in these human tissues were less than 5 microns in length. And approximately more than half were greater than five microns in length. With the chrysotile asbestos particles greater than 99 percent of the minerals were less than five microns in length. When summarizing for all of the asbestos particles that were detected in all of the human tissues in those studies, 89.4 percent of the particles were less than 5 microns in length.

The most significant conclusions from this study are that a majority of the asbestos particles found in human lung tissue were less than 5 microns in length. And secondly, that eliminating the detection or reporting of the asbestos particles less than 5 microns in length, would not be representative of the actual asbestos particle burden in these tissues, skewing the data of what is respirable and retained in human lung tissues.

The second publication that the Subgroup cited in support of recommending that particles greater than 0.5 or one-half micron be reported, recorded and reported, is further work that came from the Mount Sinai Medical College researchers. They updated their work in 2005. But we don't have time to review all of the data. This -- I mean, I'd love to spend all day talking about the data, but we don't have time. We can focus on a couple of the conclusions from the authors that support Subgroup 1's recommendation that EMPs greater than one-half micron should be recorded and reported.

First is long, thin asbestos fibers comprised only a 2.3 percent of the total fibers detected by transmission electron microscopy in these tissues.

Secondly, the majority, that is 89 -- over 89 percent of the fibers in the examined tissues were less than five micrometers in length. And approximately 93 percent were smaller than or equal to 0.25 microns in width. This reinforces the recommendations of Subgroup 1 that EMPs greater than or equal to one-half micron should be recorded and reported.

In this particular study, the reporting of asbestos fibers only 5 microns in length or longer would have resulted in not reporting approximately 89 percent of the fibers that were in the human tissues. The reporting of asbestos minerals below 5 microns provides a more complete picture of the asbestos minerals that are present in human tissues, as opposed to arbitrarily cutting off the reporting length at 5 microns.

The third publication that supports recording and reporting of EMPs greater than one-half micron is from Dodson and colleagues at the University of Texas Health Center that was published in 2003.

Again, we don't have time in this presentation to thoroughly examine the data in this publication, However, we highlight some of the conclusions as justification for Subgroup 1's recommendation that EMPs greater than one-half micron in talc, talc-containing cosmetics be recorded and reported.

They concluded that asbestos fibers of all lengths, including pathological responses -- that asbestos fibers of all lengths induce pathological responses, and that caution should be exerted when attempting to exclude any population of inhaled fibers, based on their length, from being contributors to the potential for development of asbestos-related disease.

An additional publication that supports the Subgroup 1 recommendation that EMPs greater than one-half micron of talc and talc-containing cosmetics be recorded and reported is the review published by Boulanger and colleagues in 2014.

Boulanger and colleagues concluded first that a view of experimental and epidemiological studies, toxicity of small fibers below 0.5 -- excuse me, below 5 microns cannot be dismissed. The potential toxicity of small asbestos fibers remains widely debated in the scientific community, but they can't be dismissed.

Secondly, the observation that small asbestos fibers may have lower effects in comparison with fibers greater than 5 microns is mostly founded on experimental studies in animals since few epidemiological studies took short fibers into consideration.

Additional data is needed since recent epidemiological studies suggests there is a risk for the short fibers.

Thirdly, based on published data, determining the role of fiber size and biological effects of asbestos fibers, and based on our present knowledge and the mechanism of actions Chris Weis pointed out, it appears that the measurement of airborne asbestos concentration limited to fibers with a length of greater than 5 microns leaves out other types of fibers, that is less than 5 microns that may also have adverse health effects.

Finally, as discussed by Chris Weis,

regarding the Libby, Montana asbestos that contaminated a community. The majority of the asbestos fibers were less than 5 microns in length.

The Subgroup 1 recommendation that all fibers greater than .5 microns in length should be counted and reported is supported by human epidemiological and pathological studies, and also monitoring in Libby, Montana.

Subgroup 1 recommends that the minimum aspect ratio of 3 to 1 for EMPs that was recommended in the NIOSH Bulletin 62 be adopted.

Based on the observations of fiber lengths and widths on the previously reviewed studies, there should be no upper limit to the aspect ratio for EMP.

Subgroup 1 recommends that any EMP, that is particles with aspect ratios of 3 to 1 or greater, and also greater than one-half micron in length, be considered a countable EMP. All effort should be made to identify the dimensions, the composition, and mineral content or identity of all countable EMPs.

Another definition that was identified is critical for understanding and reporting is a covered mineral. A covered mineral according to NIOSH Bulletin 62, Section 6.2 is a mineral encompassed by a specified regulation or recommended standard.

In addition for talc and for talc-containing products, covered minerals will include chrysotile, but not the other serpentine minerals, and members of the amphibole group, which is inclusive, but not restricted to the five amphiboles used commercially.

So in summary, Subgroup 1 of the Work Group recommended to use the term "elongate mineral particle" for recording and reporting of all particles that have a length to width aspect ratio of 3 to 1 or greater.

That these EMPs greater than one-half micron in length be recorded and reported, or in other words, the countable EMPs. That EMPs have no maximum length, and no maximum aspect ratio. And most importantly, for counting and reporting purposes, that every effort should be made to obtain the chemistry and mineral identity of every countable EMP.

Well, thank you for your attention, and this concludes the presentation from Subgroup 1 of the Working Group on definitions and terminology.

I guess I can introduce myself. Well, good morning again, I'm Paul Howard -- just reading what is written -- presenting the preliminary recommendations from Subgroup 2 Subject Matter Experts on analytical methods for detecting mineral fibers of concern in talc.

Now, while the Working Group and Subgroup charge was broad, we'll focus today on cosmetic products as an example of consumer products that contain talc.

Again a disclaimer, that the Working Group preliminary recommendations are from individual scientists functioning as Subject Matter Experts in their respective scientific fields. Participating in a Work Group striving for consensus recommendations, and these recommendations do not necessarily reflect the opinions or policies of their -- their respective agency, or represent proposed changes to any regulation of the U.S. Government.

In addition, any mention of organizations, manufacturers or products should not be considered as an endorsement. And the following are preliminary recommendations from the Working Group Subject Matter Experts regarding analytical methods to consider in using, detecting asbestos in talc and talc-containing consumer products, including cosmetics. The deliberations of the Subgroup and Working Group focused on specific methods required for consistent identification in measuring mineral particles in talc and talc-containing consumer products.

At first, we wanted to acknowledge, the ongoing work by the U.S. Pharmacopeia or USP Talc Expert Panel right now since 2010. And in addition, the American Society for Testing and Materials International, or ASTM, Committee D22, that are accomplishing similar goals.

The Working Group worked independent of these organizations and review published procedures, publish information from USP, ASTM, the International Standards Organization or ISO, government agencies, and scientific periodicals.

The goal of the Working Group Subgroup 2, was to develop a robust analytical protocol for detecting asbestos and other EMPs of health concern in talc, and consumer products containing talc, including cosmetics.

The charge questions that were posed to Subgroup 2 were the following. First, what general techniques of published test methods should be considered for the identification of asbestos fibers in talc-containing products? With example methods for sample preparation, as well as instrumentation needed to make an assessment.

Second charge question was, what standard should be developed for use to assess the presence of asbestos in talc-containing products? This can include reference materials, as well as reference methodology.

Additional charge questions that were put upon Subgroup 2 were the following: What combination of analytical methods should be used? Are screening methods useful for if/then approaches? And talking about screening methods, do we need a concentration method for the screening method? Transmission Electron Microscopy? Or Scanning Electron Microscopy? Both? How many mineral fibers or grid openings should be measured or counted to reach statistical significance? Are there matrix issues from talc-based cosmetics? And finally, are there sample preparation issues, or in other words, are there sample preparation issues that alter the property of the fibers?

At this time, the Working Group Subgroup 2 has answered most of the charge questions, not all. And these recommendations are presented in the following outline in the rest of this presentation.

The first is considerations of sampling and handling. The second is consideration of sample preparation. The third is what analytical methods should be considered, and we'll discuss briefly discuss X-Ray Diffraction, Polarized Light Microscopy, Transmission Electron Microscopy, and Scanning Electron Microscopy. And then finally, there will be an overview of the recommendation of Subgroup 2.

First, sampling and handling. Well, Subgroup 2 did not submit specific recommendations regarding sampling size and frequency. The FDA and other agencies have existing guidelines regarding sampling size and frequency for many different products. And these should be considered when a sampling plan is established. Examples of this are publications and guidelines from other organizations such as the USP General Chapter 1097. ISO guidelines, ISO 10725. ISO 11648 and ISO 14488. And the EPA's approach to incremental sampling of soils.

Sampling plan issues that were identified by Subgroup 2 to be considered are the following: First is the batch size, the talc or cosmetic product batch size. That is, the size of the batch that is being considered, does it or does it not contain EMPs? And, you know, is it 20 liters, is it 200 liters, is it 2,000 liters, what is the size of the batch? Because this sometimes will dictate the size and number of representative samples that should be taken according to rules for many other products.

The second thing that should be considered in the sampling plan is homogeneity. More data is needed regarding the homogeneity and concentration of asbestos in talc, and this will inform regarding a recommended sampling plan. The more non-homogenous, the more sampling is required to get a good representative composite sample of that product.

Third is other minerals and materials on the sample. The concentration of these other minerals and organic compounds in the talc, or cosmetic products may affect the sensitivity of the analyses and will then affect the sampling plan.

And lastly, but not least is the specificity and sensitivity of the analytical methods will inform regarding the sampling plan, mostly regarding the size of the required subsamples.

Next, handling considerations. The subgroup noted that standards and guidelines are currently in place for the sampling and handling of many commodities, and that these approaches might be appropriate for the sampling and handling of talc and talc-containing products. Common considerations that the Subgroup identified that should be in place are the issues of chain of custody. Documentation to verify chain of custody of the sample, including any and all subsampling for analysis should be part of the handling considerations.

Next is control against contamination. Procedures to control against contamination of the sample from any foreign material during sampling, custody of analysis should be considered, and to control against contamination of the laboratory by the sample.

Third is sufficient sample must be taken to allow for multiple reanalyses of the sample, and to provide an archive of the sample for future reanalysis if required or necessary.

And lastly, management, SOPs, and documentation. All standard operating procedures, documentation should be recorded according to internationally accepted standards, such as the

ISO 17025 standard. Always should be considered in a handling -- sampling and handling plan.

One of the key issues noted by subgroup one subject matter experts was the apparently non-homogeneity of minerals in talc. Of course, it depends on where in this flow from mine to product you are at. But this non-homogeneity is due to -- initially to geological conditions that led to the formation of the talc, and associated minerals in the earth's crust, and in the mining processes as eloquently presented earlier by Brad Van Gosen.

In addition, the degree of non-homogeneity of minor amounts of non-talc minerals in talc, will depend on the processing and mixing that occurs as part of the processing and the mixing of the talc into a cosmetic product.

Nonetheless, the concern is that asbestos and other non-talc minerals in talc or cosmetics are non-homogeneous. This could result in small, non-representative samples being taken for analytical measurements, leading to erroneous determinations of the true asbestos level in the talc or talc-containing cosmetic.

In light of this, the Working Group Subject Matter Experts discussed the methods that have been used to achieve mixing of samples with the goal of improving homogeneity of EMPs in the sample. Some of these include, as shown here, mixing and homogenization proceedings, such as tumblers that constantly rotate along multiple axes and mix the sample. V-blenders or V-mixers, which come in a variety of sizes and have been used for other applications, and vibrating mixers.

Finally milling, either ball milling or jet milling has been used to produce particle size and achieve mixing in the industry. Subject matter experts caution against the use of milling as a way of achieving homogeneity of a sample and do not recommend this use in sample preparation. Since milling can result in particle size reduction in the sample, which will not be representative of the particle size in the original lot of talc or cosmetics.

The Subject Matter Experts noted that standards in research are needed to determine the utility and validation of these methods, specifically -- specifically with talc, and each type of cosmetic product that contained talc.

In the development of a specific talc method, there are guidance documents from ASTM and USP for similar products that could be used, such as ASTM D3551, ASTM D3740, or the USP journal, chapter 1097 for bulk power sampling procedures.

The Subject Matter Experts noted the development of proven methods for improving sample homogeneity would greatly increase the confidence that analytical measurements are reflective of the true concentration of non-talc minerals in talc-containing cosmetic products.

Next, one of the most wildly used

approaches and sample preparation for the detection of asbestos in talc or talc-containing cosmetics, is to remove interfering materials from the asbestos that may be present in talc and talc-containing cosmetics and/or to isolate or enrich the asbestos fraction from a talc or talc-containing cosmetic.

We'll take a moment to briefly examine some of these methods and summarize the Subject Matter Experts' recommendation.

The most widely used approach is gravimetric reduction of a sample through a heating process known as ashing or furnacing. With this approach, the sample is heated to not exceed 480 degrees centigrade, and organic compounds and some minerals are removed.

This approach is described in several published methods including, for example, the New York PM-21 Environmental Laboratory Approval Program Certification Manual 198 and subsections. EPA's document, EPA slash -- I don't know how else to say that other than EPA/600/RN3/116, which was published in 1993.

ISO 22262:2014 edition, CTFA J4-1 method which Linda Katz mentioned earlier, and other methods which I'm not showing on the slide.

In addition, the treatment of talc samples with acid will remove acid labile carbonates and other acid labile compounds removing these interfering minerals from the sample, and by conclusion concentrating on the asbestos for analysis.

One method that has been attempted with variable success is separation techniques to separate mineral mixtures based on their specific gravity or sedimentation properties.

One method that deserves mention is density centrifugation, which has been used in mineral separation since the 1800s. For instance, a talc sample would be suspended in a dense solution and particles separated by centrifugation based on density.

Obviously the choice of the density of the solution is very critical. The problem with this method is the variable density of talc between 2.5 and 2.8 grams per centimeter cube, and the fact that some asbestos minerals are more dense than talc, such as amosite, actinolite, or crocidolite, and some are the same or less than some talcs, such as the chrysotile.

This method is endorsed for separation of asbestos from vermiculite, which is less dense than talc, it's around 2.2 to 2.6 grams per cubic centimeter. However, before this approach could be developed into a standard method for talc, more research is needed to understand separation efficiencies, and recovery for each asbestos mineral type that may be present in the talc.

This approach is described in some guidelines for isolating asbestos from vermiculite and other minerals that we might see, including ISO 22262, the 2014 edition. And in New York's

PM-21 Environmental Laboratory Approval Program Certification Manual 198 and subsections of that.

The Fluidized Bed Asbestos Segregator or FBAS, is being used to separate and concentrate asbestos minerals from soil samples. With this method, the dried sample is diluted with sand, and air is drawn through the circulating vibrating mixture to separate fibrous minerals with the air flow, and to collect asbestos and other fibrous minerals on filters.

There is no standard protocol or guideline regarding the use of this method with talc or talc-containing cosmetics. Publications regarding the use of the fluidized bed asbestos segregator with soils are shown on this slide and include a quote from Jed Januch, David Berry and colleagues in the Analytical Methods published in 2013. Daniel Farcas, Martin Harper, Jed Januch and two colleagues in the Environmental Earth Sciences in 2017. And lastly, Julie Wroble and colleagues published in PLOS-ONE in 2017 regarding the Fluidized Bed Asbestos Segregator.

However, I want to restate something that I stated. There is no standard protocol or guideline regarding the use of this method with talc, or talc-containing cosmetics.

Finally, there are many methods that could be applied to the separation and concentration of asbestos from talc for enhancing quantitative measurements. Research is needed to understand the application and limitations of each of these methods. With emphasis -- with emphasis on the efficiency of asbestos mineral recovery with the methods.

In addition, standards are needed with known levels of different asbestos minerals for the validation of each method. And to serve as intra and interlaboratory standards for proficiency testing. They do not exist at this time.

Analysis. Now, turning from

handling of sampling and sample preparation to the analytical methods. Well, powder X-Ray Diffraction (or XRD) is a well-established technique used for the identification and quantification of powdered minerals based on X-Ray Diffraction patterns. When monochromatic x-rays irradiate a crystal, some energy is diffracted along planes. This diffraction is characteristic for each crystal, and can be diagnostic of mineral types in a sample as shown in the figure for chrysotile asbestos, amosite, and crocidolite. Standards exist, and the advantages of XRD are: 1) that it's a proven method for mineral powders, and 2), that there is availability of a wide range of standards for this method.

The disadvantages of powder XRD are its sensitivity, and interference with some minerals with the detection of some asbestos minerals, such as chlorite interferes with XRD the analysis of chrysotile.

There are several guidelines

regarding sample preparation and the use of powder XRD to detect asbestos in minerals, including guidelines from NIOSH, ISO, EPA, ASTM, USP and the U.S. Geological Survey.

However, powder XRD is not applicable for individual particle analysis. It's a bulk method, and there was a need for standards with low levels of minerals in talc to validate the sensitivity of this method with talc or talc-containing consumer products.

Polarized Light Microscopy. Yeah, we just really don't have sufficient time to really go and describe the fundamentals and the applications of Polarized Light Microscopy. It's an essential method that has been used for many, many decades to identify minerals, especially the asbestos minerals. Polarized Light Microscopy uses polarized light and oils with specific optical properties to take advantage of the optical properties of the different minerals as shown in this slide for chrysotile asbestos.

The advantages of this method are that the method has been used and validated for many decades. And each particle can be identified based on optical behavior under the test conditions.

The disadvantages, there are limitations of optical resolution. That is, there is a size limit below which Polarized Light Microscopy cannot allow one to visualize a particle. There are practical limits to the sensitivity of the method as well. Wherein, as the concentration of the asbestos mineral decreases, the certainty of detecting a particle also decreases.

The limitations are exacerbated when the EMP are small, that is less than one micron, and especially those with higher aspect ratios, greater than, for instance, 5 to 1 aspect ratio that are present in low concentrations. There are several established methods for the analysis of samples with Polarized Light Microscopy for the presence of asbestos minerals, for which some are shown on this slide, including established methods from NIOSH, OSHA, CTFA, EPA, and ISO.

Most importantly, the Subject Matter Experts highlighted the need for standard reference materials for talc, with low levels of smaller EMPs of each of the asbestos minerals, in order to qualify how low this method can go in measuring small EMPs.

Well, as you will see in the next few slides, the Subgroup 1 of the Working Group Subject Matter Experts recommended that the analysis of talc for asbestos include electron microscopy analysis. This recommendation to use electron microscopy begs the question, why is electron microscopy needed for measuring EMPs greater than or equal to one-half micron.

Well, there are two reasons why the Subject Matter Experts recommended electron microscopy. The first reason electron microscopy is recommended is due to the limitations of visible light microscopy. The theoretical limit of resolution, that is the minimum separation between two objects can be seen for all microscopes is defined by this equation shown here, for which there will be a test afterwards.

Breaking it down, it's really the resolution power, the smallest two objects separation that can be resolved, is a function of the wavelength divided by two times -- I lost my notes -- two times the refractive index of the materials, and the sign of the incident angle of the light. Or in other words, the minimum limit resolution of a visible light microscope is approximately one half of the shortest wavelength of the incident light.

In a case of Polarized Light Microscopy where the shortest wavelength of the visible light is approximately 0.4 microns or 400 nanometers, the limit of resolution should be approximately 0.2 microns.

In fact, limitation PLM resolution

is described as around 0.2 microns or greater by several documents, including OSHA Internal Document 160. NIOSH Publication 9002. NIOSH Internal Document 191, and EPA Publication 600/R-93/116. This is important, since small EMPs, let's say one micron or less with an aspect ratio of 5 to 1, would have a particle width of 0.2 microns, which is at or beyond the limit of resolution of the visible (light) microscope techniques.

Again, the resolution of a microscope is directly related to the incident radiation. And the wavelength of electrons in a 100 to 200 kilivolt Transmission Electron Microscope or electron microscope, is less than two-thousandths of a nanometer.

In reality, the limit of resolution of a 100 to 200 kilovolt electron microscope is considered to be approximately 0.2 nanometers, or two thousandths of a micron. The limitation is due to aberrations in the magnetic lenses, not the incident wavelength.

This observation that an electron microscope can resolve EMPs with at least 1,000 times better resolution begs the question: Is there a situation where EMPs were not detected by visible light microscopic methods such as PLM, however, examination by electron microscopy, such as Transmission Electron Microscopy did detect EMPs? Well, the short answer is yes. There are several examples on the FDA talc and cosmetics website where samples that contain EMPs detected by TEM, were not detected by Polarized Light Microscopy.

I do want to draw your attention to the data on this slide. This slide shows the detection of tremolite particles in a cosmetic product, and this was previously shown by Chris Weis in his presentation.

The Polarized Light Microscopic analysis resulted in the conclusion that asbestos was not present. However, when the same examples were examined using Transmission Electron Microscopy analysis, we see that many particles are present, the distribution being shown: length in microns along this axis.

The significant percentage of the particles are less than five microns in length, the red line being for five microns. These particles are greater than five microns, these particles are less than five microns.

They're being detected by Transmission Electron Microscopy at a much higher resolution than that that's capable with Polarized Light Microscopy, so here we have an example of this.

The second reason that the Working Group's Subgroup 2 Subject Matter Experts recommend electron microscopy for analysis of EMPs in talc and talc-containing cosmetics is the advanced techniques that are available with modern electron microscopy instruments.

So this will be described in

subsequent slides. An analyst is able to conduct elemental chemical analysis and electron diffraction pattern analysis on individual particles in the field of view when using the appropriate transmission electron microscopy instrument.

These analyses can be diagnostic for the particles' mineral identity. This capability of particle by particle analysis does not exist with visible light microscopes or with any other approach, other than transmission electron microscopy or scanning electron microscopy.

The Subject Matter Experts of Subgroup 2 had three general recommendations for Transmission Electron Microscopy. First, the Subject Matter Experts recommend that the Transmission Electron Microscope have the capability of operating at 200 kilovolts.

Secondly, the Transmission Electron Microscope should be capable of elemental analysis using Energy Dispersive Spectral Analysis, or EDS,if

I happen to say that.

And third, that the Transmission Electron Microscope be capable of mineral crystallographic analysis of individual particles using the Selective Area (Electron) Diffraction analysis, or SAED.

Let's look briefly at these three specific recommendations.

The Subject Matter Experts on Subgroup 2 recommend that a TEM capable of operating at 200 kilovolts be used for the analysis. While electrons at approximately 100 to 120 kilovolts may have sufficient energy or electron penetration of many minerals, 200 kilovolt electrons are sometimes needed to penetrate some dense tremolite particles and thick cleavage fragments.

Electron penetration is required to generate diffraction patterns that can be diagnostic of the mineral. While this recommendation is not consistent with the AHERA protocol which recommends 100 to 120 kilovolt Transmission Electron Microscope analysis, the Subject Matter Experts consider this an important criterion to recommend.

Subgroup 2 Subject Matter Experts recommend that Transmission Electron Microscope be equipped and capable of conducting Energy Dispersive Spectral analysis. With this method, one can capture some of the X-ray emissions from a single specific particles as a result of the electron irradiation, and these x-ray emissions are diagnostic of the elemental composition of the particle.

For instance, as shown in this figure, following electron imaging of a single particle, you can capture x-rays that are diagnostic of that particle having magnesium, silicon, and calcium, suggesting that the irradiated particle was a calcium amphibole, and probably tremolite or actinolite. Further examination would be required to confirm or refute this diagnosis, but this is very critical information.

The Subgroup 2 Subject Matter Experts additionally recommend that the Transmission Electron Microscope be equipped to conduct Selective Area Electron Diffraction on the individual EMP. And then that the technician or supervisor be trained in the analysis of electron diffraction patterns or minerals.

These patterns can be clear indicators of the crystal structure of the particle. Selective Area Electron Diffraction along with Energy Dispersive Spectral analysis, and the image analysis, allow a trained technician to determine the mineral nature of each individual EMP particle greater than one-half micron.

Subgroup 2 Subject Matter Experts noted their established methods for the detection of asbestos using TEM, such as the examples shown here listed for ISO, ISO 10312. For EPA, the EPA/600/R-94/134, NIOSH Bulletin 7402 and also the AHERA Protocol.

The Subject Matter Experts recommend that standards be developed that contain talc with specific asbestos minerals at expected low concentrations to allow microscopists to evaluate and validate Transmission Electron Microscopy methods specifically for EMPs in talc and talc-containing cosmetics.

Next, Scanning Electron Microscopy. The scanning electron microscope is a powerful electron microscopy method and with this equipment, one is able to quickly scan large areas, zoom in, and easily determine particle size. The structure as shown in this slide for a significant tremolite EMP that was found in a sample from a talc mine in Death Valley as previously shown by Brad Van Gosen.

With the right software and scope configuration, one can obtain truly amazing three dimensional images.

The Subgroup 2 Subject Matter

Experts also noted that scanning electron microscopes can be equipped with x-ray detectors and software capable of Energy Dispersive Spectral analysis that's generating elemental composition for specific EMPs as shown in this slide.

Although the accelerating electrons are limited in energy in Scanning Electron Microscopy, it's usually no higher than 35 kilovolts, as shown in this slide for a tremolite asbestos particle, you can obtain sufficient information and see the presence of oxygen, magnesium, silicon, calcium, and a small amount of iron.

However, the Subject Matter Experts noted that despite some scanning electron microscopes having Electron Back-Scatter Diffraction, or EBSD capability, there are currently no validated methods at ISO or ASTM or any other agency or organization for the use of Electron Back Scatter Diffraction of individual mineral EMPs.

This lack of ability to obtain electron diffraction patterns individual EMPs is currently a limitation of Scanning Electron Microscopy.

Other methods -- the Subject Matter Experts noted other methods such as Raman microscopy and infrared microscopy have been used in the past to detect asbestos minerals. These are usually bulk powder methods, and the sensitivity and selectivity of these methods for low levels of asbestos in talc and talc-containing cosmetics has not been established sufficiently to warrant further recommendations of these methods. In addition, these do not look at Raman and infrared signatures from individual particles, but from the bulk sample.

In summary, the Subgroup 2 Subject Matter Experts recommend the following procedure for analysis of asbestos minerals and talc in talc-containing cosmetics.

First, the Subject Matter Experts did not specify specific sampling and handling protocol at this time.

However, any protocol should be one that results in confidence that the sample is representative of the distribution of asbestos in the overall batch of talc for talc-continuing cosmetics.

Second, on the sample processing, there are available approaches for sample processing or sample preparations to remove other minerals in organics, and possibly concentrate the asbestos. However, these approaches should be validated with standards of talc in talc-containing cosmetics with low levels of specific asbestos minerals.

The Subject Matter Experts recommend that XRD and PLM are appropriate for the beginning analysis. The Subject Matter Experts recommend Polarized Light Microscopy as a required analysis being sampled using established guideline methods for asbestos by an analyst that's trained in this method.

Powder XRD, or X-Ray Diffraction, is also a useful method for detecting asbestos. However, it may be limited due to sensitivity and the fact that you're doing a bulk analysis on the sample.

The Subgroup 2 Subject Matter Experts recognize the capability of Scanning Electron Microscopy as a next step. However, the inability to conduct individual particle electron diffraction analysis at this time, limits Scanning Electron Microscopy to an "optional".

If a sample has been analyzed XRD and PLM and EMP -- asbestos EMPs are detected in the talc for talc-containing cosmetics, that could be recorded and reported. If, however, using X-Ray Diffraction or Polarized Light Microscopy, there were no EMPs greater than one-half micron detected, then it is obligatory to then conduct Transmission Electron Microscopy analysis. This should be conducted by a trained and experienced analyst. And in this way the TEM, the transmission electron microscope becomes the key analytical tool in the analysis of talc or talc-containing cosmetic samples for asbestos mineral EMPs.

The Subgroup 2 Subject Matter Experts did not specify, at this time, the number of grid openings to count, or the number of particles to analyze to achieve the sensitivity required to state that no asbestos was detected.

Well, thank you for your attention to this presentation, and this concludes the presentation from Subgroup 2.

MS. KARI BARRETT: Thank you so much for two very good presentations. We will now bring up Dr. Steven Wolfgang who is the Consumer Safety Officer of Cosmetics and Colors at FDA's Center for Food Safety and Applied Nutrition. He will close this section of the agenda with recommendations from the Work Group on content and format of the analytical reports, and then provide a recap of the overall preliminary Work Group recommendations.

DR. STEVEN WOLFGANG: Thank you, Kari. Good morning, everyone. I am the final speaker of the morning session covering deliberations and recommendations coming from the IWGACP.

Okay. As the Chair of Subgroup 3, I will first speak on the deliberations on data reporting and analysis, and the recommendations on content and format of analytical reports coming from asbestos-testing laboratories.

Secondly, I will recap the IWGACP's overall recommendations on analysis of talc and talc-containing products, including thoughts from the Work Group toward further development of analytical methods worthy of being recognized as public standards.

In so doing, I will try to hit the high notes, including showing you the preliminary recommendations that appear in the Federal Register notice that published several weeks ago announcing this meeting.

I make this disclaimer on behalf of the IWGACP, a group of dedicated scientists whom I'm honored to have had the opportunity to collaborate with. This is the same statement that was made earlier by Paul, specifically that the IWGACP preliminary recommendations are from individual scientists functioning as Subject Matter Experts in their respective scientific fields, are participating in a Work Group striving for consensus recommendations and do not necessarily reflect the opinions or policies of their agencies or represent proposed changes to any regulations of the U.S. Government. Any mention of organizations, manufacturers or products should not be considered as an endorsement.

The first of two topics I will cover is a summary of the deliberations of Subgroup 3 on data reporting and analysis, which led to the issuance of the IWGACP's recommendation on the format and content of lab reports.

The charge issued to Subgroup 3 is a subset of the overall charge of the IWGACP. That is to say, reconciliation of differences in the conclusions, laboratories that test talc in talc-containing products seeking to determine if asbestos is present, arrive at.

We position the analyst as a neutral observer who records and reports what he or she observes using the analytical tools.

If the methods and reporting of data are carried out in a standardized manner, then the chances for disagreement can be reduced. If there are differences in interpretation, the data, that is to say the images, the spectra, the diffraction patterns, et cetera, serve as a source of irrefutable evidence.

Thus, to a standardized approach through reporting --just the facts-- Subgroup 3 deliberations sought to answer the following questions. Firstly, which attributes of mineral particles of concern should labs report? Secondly, what is the suggestive content of a lab report? Thirdly, how should data be presented in the lab report so as to promote consensus in data analysis and interpretation?

Avoiding bias and interpretation of data is the ultimate goal, and that starts with unbiased reporting. Therefore, the format and content of a lab report, as shown on this slide, indicates the questions: What should a lab report contain? --In other words, how will the data be presented, what should be provided in narratives, tables, figure, images?

Secondly, how should lab report

EMPs that might be regarded as either asbestiform or non-asbestiform mineral analog? --Since we recognize there is ambiguity in what is regarded as asbestiform versus non-asbestiform.

And then finally: What is the client's role in the interpretation of the lab data? ---The goal here being that the client receives data in an unbiased fashion, and then it's up to the client to determine what to do with the data via, for example, characterization or a health hazard exists.

With respect to content, this list constitutes what the IWGACP regards as the minimum that should be included in a lab report.

For example, tabulation of data showing length, width, for each countable particle, including the calculation of the aspect ratio, is very essential.

Secondly, the identification of the mineral constituents in each countable or particle as mentioned earlier by Paul, covered minerals would include amphibole and chrysotile.

Thirdly, images of particles, spectra, and diffraction patterns should also be in that lab report.

Next, a detailed description of how microscope specimens were prepared and examined should be in every lab report. And then finally, measurements or estimations of amounts detected, which are typically present in any lab report.

If measurements such as weight percent or the number of fibers relative to the mass are provided, the limits of detection and quantitation ought to be given, as well as any assumptions made in calculating or expressing quantities detected.

And finally, if minerals are to be reported collectively under various classifications, the report should provide an explanation of how the minerals were identified and classified.

Subgroup 3 working in conjunction with the IWGACP at large, focused on the covered minerals, that is amphibole and chrysotile and high level classifications of -- these are high level classifications for EMPs. However, these -- the Work Group recognized that labs are often more specific in their attempts to classify minerals.

This slide provides examples of spreadsheets labs might be using for recording analytical data, automating calculations, and developing electronic deliverables to their clients.

Subgroup 3's EPA members pointed us to their NADES or National Asbestos Data Entry Spreadsheet Collection. Subgroup 3 also found examples of spreadsheets for data entry in the ISO and ASTM asbestos analytical standards shown on this slide. That concludes my talk on the format and the content of lab reports.

My second and the final topic of this morning's session is a recap of the IWGACP's deliberation on testing of talc-containing products.

The IWGACP's deliberation on terminology and definitions, analytical methods, and data reporting during 2019 led to six preliminary recommendations appearing in an executive summary posted on the FDA web page providing materials related to this public meeting.

Starting with the IWGACP deliberations on mineral terminology, the first of three topics. Various terms are used by geologists in an attempt to precisely describe the morphology of asbestiform and non-asbestiform analogs of minerals, such at tremolite.

Before, electron microscopy images of tremolite particles and corresponding terms on this slide appeared in the presentation on mineralogy of talc and asbestos by Brad Van Gosen this morning.

The IWGACP concluded that it would be difficult to determine, if a particle, such as the one in the lower left quadrant, this one here, is derived from an asbestiform bundle such as the one shown on the lower right---or alternatively, from the prismatic particle that appears in the upper right quadrant.

This is another image shown by Brad Van Gosen earlier today illustrating the ambiguity that often exists when a tremolite particle is observed in the company of other mineral particles.

It should be noted that this image, as well as the ones on the previous slide, are of specimens of ore collected in an abandoned talc mine. Particles of tremolite we find in abandoned mines may bear little or no resemblance to the parent tremolite particles which grew in nature as shown on the previous slide.

When talc ores that contain amphiboles are processed, such as in the manufacturing of raw material talc, it would not be unexpected to find tremolite particles such as the one shown on this slide.

In fact, when FDA analyzed cosmetics, we found tremolite particles resembling the particles shown here. Thus, IWGACP considered the many terms and definitions used by geologists to describe elongate particles, such as the one shown here, and ultimately wondered how important it would be to make a distinction between asbestiform and non-asbestiform habits of the amphibole minerals.

With regard to the second topic that Paul covered, IWGACP deliberations on analytical methodology, IWGACP regards these four analytical instrumental techniques to be the toolbox for analysis of bulk minerals, such as talc, as well as individual particles found in bulk minerals or products manufactured using minerals as an ingredients. Each method in the analytical toolbox fulfills some nominal function as shown on this slide. And no single method gives the complete picture.

Individual methods can thus be regarded as complementary. Another way of saying that is that, perhaps, no single method can be regarded as confirmatory. Here are some key conclusions and recommendations that came from the Subgroups and the Work Group at large.

After deliberating for many months on the three high level topics, the IWGACP arrived at several key conclusions about how labs ought to apply the methods that have been successfully used to analyze air and bulk samples for asbestiform and related minerals, to samples which consist of or contain talc.

IWGACP suggests that the term EMP can be used to describe any mineral particle having a minimum aspect ratio of 3 to 1.

Secondly, IWGACP regards Transmission Electron Microscopy (or TEM) with EDS, (which is Energy Dispersive Spectroscopy), and Selected Area Electron Diffraction (or SAED), as the most definitive tool to detect EMPs of amphibole or and chrysotile.

Thirdly, EMP shorter than five microns ought not be discounted given the resolution of the electron microscopes, such that labs ought to report every amphibole and chrysotile EMP they detect down to a length of 0.5 microns.

In reporting the amount detected, the number of particles in the population seems at least as important as the weight percent.

In summation, the conclusions of the IWGACP can be regarded as generally consistent with the recent work products from other groups of experts deliberating on these very same issues associated with testing for asbestos and other mineral particles of concern.

These three independent bodies are shown on this slide, they were mentioned earlier -- in today's talk by other speakers.

In closing, I will share the preliminary recommendations of the IWGACP.

Firstly, IWGACP recommends adoption of the term EMP as any mineral particle with a minimum aspect ratio of 3 to 1. Next, for particles meeting the minimum for aspect ratio, IWGACP recommends that labs report those particles having a minimum length of 0.5 microns toward accounting for the detected EMP populations, which as stated in recommendation three, and in accordance with the definition of the term "covered minerals" in the NIOSH current information bulletin 62, include particles identified as an amphibole mineral or chrysotile.

Lastly, on this slide, the test protocol should provide instructions for counting in which primary and secondary structures are taken into account with the intent to express the number of fibers detected.

The penultimate recommendation on this slide is to use TEM with EDS and SAED when analyzing products that contain talc, noting that the EMPs which are present are often extremely fine, and rest below the resolution capability of the light microscope.

The use of SEM as an adjunct to TEM is based on the recognized limitations of the SEM that would discourage it from being used by itself, instead of TEM.

The final recommendation is regarding accounting and expression of the amount of EMPs detected, recognizing that mass percent values do not adequately express the number of fibers that might be released when a product is used for the two reasons shown on this slide.

This final slide expresses what the IWGACP regards to be the main hurdles that remain toward writing a written protocol that is robust with respect to its repeatability and reproducibility. Importantly, potential sources of variation in the realm of sampling, sample preparation, and testing need to be understood and addressed.

The development of reference

standards specific to talc and talc-containing products also remains a challenge that if met would help ensure proficiency and consistency.

Thus, this slide shows what the IWGACP identified as focal points for development of methodology for inter-laboratory validation leading to concurrence.

This concludes the presentations from the IWGACP covering its deliberations and preliminary recommendations. You are invited to provide your comments to the docket. Thank you.

MS. KARI BARRETT: Thank you, Dr. Wolfgang.

On that note, in regards to providing comments, in your folder today, you do have a sheet of paper, it talks about how to comment. Also, just a couple of announcements before we break for lunch. There is another conference room, Room A, that is available for anyone to have lunch in. There has been some round tables setup. So if that's helpful for you, please make use of it.

Also, too, for those who are giving public comments starting at 1:00, and before our break at 3:30, when you come back into the room, if you could just be sure to sit sort of near the podium, maybe in an aisle or the second row of tables, I think, will be available to you, just so that it's easy to get up and down to the podium.

With that, we will go ahead and break for lunch. We will start at 1:00 p.m.

(Lunch recess.)

MS. KARI BARRETT: Welcome back everyone. Again, my name is Kari Barrett and I'm part of the Communications and Public Engagement team for our Food Center at FDA.

So now with our public comment session, we're here and ready to listen. Before we do begin, I do want to turn to our distinguished panel members. And we're going to start down the table and have folks just introduce themselves. Then I'll take just a few minutes to talk about our process. I appreciate you being ready to go, and then we'll kick off.

So let me start at the far end of the table for our panelists.

DR. KRIS HATLELID: Hi, I am Kris Hatlelid. I am with the Consumer Product Safety Commission.

MR. FRANK HEARL: Hi, I'm Frank Hearl. I'm with the National Institute for Occupational Safety and Health.

MR. BRADLEY VAN GOSEN: Brad Van Gosen, Research Geologist with the USGS, U.S. Geological Survey.

DR. STEVEN WOLFGANG: Steven Wolfgang with the Food and Drug Administration, Office of Cosmetics and Colors.

DR. DAVID BERRY: David Berry, a toxicologist with EPA in Region 8 Denver.

MS. DEBORAH SMEGAL: Debbie Smegal with the Office of Cosmetics and Colors, the Associate Director.

DR. LINDA KATZ: Linda Katz, the Director for the Office of Cosmetics and Colors at the Food and Drug Administration.

DR. CHRISTOPHER WEIS: My name is Chris Weis. I'm a toxicologist with the National Institute of Environmental Health Sciences.

MS. KARI BARRETT: Great. And thank you all. And it should be noted that all of our panelists have been active in the work group.

Okay. So for today's public comment session, as you can see we have a number of people offering public comment. We have two groups. We have our first group, which will be offering oral comments in a four-minute time span.

As noted this morning, there is a clock to help you in tracking time with your remarks. When it does get to yellow, please consider wrapping up. When it is at red, we will then move on to the next presentation.

For the second group, they will have nine minutes, and they will also have slides. And so again, we'll ask for the same protocol of being mindful of the time.

Also want to note that when you do come to the podium, I will call your name, but when you come, if you'll repeat your name and title and affiliation for our transcriber. And I will be helping to sort of facilitate part of this session. My colleague, Janesia Robbs, will be coming up at one point, too, to help in facilitating.

So with that, I think we're ready to begin, and Alan Segrave is our first commenter. So Alan, please begin.

MR. ALAN SEGRAVE: Hello, good afternoon. My name is Alan Segrave. I'm with the Bureau Veritas. I'm a geologist and a lab manager in Atlanta, Georgia.

Listening to all of the different talks this morning, there was much of it that I had heard before. A few things I hadn't heard, and so I really enjoyed the topics. One of the things that I'd like to say, and I agree with Dr. Katz is that standard terminology between microscopists, industrial hygienists, and toxicologists does need to happen.

Similarly, microscopists can call certain things asbestos when they're, in fact, not. And the converse with cleavage fragments to asbestos.

So I think getting into the standardization is an important factor. Related to the geology, there are a number of cosmetic talc deposits that generally lack amphibole. And talc is not analogous to the Libby, Montana vermiculite. But while there may be similarities in mineralogy, if you find amphibole in talc, the Libby amphibole is quite different. And I thought it was interesting to note that from 1994 to 2008, there was no asbestos found in any cosmetic talc products during that time period, which is analogous to the use of many of the protocols that are in place, X-ray Diffraction, TEM, and PLM.

And when used properly, I think those are excellent tools.

As an example, when you do selected area electron diffraction on a talc fiber, you may get amphibole-looking patterns. So if you immediately call that an anthophyllite fiber, you're absolutely incorrect.

Similarly, with PLM, resolution is limited to single fibers. However, if asbestos is present, you'll typically find those in bundles, which are in the range of resolution by PLM. So what is research needs that we need to address? I did not see the reference to any of the articles at the Monticello conference held two years ago in Monticello, Virginia, which discussed testing protocols, toxicology studies, dimensional analysis of amphiboles. I think it would be useful to review some of those, and the remaining agencies, industry, academia present.

The general consensus there was that at least for mesothelioma, fibers less than five microns really did not cause mesothelioma. That certainly could be debated, but I would also point to the Italian talc. I've been to the Italian mine, I did not see any indications of asbestos in that talc mine. And look at the epidemiological studies over a 72-year period for that talc, and you'll find no mesotheliomas was there as well.

Consider the dose response. You know, authors like Davis who did different studies with rats using asbestiform and non-asbestiform and measured those responses where non-asbestiform particles of amphibole really had no mesothelioma.

So thank you for the time to allow me to comment.

MS. KARI BARRETT: Thank you. We'll go to our next commenter, Kristi Muldoon Jacobs with the United States Pharmacopeia.

DR. KRISTI MULDOON JACOBS: Good afternoon. My name is Kristi Muldoon Jacobs, and I'm the Director of Regulatory Science at the U.S.

-- United States Pharmacopeia. Thank you for the opportunity to present our comments here today.

USP is an independent, scientific, non-profit public health organization, dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements.

Through a long-standing collaboration with FDA, we have worked continuously to benefit public health through accessible quality medicines.

USP's public standards are developed through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep with the evolving science and technology. The process utilizes the work of independent experts in close collaboration with stakeholders and government agencies such as the FDA.

We would like to thank the

Interagency Working Group for acknowledging the work of USP, and the USP Talc Expert Panel. The Expert Panel has been actively working on developing recommendations for modernizing the USP talc monograph to ensure that the tests included in USP&F have the adequate specificity to ensure the absence of asbestos in talc for pharmaceutical use.

Our comments today focus on clarifying the Federal Register notice that was provided as pre-meeting information in two places as it pertains to USP.

In the first instance, the FRN states that talc suppliers to the pharmaceutical industry use methods for testing asbestos in talc raw materials to certify that talc meets the USP's requirement for absence of asbestos. We know that the FRN references a USP revision bulletin dated August 1st, 2011.

USP wishes to clarify that the revision bulletin does not represent the language and the currently official version of the USP talc monograph, which was published in 2013 and can be found in the current USP&F.

In the second instance, the FRN states that in 2014, the talc USP Expert Panel recommended an update of the USP talc monograph to require an electron microscopy method for the measurement of asbestos in talc. And it references the 2014 USP Stimuli article titled, Stimuli to the Revision Process Modernization of Asbestos Testing in USP Talc.

The USP wishes to clarify that the referenced article discusses the expert panel's recommendations for revision to the currently official test for the absence of asbestos in the USP talc monograph to include, omission of the infrared spectroscopy test, and inclusion of a revised X-Ray Diffraction procedure to be used in combination with one or more of the microscopic evaluations which MAY include Polarized Light Microscopy, Transmission Electron Microscopy, or

Scanning Electron Microscopy methods.

Currently, the USP talc method's Expert Panel is addressing the task of identifying appropriate analytical methods and reference standards for testing asbestos, for testing for the absence of asbestos in talc for use in pharmaceutical products.

Additionally, USP is also planning a Roundtable meeting on March 13th, 2020, where representatives from industry, regulators and academia will be invited to discuss the recommendation of the Talc Experts Panel on modernization approaches using appropriate analytical methods, sample preps, and limits for testing for absence of asbestos in talc for use in pharmaceutical products.

Thereafter, we intend to publish proposed revisions to the USP talc monograph and stimulate article for public comment. We look forward to continuing our engagement with FDA and other stakeholders in this important topic. Thank you for your time and for this opportunity to clarify the record and the work of USP. Thank you.

MS. KARI BARRETT: Thank you for your remarks. Our next speaker is Mark Pollak, Personal Care Products Council.

MR. MARK POLLAK: Good afternoon. I'm Mark Pollak, Senior Executive Vice President and Chief Operating Officer of the Personal Care Products Council, which is the leading trade association representing cosmetic and personal care product companies. The council's approximately 600 member companies represent the vast majority of the U.S. beauty industry.

Our membership includes manufacturers, distributors, and suppliers who produce the majority of personal care products sold in the U.S.

PCPC has reviewed the preliminary recommendations of the Interagency Working Group on Asbestos in Consumer Products, and offers these brief initial comments.

Before developing the preliminary recommendations, the Working Group would have benefited from seeking the input of people with the most knowledge regarding cosmetic grade talc-- the pharmaceutical food additive and personal care product manufacturers and their ingredient suppliers.

Indeed we heard today that the working group and the three subgroups have met more than 40 times in 2019. And until January of this year, the cosmetic and personal care products companies were generally unaware of the attempts by the Working Group to rewrite long-standing scientifically based definitions regarding consumer grade talc, and to redefine what constitutes purported contaminants in talc.

Time does not permit me to address each of the preliminary recommendations. Accordingly, I will identify an example that highlights the need for some full analysis, scientific support, and industry input.

The Working Group's Executive Summary offers several preliminary recommendations regarding elongate mineral particles or EMPs. However, the summary does not support the supposition that all EMPs are biologically harmful, or that a change in the long-standing and well-considered definition of asbestos is necessary.

The vast majority of scientists, including the International Agency for Research on Cancer distinguished between carcinogenic asbestos, and harmless non-asbestiform minerals. That distinction needs to be maintained. The executive summary indicates that counting all EMPs will simplify testing, but eliminating the distinction between asbestos and non-asbestiform minerals neither simplifies testing nor improves product safety.

The summary recommends counting all EMPs under a single classification, but then reporting additional information that would allow further classification based on measurements such as mineral type and dimensions in the future.

Counting all EMPs would provide misleading reports suggesting the presence of asbestos when none exists. And reporting unspecified additional information for future classification would prove unnecessarily complex. The key to effective testing is identification of asbestos, not harmless minerals.

In summary, the Working Group's preliminary recommendations require revisions. A scientific fact-based outcome can be obtained through a transparent process with input from all interested parties.

PCPC recognizes that these are preliminary recommendations, and that any change to existing regulations or the promulgation of any new regulation will provide an opportunity for interested stakeholder input. Nevertheless, we would encourage greater transparency into the processes and work during this preliminary stage.

We want to thank you for setting up this meeting and look forward to participating in an open and fair process, consistent with the requirements of the Administrative Procedures Act.

MS. KARI BARRETT: Thank you. Our next speaker is Isabelle Chaudry, National Women's Health Network.

MS. ISABELLE CHAUDRY: Thank you for the opportunity to provide oral comment. My name is Isabelle Chaudry, and I am here to speak on behalf on the National Women's Health Network.

The National Women's Health Network is supported by a national network of individual members. We do not accept financial support from drug or device makers or personal care product manufacturers.

As a senior policy manager at the National Women's Health Network, I lead our organization's work to ensure that cosmetic products are safe.

Cosmetic and personal care products are a disproportionally large source of chemical exposure for women and girls in this country. Talc is found in many cosmetic products that women use in the most sensitive parts of our bodies, including baby powder, lipstick, blush, eye shadow, foundation, and face powder.

Independent labs throughout the country over the course of several decades have documented the presence of asbestos in consumer talcum products, such as Johnson & Johnson's Baby Powder.

With new science and research suggesting that cosmetic products can be a contributing factor to the health crises many women and girls are experiencing, we believe that testing methods for asbestos in these products are of the utmost importance.

Exposures to talc has been suggested as a causative factor in the development of ovarian carcinomas, gynecological tumors, and mesothelioma. Over the past several years, case control and cohort studies examining the link between talcum powder use and incidences of ovarian cancer have been carried out.

Recent meta analysis published in December 2019 included data from three cohort studies and 24 case control studies. The 2019 meta analysis summarized results from a total of a over 16,000 cases, and over 200,000 controls.

Researchers found that regular, perineal talc use increased the risk of developing both serous and endometrial ovarian cancer. Researchers also found that post menopausal women who regularly use talc-based powders and who had taken or were currently taking hormone therapy, were at a greater risk of developing ovarian cancer.

The FDA has deferred to manufacturers for over 50 years when assessing the safety of talc powders and cosmetics. This practice is dangerous and has the consumer's health at risk.

There have been too many incidents of asbestos-contaminated talc, in 2017, 2019, and just this year, independent testing uncovered possible asbestos contamination in various cosmetic and personal care products.

Exposure to asbestos kills an estimated 15,000 Americans every year. There is no safe level of asbestos exposure. Having adequate testing methods for asbestos in talc and cosmetic products containing talc is critical to the health and safety of consumers who are often not aware that inadequate testing methods may have been used to test the product that they use.

Although the FDA considers asbestos-contaminated talc unacceptable for use in cosmetics, there are currently no laws prohibiting its use in cosmetics. We hope that Congress will take action to give the FDA authority to regulate cosmetics, including ingredients used in cosmetics in a meaningful way. And while we are delighted that the FDA is using its powers, the powers that it has, to take measures to regulate these testing methods, the reconsideration of testing standards and safety parameters for the talc use in cosmetics used by millions of people is a positive step --

MS. KARI BARRETT: We will need to wrap. Thank you very much. We have your full set of comments in the docket.

Linda Reinstein, Asbestos Disease Awareness Organization.

MS. LINDA REINSTEIN: Good afternoon. I'm Linda Reinsten. I'm the co-founder of the Asbestos Disease Awareness Organization, ADAO. We've been dedicated for preventing and eliminating asbestos-caused diseases for over 15 years.

Now, I watched my husband gasp for air and die in front of us as a result of mesothelioma. This is real.

Like most Americans, I had never heard of mesothelioma. And I didn't think about where Alan's exposure was at the time. Was it talc? Was it occupational? I just thought about the treatment for my husband.

Three years after radical surgery, chemotherapy, and nearly $1 million of medical expenses, my husband died in front of myself and my 13-year-old daughter. This is real.

The evidence is abundantly clear, there is no safe level of asbestos exposure, and I want you to know I'm not alone. Each year, 40,000 other Americans experience the same kind of pain and loss that our family went through.

Ironically, today is World Cancer Day, which provides this unique opportunity to discuss and advance testing methodologies and the terminology. But I want you to think for a second, the hazards have been known. We have known for over 100 years that asbestos caused cancer, and 50 years for the FDA.

I am -- I understand about product testing. I want to share details about our robust and extensive product testing that ADAO did, beginning in 2005.

It took us about 18 months to test 200 products. I understand testing methods. We released our testing results, which confirmed by three labs, that asbestos was found in four consumer products and a kid's toy; nothing was done.

What was done is the industries challenge our science, it is what happens today. If you don't want to use TEM, and the most advanced testing methodology, there is nothing that binds you to doing that.

It takes months to get contaminated products off store shelves. And if it isn't people like ADAO, EWG, PIRG and others actively testing, consumers remain at risk.

The testing standards and the agency recalls, when there is a delay, it compromises the public health. I have to be honest, I've seen it all in 15 years. Corporations, often knowingly, use archaic, low-level equipment, and methods to get the results that they want. This meeting is important to advance the science and the methodology.

Americans hold the FDA and EPA responsible for safe water, air, soil, food. We cannot compromise one aspect of that. We also need Congress to do their job, and I can tell you, they are concerned. There is the Alan Reinstein Ban Asbestos Now Act that just passed out of the Energy and Commerce Committee by a 47 to 1 vote. Everyone wants to prevent cancer, and we can do just that.

I want you to think about the testing methodology and what you hear now about cleavage fragments and the methods that are used. I want you to think about the people, the consumers, and the human impact it has when there is contaminated products.

My time is very brief here. I will submit formal comments for the record. But most importantly, I hope you analyze every person who has made a comment here, and look to see how they're connected to the industry. Are their comments for sale? I challenge each of you to do your due diligence, please, today and identify the science versus the propaganda.

Thank you, and I'll leave this up on the table, it's consumer crayons that were tested positive for talc.

MS. KARI BARRETT: Thank you for your comments. We are now going to move -- change our formats to the nine-minute presentations with slide decks. And our first speaker is Andre Nel, University of California, Los Angeles.

DR. ANDRE NEL: Good afternoon. I'm Andre Nel, Professor of Medicine at UCLA, and Associate Director of the California Nano Systems Institute. I am a physician, Board-certified in internal medicine, allergy, and immunology. And

I'm also a scientist overseeing a large research program article on engineered nanomaterial toxicology.

The title of my presentation is, It Is Important to Distinguish Between Asbestos Fibers and non-asbestiform Elongated Mineral Fibers During Analysis of Talc-containing Consumer Products.

My comments fall into the category of terminology use for which I've taken three quotes from the IWGACP's document to my comments. The first is lack of consensus regarding what should be asbestos.

The second, because both types of elongated minerals are suspected of having biologic and activity with similar pathological outcomes, the distinction is irrelevant.

And the final, covered minerals include chrysotile and members of the amphibole group inclusive, not restricted to the five amphiboles used commercially.

My first statement is that the fiber

pathogenicity paradigm distinguishes between the effect of long biopersistent asbestos fibers and elongate mineral particles including non-asbestiform amphiboles that lack similar disease-causing features. Most of my comments will be confined to disease of the pleura. The Fiber pathogenicity paradigm is a widely used disease construct to explain the causation of pathologies in the lung, including mesothelioma.

The disease construct has emerged over years of intense research to provide a solid framework for understanding fiber toxicology. As we've heard this morning, and as shown on the left -- on the diagram on the left-hand side, the paradigm highlights three fiber properties that determine pathogenicity in the lung. The width of the fiber determined where in the airways the respired materials will deposit. To get to the pleura, the width or the diameter of the asbestos fibers needs to be narrow enough to deposit in the deep lung region from where the fibers gain access to the pleural space.

A second feature is fiber length which determines clearance or removal by macrophages, the function of which becomes progressively impaired for the macrophages with fiber lengths above five microns.

Fiber length is also important at the pleural damage site where the lymphatic drainage pores becomes obstructed by longer fiber lengths.

The third feature of pathogenic importance is fiber chemistry composition and crystalline properties. These properties determine the surface reactivity on the fiber which play a role in biocatalytic injury in the lung. The composition also determines the breakup of fibers in the lung with a tendency for amphibole fibers to resist dissolution, leading to biopersistence which is important for chronic disease.

And though non-asbestiform

amphiboles may occasionally, but less frequently obtain similar length and diameter characteristics as pathogenic fibers, non-asbestiform amphiboles do not exhibit the durability and biopersistence of asbestos fibers.

It took years of research to develop the pathogenicity paradigm. Moreover, over the last 15 years or so, material scientists have been able to introduce size and length control of biopersistent engineered materials to confirm with accuracy the length and aspect ratio thresholds for pathogenicity of the pleura.

The implication of what I just told you, in my opinion, is that talc testing methods are being considered for assessment of asbestos contamination should separately report asbestos fibers and non-asbestos amphiboles since they do not exhibit the same pathogenicity features.

In line with that comment, my second statement is that it is not definite in light of cellular and animal experimentation studies to state that asbestos fibers and non-asbestiform amphiboles have similar pathological outcomes, and that the distinction is irrelevant.

The tenets of the fiber pathogenicity paradigm applies to cellular and animal experimentation.

Cellular studies have shown that the dimensional and compositional features I just told you about also determine response outcomes in these mesothelial cells and macrophages where differences in the characteristics of asbestos fibers and non-asbestiform minerals is reflected in different biological response outcomes, such as cell viability for manipulation, et cetera.

The animal studies also demonstrate the importance of fiber length, diameter, retention, direct exposure via the pleura and peritoneum, and also demonstrate lack of carcinogenic potential of non-asbestos amphiboles in support of the fiber paradigm similar for inhalation studies in rats, mice, and hamsters.

So in my opinion, the implication here is that there is evidence that the pathogenic potential of asbestos fibers differs from non-asbestiform EMPs in animal carcinogenesis in cellular studies, refuting the claim that the distinctions between these materials is irrelevant.

I also want to state that the biological differences between asbestos fibers and non-asbestiform mineral elements are also reflected in studies in humans. Where my statement is that occupational and therapeutic talc exposures in humans do not show increased risk of mesothelioma, even when admixed with non-asbestiform EMP contaminants.

The tenets of the importance of the feature of fiber length width and biopersistence have been confirmed by research on asbestos fibers in humans. In fact, the documentation of pathogenic fiber features have been used for the safer design of vitreous fiber products through the tuning and adaptation of fiber length, diameter, and biopersistence properties.

Epidemiology studies in talc miners and millers fail to demonstrate an increased risk of mesothelioma.

My final statement is that by establishing rigorous tests of talc testing guidelines which I endorse, it should be feasible through the use of modern characterization techniques to distinguish asbestiform from non-asbestiform amphiboles. This will preclude changing terminology to achieve consensus.

FDA has not previously used the inclusive definition, as far as I can tell, as it's incongruent with mineralogical definitions and the position of OSHA. NIOSH Bulletin 62 was released in 2011 to remove confusion. The bulletin recognizes that the earlier the inclusion of non-asbestiform amphiboles in fiber counting was based on inconclusive science and epidemiology.

Bulletin 62 discusses the platform for fiber pathogenicity which remains valid today and is supported by more recent research on high aspect ratio nanomaterials.

Finally, the implementation of rigorous test methods and criteria without bias for which minerals are present in talc, will allow each mineral element to be identified on its own merit, rather than adopting terminology for which there is no conclusive evidence. Thank you.

MS. KARI BARRETT: Thank you very much for your remarks. We'll go to our next speaker, William Longo, MAS, LLC. And again if you'll just say your name and affiliation for the transcript.

DR. WILLIAM LONGO: My name is William Longo, and I am the president of MAS or Materials Analytical Services.

I would like to comment today on the research that we have done using heavy liquid separation for both amphibole asbestos, as well as our chrysotile asbestos that we have recently cracked the code, so to speak, where we can now do both. Next slide -- oh, I have my thing here -- never mind. Nope. There we go. Thank you for the help.

Why heavy liquid density? Let's see, I think I jumped one. Oh, overview. So why use heavy liquid concentration methods for cosmetic talc analysis? Second is a very brief history of heavy liquid density separation, specifically for cosmetic talc, not going all the way back. Analytical sensitivity, how high can we go using this concentration method. The types of amphibole asbestos we routinely see using this separation method is tremolite series, anthophyllite series and now a development of the chrysotile asbestos heavy liquid separation methodology at MAS. And all of the results that we have been doing for a while has been reported in fibers per gram.

Why? The standard TEM bulk

analysis, ASTM, EPA, ISO, has a detection limit of approximately -- depending on filter size, how much material, how many grid openings -- between 2 million to 14 million fibers per gram, or approximately 0.001 to 0.01 real weight percent. Not the made up fiber for analytical protection limits on weight percents.

The standard PLM analysis are 93.1 to .5. And XRD, in my opinion, we've done a lot of XRD on cosmetic talc, useless. Why use it if you're going to use Polarized Light Microscopy anyway, and can give you at least some fiber information, as well as a better sensitivity.

So if we look at some of the standard TEM bulk detection limits, and this is coming off the protocols for Johnson & Johnson, RJ Lee Group, AMA, AMA Analytical for FDA 2010, 2019, and McCrone.

Depending if it is 10 or 20 grid openings, they have a detection limit of between 7 -- 2 million up to about 14 million. When I say detection limit, obviously, this is the concentration that you must have in your cosmetic talc to statistically define one fiber.

So how can we improve that -- oh, skipped one here. Sometimes some of these methods have that you have to find 3 to 5 of any one species of type of asbestos before you can call it quantifiable. This was a lot of work in the 1970s and '80s by McCrone. So if you have to have, say for tremolite fibers or you find the four that should be actinolite fibers, anthophyllite fibers, 28,000 asbestos fibers would still be non-quantifiable.

This is because of background contamination. And in my view, if you have a professional lab, you should not have background contamination in your samples. You should be running process blanks, meaning everything but the talc, and it should be below your detection limit. And there is no background contamination in the outside environment, in my opinion, of tremolite and anthophyllite unless you have a source.

So that's another area that needs to be looked at is, why eliminate those EMPs when there is no background contamination.

So how do you increase the sensitivity? You can remove some of the material, such as acid dissolution for calcite. If you want to get rid of the pigments out of the face powders, which have things like TiO2 or aquamarine or liposomes particles, you got to go to something like an aqua regence to get rid of those. And the organics you want to get rid of, or you can increase the amount of grid openings. So 20 grid openings for a typical analysis, 7 million. If you jump that to 500 grid openings, you can reduce that to 280,000. If you jump that to 1,000 grid openings, you can reduce that to 140 fibers per gram. 500 to 1,000 grid openings, a lab that is going to really investigate this should take anywhere from three to five days, eight hours a day.

We chose not to do that, and decided to go to heavy liquid density separation. Wow here is an interesting one from Dr. Hutchinson. He is from the University of Minnesota. He was a Johnson & Johnson consultant. And he was asked to analyze Dr. Lewin's sample from that 1971, '72 XRD work where Dr. Lewin said there was 3 to 4 percent chrysotile. In reality, it was probably chlorite. But Dr. Hutchinson did something in 1972 that I have not seen until the late -- mid to late 2000 -- 2015, 2016. He looked at TEM. He looked at Lewin's sample, and he used 900 grid openings on a 200 mesh grid. He looked at the Shower to Shower Johnson sample that Lewin looked at, another split. He looked at 2100 grid openings. He found chrysotile asbestos in both of those samples, and estimated that it was 0.1 percent by weight. I could find no record that Johnson & Johnson ever informed the FDA that those samples were indeed positive on this one for chrysotile. That shouldn't be there.

So let's look at a brief history.

The earliest document that I found from Johnson & Johnson was work by the Colorado School of Mines where the memo to Johnson & Johnson said,

you know, we're going to develop an effort to remove the asbestos, in '71 it would be Vermont, from the talc ores during the identification process and flotation.

They went on to actually develop this, and could reduce it some. But then I recently ran across this memo, where they were using double liquid density separation, light fraction for chrysotile, heavy fraction for amphiboles, and they were using iodine to stain the chrysotile to see it easier in the Polarized Light Microscope. I see I got a minute and 39 seconds, so I've got to run through this pretty quick.

Using heavy liquid density separation for amphiboles, we analyzed 72 historical Johnson & Johnson cosmetic talcs. And for -- we used the Blount method published in 1991. And out of the 72 samples that Johnson & Johnson provided, from approximately 1960, all the way up to 1996, as well as Imerys, we had 41 positives or 57 percent.

For the amphiboles on TEM, we have a detection limit of between 4,000 to 9,000 fibers per gram validated, meaning we've run all of the standards and -- so we increased the detection limit by 800 to 1,750 times, 42 out of 70 positives.

And now for the chrysotile. They started staining it with iodine. We decided to use Betadine, and we can stain the chrysotile before, and wash it out and go through heavy liquid density, then we go to an optical microscope we have that has a high definition monitor. It's hard to see, but that's a Petri dish, and there is the filter. And at 1,000x with the technician looking at the monitor, there is a chrysotile bundle at a 0.0001 percent in talc.

This has been stained with Betadine, and you can see the talc --

MS. KARI BARRETT: Mr. Longo, we will need to wrap up.

DR. WILLIAM LONGO: Real quick.

MS. KARI BARRETT: Thank you for your comments. I know that your full presentation will go in the docket. Thank you very much.

DR. WILLIAM LONGO: Thank you. MS.

KARI BARRETT: Yes, thank you. MR.

WILLIAM LONGO: Thank you, everybody.

MS. KARI BARRETT: Our next speaker is Scott Faber, Environmental Working Group.

MR. SCOTT FABER: Hello my name is Scott Faber. I'm the Vice President of Government Affairs for the Environmental Working Group. Some of you may recognize this statement. It was taken from FDA's 2014 response to petitions seeking a warning on cosmetics made with talc. And for those of you who are watching at home it reads, "You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed."

Clearly there is now ample evidence to justify the warning that has been sought by consumer advocates for decades, and more recently has been proposed by representatives Debbie Dingell and Jan Schakowsky.

Just last month, SAI labs on behalf of EWG detected asbestos in the Princess Girls online deluxe makeup pallet, marketed online by IQ Toys. Thankfully, FDA is treating this issue with the seriousness it deserves by conducting your own testing, by making clear that products which contain asbestos are adulterated, and by holding today's meeting on testing methods for asbestos in talc.

As Dr. Katz noted at the beginning of this meeting, FDA has known that cosmetic produced with talc could contain asbestos for many years, since at least 1971 when researchers at the

Mount Sinai School of Medicine raised concerns. But rather than require a warning or take other steps to reduce the risks that products made with talc could contain asbestos, FDA instead adopted the honor system enshrined in this 1976 memo, that endorsed tools that do not detect all asbestos and which continued to put consumers at risk.

Even today, companies have no duty to share -- no duty to test for asbestos. No duty to use the most sensitive testing methods. And if they do test, no duty to share those test results with FDA.

And as you know, FDA and EWG, and others, have found thousands and thousands of other products, including loose and pressed powders used around the nose and mouth that are made with talc and that could contain asbestos.

I'm not the only person who thinks that it is long past time for FDA to act. Today's meeting is important, but conducting testing or defining the state of the art for testing is not enough. That's why nearly 25,000 Americans, just in the last few days, have joined a petition calling on FDA to require companies to use the most sensitive state-of-the-art testing to test for asbestos in talc, and to make those results public.

We also believe it's time for FDA to require a warning on products made with talc so consumers can make their own choices. FDA should also expand inspections of facilities that make products with talc. And in the course of those inspections, demand safety records to know which testing methods are being used, and with what frequency.

And FDA should make all of those test results public. If a company declines to share those results with FDA, FDA should tell us. We should know, we should decide for ourselves whether those products are safe to use in our own homes.

In conclusion, I'll just say that

it's time to end the honor system that has failed consumers so badly for so long. It's taken us more than 50 years to recognize that products made with talc contained asbestos. Let's not wait another 50 years to finally protect consumers. Thank you.

MS. KARI BARRETT: Thank you for your remarks.

Our next speaker is Robyn Ray, EMSL Analytical. Again, if you'll say your name and affiliation for the transcriber.

MS. ROBYN RAY: Hello, my name is Robyn Ray, and I do work for EMSL Analytical as a national project manager, and also as a senior analyst. I've worked there for the last 19 years and here are my conflicts of interest and affiliations.

So while I was preparing this talk today, I wanted to focus my points through the lens of the preliminary recommendations that have been provided already.

As I was reading these recommendations, one of my first thoughts was, why are we limiting this to just a talc matrix? Over the last year, I have seen fibers of chrysotile in magnesium hydroxide brucite powder. I found tremolite in a 100 percent clay facial mask. And I've seen zeolites listed as ingredients in aerosolized dry shampoos.

Cosmetics contain a variety of mineral components, and if the object of testing is to identify EMPs, I think the search should include other things, other than talc. Such as zeolites and erionite should also be listed as covered minerals.

When we talk about asbestos analysis in any materials, there are numerous common techniques that become applied. Examination in each one of these instruments is for different purposes, and that's why it's difficult to compare the results, because they are looking at different portions of the overall picture.

But no matter what method you develop, these advantages and disadvantages need to be considered. The only way to overcome limitations of one is to apply a combination of several. For instance, when you are trying to relate results to a specific manufacturing lot, you need to consider both the representativeness of the sample, and the effective analysis area of each instrument.

In XRD, we analyzed about a dime-sized amount from the center of this slide. Next to this slide, I've put two TEM grids. Those grids are three millimeters in diameter and are indexed to contain 100 discrete grid openings.

During the TEM analysis, we only analyze a subset of those samples. During PLM, we will look at the entire contents of one or more cover slips. And onto the left, you can see sort of a basic representation of the area analyzed with XRD being the pink square, PLM being in orange. The blue representing the TEM grid, and the black dot in the center being the area that we've only looked at by TEM.

If we think back to what we know of asbestos disease, we need to remember that the risk assessment has been based off of PCM data. And since PCM is a non-specific fiber count, it never identified or included the smaller fibers that were no doubt present. The industry proceeded to use the assumption that the fibers were detected were correlated with the fibers actually causing the disease.

So in that regard, I agree that any method for talc or cosmetics should include TEM to obtain a better representation of the fibers included in the sample. But TEM should not be used alone. XRD and PLM offer valuable information and protections against the small sampling size of TEM.

I also agree with the preliminary recommendations that the ISO 10312 counting rules be implemented, as they are the most robust counting rules we currently use. But I encourage the working group to specify a minimum level of identification. Without that, different labs will use different levels, and will produce different results.

Part of the identification process is a mineral identification. And the complete characterization of any mineral requires more than one analytical technique.

In the methods that we currently use commercially, we used relative peak heights to determine whether or not the mineral is asbestos.

Here you can see the downside of that where we have talc and anthophyllite from the same mine, but the peak heights are nearly identical.

In this case, we had to use electron diffraction to be able to tell them apart. But during the analysis, you also have to consider that there are many other minerals that appear very similar, such as pyroxenes where the chemistry diffraction can be very close.

So you tend to rely more on quantitative chemistry. Looking at the measured oxides in the fiber and comparing it to the nomenclature documents of the IMA. And there is no consensus standard outlining this procedure for TEM. And each lab will use its own approach based on their experience and understanding. Therefore, even with TEM, EDS different labs may identify the same mineral differently, based on their ability to interpret the data.

This is not only an issue because there is a lack of relevant material for standards to calibrate our systems, but due to the necessary experiences needed to perform this identification.

For talc methods, there is one technique that Dr. Longo had sort of discussed with the heavy liquid separation. The ISO 22262 method is specific to talc analysis and it does provide two approaches, filtration and density separation.

Using the density to separate the talc does help concentrate it, but this comes at a cost, because the centrifugation time determines the smallest particle that will be included. The smaller the particle you want, the longer you're going to have to centrifuge your sample.

Another downside to this technique is since the density difference between talc and chrysotile is so small, you will have to use two liquids to be able to report both.

The most applicable technique, if you're interested in quantifying both amphiboles and chrysotile on the same preparation is TEM by filtration. And this is the approach that we typically use in our lab.

So in conclusion, I hope that you understand that there is no one analytical technique, and no one method will be sufficient. The best science and mostly legally defensible data will be produced by using a variety of different techniques, include a robust sampling protocol.

Identifying EMPs will require more standards, more experience, and more standard methods to produce consistent results. Some labs have experience with this and others do not, but we need consensus standards to guide us all.

We cannot test to zero. We can continue to work on sampling techniques and methods that increase our ability to find fibers, but I do not think we should just limit the analysis to the talc matrix.

As I said, clay, zeolites and brucites also contain minerals of concern, and can -- are oftentimes used in cosmetics. These mixed fibers populations found in cosmetics may make it difficult to pinpoint all of the agents that are causing adverse health outcomes. But nonetheless, since asbestos-related diseases have long latency period, we would always need the most complete data set possible now. In other words,to preserve our ability to refine it in the future as new evidence becomes available. Thank you.

MS. KARI BARRETT: We'll go to our next speaker, Diana Zuckerman, National Center for Health Research.

DR. DIANA ZUCKERMAN: Hi, I'm Dr. Diana Zuckerman, president for the National Center for Health Research. Thanks very much for the opportunity to be here today.

Our non-profit research center focuses on safety and effectiveness of medical products. And we also look at safety of various environmental exposures, including environmental exposures in the home. And I'm speaking today of my perspective. I have a post doctorate in epidemiology from Yale. I was a researcher and a faculty member at Yale and at Harvard, and then I worked for a dozen years in the House of Representatives and the U.S. Senate and the White House.

So I have that perspective both in terms of policy, and in terms of my scientific background. And for 20 years, I've been president of the National Center for Health Research. So our perspective really is on the public health, and that's what I'm going to be focusing on today.

So as you've heard and as you know, it has been said by the World Health Organization that there is no known safe level of asbestos, and that avoiding contamination with asbestos and similar mineral particles is very important. That inhalation can cause a formation of scar-like tissue in the lung, and may result in lung cancer and mesothelioma.

Talc fibers can be very similar to asbestos, as you know, and can form from asbestos, and the Mine Safety and Health Administration and OSHA use these same exposure limits for fibrous talc and asbestos, and I think that's something to really emphasize, and I hope you'll think about it today.

We know that animal studies have found lesions caused by talc exposure, and we know that talc fibers have been found in lung tissue in people with cancer. So when we're thinking about a relationship between talc and asbestos, we have to remember, of course, that they both come from mines. Talc comes from mines that also contain asbestos, and, perhaps, almost always or always contain asbestos.

The removal of asbestos by purification of talc ores is, quote, "extremely difficult", and many experts would say impossible. And monitoring methods are absolutely needed to detect asbestos in talc, and better monitoring methods were needed.

What I was impressed by in your Working Group preliminary recommendations, was not just the idea that there was no consensus, but I really want to emphasize the fact that I think the distinct -- I agree with you that the distinction seems irrelevant. It's a distinction without a difference.

The Working Group, as you know

you've agreed with the NIOSH Bulletin 6210 regarding the adopting the term EMP as any mineral particle with a minimal aspect ratio of 3 to 1. And you also said that EMP includes asbestiform -- I'm sorry, asbestiform and non-asbestiform particles that have dimensions that are respirable. And I think that you've gone -- you've said things that are very essential as we think about whether this is a distinction worth making, and from a public health point of view, I think not a distinction worth making.

So as you know, you can look at these photographs and they're both very, very similar for asbestos and talc. This is from the FDA's own document. And that asbestos toxicity is determined by fiber dimensions in surface area, perhaps, by biopersistence at the site of the tumor or scarring, chemical composition, and surface properties.

And what are the mechanisms that explain why asbestos causes cancer? Direct interaction with cellular macromolecules, production of reactive oxygen species, and cell-mediated mechanisms, such as inflammation.

And we have clues from animal studies that help us explain this. And it refers to different sizes and forms of particles, as well as asbestos fibers and cleavage fragments, and that both types can cause cancers.

So why are we distinguishing between asbestos and talc, and I wasn't familiar with the previous speaker's work, but she's also said some very important things about other minerals as well.

So are the long, thin fibers the only ones that are dangerous? No, it seems that that's just one that have been counted, but they're not the only ones that are dangerous, because short fibers are common in the lungs and in tumors and can cause ROS and cell death.

IARC has mentioned that fibrous talc is carcinogenic and that the term, asbestiform fiber means, "Any mineral, including talc, when it's grown in an asbestiform habit."

You know what the measurement issues are, I don't think I need to go into that. But also just want to say that, although, as you know, TEM is much more sensitive, but it also misses a lot of area. So if FDA defines a lower limit, based on certain methods, as you have suggested, let's make sure that those methods include as much information at possible, otherwise the results will be misleading.

Basically, I wanted to congratulate the Working Group, because I think the work you've done is really important, and very helpful. I just want to really focus on that public health issue of what harms patients. We know that not just asbestos, but talc itself can harm patients in very serious ways that can kill them. And that it's very important to look at that public health perspective because these are products that are in all of our homes, and that almost all Americans are being exposed to.

So again, there is no safe level. It's in all of our homes and there are safe alternatives. So rather than focusing only on distinguishing between the contamination of asbestos and talc, I think we should be looking at the talc itself and whether EMPs can really tell us what we need to know, rather than focusing on which minerals are involved.

And I guess my last comment is just to say that, having worked with many patients and consumers over the years, what they really want to know is whether a product is safe. And it isn't -- it doesn't matter to them exactly which mineral is contaminating, which mineral is unsafe. What they want to know is whether the product itself can harm them or not.

Thanks very much.

MS. KARI BARRETT: Thank you for your comments. At this time, I'd like to invite my colleague up, Janesia Robbs up, she will help facilitate the next portion of public commenters. Janesia?

MS. JANESIA ROBBS: Thanks, Kari. All right. Next we'll have Steven Compton from MVA Scientific Consultants.

DR. STEVEN COMPTON: Good afternoon. My name is Steven Compton. I'm with MVA Scientific Consultants. I'm an executive director and a senior research scientist. My background is in microscopy and condensed matter physics, and for the last decade, I've been working with Dr. Millette and other scientists at MVA to examine nanomaterials engineered and natural microscopic particles.

As it relates to the topic today, I've been retained by companies in industry, and in litigation to analyze different mineral samples and cosmetic powders for the presence of asbestos in talc-based samples.

Generally, the non-litigation work that we've done is considered confidential, so any of the results I'll be talking about today will be from work that we've done where we were retained by plaintiffs in litigation -- or those kinds of cases. But -- and this is kind of crucial, the science doesn't change depending on who our client is. We should all be here as advocates for sound scientific principles.

Now, any proposed method needs to address two components, what instrument is used to analyze the sample and how is the sample prepared for that analysis.

We've already been through some of this, so I'm going to go kind of quickly, X-Ray Diffraction is capable of cataloging major and some minor crystalline components in a powder. This can be a useful for a screening tool, but it lacks a sensitivity when compared to other methods that makes it likely to produce false negatives, and it's not a visual technique. So it provides no information on mineral fibrosity.

The PLM on the other hand does provide some visual representation of a sample, and it's the workhorse of the asbestos testing industry when it comes to building materials and consumer products which may have been formulated with commercially viable asbestos as an ingredient. But it struggles with very thin fibers, i.e. samples that have been ground or milled into a fine powder. The optical properties can, at times, be ambiguous or difficult to determine either because the fiber might be too thin, or because of arbitrary human-determined cutoffs in solid solution series minerals, some of which are regulated, some of which are not.

TEM on the other hand looks at fundamental properties of individual particles, crystal structure, elemental composition. These are the properties being used by geologists to define the minerals in the first place. So the drawback with this method is simply sample size. For a positive result, that may not be an issue, but for a negative result how representative is a single analysis, and does that sample accurately represent an entire lot or an entire mine?

So we can look at it for real world studies. This is a study of 13 different off-the-shelf historic consumer talcum powder products from a certain manufacturer, and these were analyzed using X-ray diffraction, PLM, and TEM. All 13 tested positive by TEM, when analyzed by PLM, 8 were positive, 62 percent. When analyzed by XRD, 2 were reported positive, 15 percent.

So this is giving you some idea of the relative effects of some of the different test methods that have been utilized, historically. And this data is part of what was published in 2014 by Gordon, Fitzgerald, and Millette.

Now, in 2015, Dr. Millette published a procedure for the Analysis of Talc for Asbestos, and it ultimately came to the recommendation that, like I said earlier, XRD can be a useful screening tool, but really a combination of PLM and TEM is the most appropriate for an investigation of asbestos in talc.

Now, one thing Dr. Millette did not explicitly state, no doubt because he believed it was obvious, is that a positive result by one mandatory method cannot be negated by a negative result when using another method. You can't unsee asbestos.

And this carries with it two important implications. One, that a single method may be a sufficient stopping point if the result is positive. But second, TEM and PLM alone, if negative, are likely to be insufficient.

So the reason for this that there is not a 100 percent overlap of particles detectable by PLM and TEM. Here is an example of an off-the-shelf cosmetic powder whereby TEM, the aspect ratios -- the mean aspect ratios of single fibers identified by the TEM were approximately 7 to 1.

Some industry experts would argue

that that must be it's cleavage fragments, but when analyzed by PLM, you clearly see ongoing asbestos fibers. So we're not looking at the same exact subsample, essentially.

Now, this set of examples from a single producer also illustrates the interplay. Four samples analyzed, two of those samples tested positive by TEM. The second two were negative, but one of those was positive by PLM. So there needs to be some kind of overlap involved.

Now, these samples were analyzed without any kind of a pre-concentration, but when it comes to sample prep, there are a variety of ways in which a sample can be prepared for analysis, whether that analysis is XRD, PLM or TEM. Unaltered samples have the lowest potential for a sample loss or changes to fiber chemistry, but this approach will require additional time at the instrument in order to improve sensitivity levels. And again, we can look at some real world results.

This is some testing of 2017,

I looked at some mineral samples collected from the Val Chisone mine in Italy, from that mining property. And the asbestos range in samples where it was detected, as low as 1.59 million fibers per gram.

Non-detect samples had an analytical sensitivity as high as 14 million fibers per gram. These numbers are kind of consistent with what Dr. Longo was saying earlier.

In 2018, I looked at some mineral samples from a Vermont mine. And again, asbestos levels present as low as 1.35 million fibers per gram, non-detect samples had an analytical sensitivity as high as 7 million fibers per gram.

To improve the sensitivity of TEM, we can either examine additional grid openings or we can incorporate steps to eliminate particles that aren't of interest from the sample during that sample prep phrase.

Now ashing, and acid digestion, these are both commonly used for non-friable organically bound building products, they're standardized approaches, but they do nothing to eliminate platy talc from the sample.

Acid/base digestion has been very effective at removing some minerals in order to isolate amphiboles. It's also a standardized approach commonly used for the detection of amphibole present at low levels as accessory minerals. Unfortunately, talc appears to be resistant to this approach.

Elutriation, either using air, like a fluidized bed or water using aqueous elutriation can isolate respirable particles. And it seemed like a good idea, but great care needs to be taken that fibers are not lost in that prep.

In 2010, I did aqueous elutriation of an industrial talc. The image on the left is before, the image on the right is after. So some of the long, thin fibers that should have a small aerodynamic equivalent diameter were lost. So it needs to be carefully validated. Of all the concentration methods that are available, density separation shows a lot of promise, I'm not going to get into that since it's been talked about at length. It's a standardized approach, the ISO method has some issues with it that we can talk about later.

But the bottom line is that the IWGACP is on the right track for developing the clear and concise set of definitions for laboratories to use, and that's exactly what laboratories need.

The takeaway message is that a combination of TEM and PLM has historically proven to be useful. Sample prep considerations should be offered, but most importantly, counting rules should consider biological response by the medical data, not be confined or constricted by some of the commercial definitions that have been used in the past.

MS. JANESIA ROBBS: Thank you for your comments. Next we have Sean Fitzgerald from

Scientific Analytical Institute.

MR. SEAN FITZGERALD: Good afternoon, I'm Sean Fitzgerald. I've got a lot to go through, so I'm going to go kind of quick.

Thank you for the opportunity. I'm Sean Fitzgerald, I'm a professional geologist, I'm a mineralogist and I've been working in asbestos testing laboratories all over the country for over 30 years. And I'd like to thank the Working Group for acknowledging the big elephant in the room, and that's definitions: What is it we're talking about when we say the word "asbestos."

We have dozens of different definitions for that word, and we -- we're constantly stuck with what we publish in the Federal Register as the asbestiform varieties of these six specific minerals.

Well, thank you again, for going outside of that box. And in that definition, we have this other term that's kind of a hugger-mugger, "asbestiform", as a specific type of fibrous habit.

So these definitions that are foundational to what we're saying is or is not, are confusing. And is asbestos really something that you define, which is a really great concept. So we've gone through this today and I am very thankful for the other presentations today, so I don't need to go into Polarized Light and its limitations, but I would like to make this point.

When we originally sat down and said, what are we going to do with asbestos in building materials, we said this 1 percent rule because manufacturers never actually intentionally put less than 1 percent asbestos, raw asbestos, as a material. And we also said, in the Federal Register, that we'd better be careful about regulating anything below 1 percent, because we know some mineral resources, like vermiculite from Montana, can contain less than 1 percent. And that's exactly -- so this is not a new issue, this is a revisitation of an issue that we've dealt with before.

In the XRD, of course, we have limitations there that we've gone into in detail, and with electron microscopy, I am so glad, as an electron microscopist, to hear what you're saying to us today. We need to use Transmission Electron Microscopes, because we can magnify materials to very high levels. We can get the chemistry, and we can get the other thing that tells us what mineral we're looking at, that is the -- by electron diffraction, that is the layers of -- that define the mineral itself.

And yes, SEM is still useful, because we can still magnify very high, and we can still get the chemistry by EDS. But no, we can't get diffraction patterns, so we can't necessarily know what the structure of the mineral is that we're looking at.

Here is a penny slide just on this topic, because I've actually used this, when people are like, what is asbestos and how small it is, it is a -- I took some grains of rice out of my lunch and some hairs out of my head and I put it on a penny. And I took the smallest amount of asbestos and put it underneath Lincoln's nose, to show that hundreds of thousands of individual fibers can be so small that you wouldn't even see it without a little circle around them.

And if we take that asbestos and put it in the PLM and compare it with the TEM, we see that most of the fibers in that population, which we've already discussed, I'm just a more visual guy, are much too small to see by light microscopy.

Going back to that elephant in the room, that definitional thing, what is talc? As it turns out, talc is very similar to asbestiform minerals, their magnesium silicates, and actually talc can form from the very same types of minerals that when fibrous, we regulate as asbestos.

Van Gosen talked about this a little bit, about the different ways that talc can form in the earth. And if we look at the ways that they form, three of those four different ways actually involve the asbestiform minerals.

So it doesn't come as any surprise as a mineralogist that the minerals commonly associated with talc include serpentine, tremolite, anthophyllite, and actinolite, which you've already talked about at length.

Here's some pictures that I took years ago of some tremolite, anthophyllite, and chrysotile identified in a talc sample. This is an interesting one. Here we have what a lot of analysts would say, it doesn't necessarily count as anthophyllite, because this kind of pencil tip-morphology would be a cleavage fragment, so we couldn't count that. And the other hoop structures, the talc bundle and the talc fiber are mineral talc, so those don't count either. But this picture was taken as the anthophyllite asbestos standard. [Laughs] All right?

So when we have asbestos, if we look at the actual supplemental information when we have our asbestos standards, we have a substantial amount of talc because these things grow together. We know this. If we look at high resolution TEM of asbestos fibers, we see that the inter-fibril areas includes the sheet silicates, T for talc or S for serpentine. When serpentine is a scroll, it's chrysotile. When it waves back and forth, it's antigorite.

And we've published on this. Ann Wiley in the back was coauthor with Dave Veblen that talked about -- and we're talking about asbestos and its health effects, maybe we need to consider the intergrowths of these -- the intergrowths of sheet silicates with talc.

My laboratory, Scientific Analytical, we've tested over 600 cosmetic talcs in the last five years. And I was surprised when I was putting this deck together, that over 100 of them had countable asbestos structures. And these were not uncommon brands, and they weren't all historical problems. These were some things that were fresh off of the shelf. I thought this was important, especially when I found asbestos in cosmetics, so I started writing a method, just using a standard filtration, it was Groundhog Day a couple years ago when I decided to put together several samples of cosmetics where I found asbestos and send them to my friends in different laboratories. And I asked them, how many structures do you see that would be countable if it was on an air test. And what we see is that the seven labs that responded were fairly, repeatedly able to detect asbestos in these samples.

So what are these samples, sure enough, Justice Just Shine Shimmer Powder was one of the first that was made public, and created interest from the FDA. And what came after that, well, we found asbestos in Claire's, and sure enough the asbestos was clearly countable in the TEM analysis test materials. Here we might look at the aspect ratio and wonder if it's countable, but if we do a close up of the tip, we see that it actually comprised of several fibers together. So there is some subjectivity of whether or not something counts from lab to lab.

And since I'm working with European labs who base their asbestos testing protocols on SEM, I also took pictures of the same samples to share with those laboratories. Here is a splaying of tremolite. There might be some laboratories that would say, this doesn't necessarily constitute the asbestiform habit--- but this would, by any counting protocol.

So at the end of the day, what we have to deal with here is we have several different cosmetics where we shouldn't have anthophyllite and tremolite that fits the definition of asbestos countable structures by any method in talc products sold to children.

So we need a method that works. And I would also like to thank Dr. Longo and

Dr. Moline and Dr. Metcalf for coming here to D.C. a few weeks ago and talking about these different methodologies. Longo actually just told us about his floatation work -- and there is an error on this slide. He actually said that it could get down to around 4,500 individual fibers, not 4,500 million. But he also said that he couldn't find chrysotile, so I'm more encouraged that we just heard that he has developed a method to do that.

He concluded that we should ban the use of talc in cosmetic products, it's the only way we cannot get asbestos in talc. And I don't necessarily -- I can't go that far, but I really appreciate the work that's been done by this panel, and the opportunity to talk to you today. Thank you.

I've got a couple of seconds, so I think you should also consider antigorite. You said that chrysotile was the only type of asbestos that should be considered. We note that there is negative health effects from asbestiform antigorite and sepiolite. We need to be able to differentiate, sepiolite that can be intergrown in talc, and commonly occurs in talc, from chrysotile. Thank you.

MS. JANESIA ROBBS: All right. Thank you for your comments. Next we'll have Frank Ehrenfeld from the International Asbestos Testing Laboratories.

MR. FRANK EHRENFELD: Good afternoon. Let's see if I can -- and so it's the arrow to the right? Okay.

I am the laboratory director at IATL International Asbestos Testing Laboratory, but today, I am representing ASTM International, and I'm going to discuss some of the analytical methods that we are developing to meet the needs that have been discussed here today.

So I'm going to talk again about ASTM, about the committee that is working on this, our roster and where we are at, especially the current status of these methods and the next steps and expectations. I'm not going to cover ASTM International in detail, it has been mentioned previously throughout the day. I would submit to you that the plane that you flew in on and the car that you drove here, all were manufactured according to ASTM and other organization standards.

ASTM is an international organization. We have ties to governments and regulators throughout the world. This is a leading component of anything dealing with trade and other regulatory components of nation-to-nation agreements and treaties on economic development.

The organization has a number of memorandums of understanding. Again, with governments and regulators about using these standards. Again, ASTM is recognized.

I draw your attention to the organization's mission statement talking about possibly impacting public health and safety, consumer confidence, and quality of life, and that we have volunteer technical experts. There are 19 of us in the room today from ASTM International. It would be 20 if Don Halterman was here, and 21 I know is at least listening and sending me text messages of the proceedings.

D22, we will be celebrating our 70th anniversary next year. We have a lot of members and a lot of published standards. The various subcommittees are listed there, D2207. Again, it's more than asbestos, but it's sampling, analysis, management of asbestos, and other microscopic particles--can you say EMPs?

Here's the basic structure of ASTM committees down to the task group level, which are assigned method development up through the committees, and then onward and upward into the process of furthering along consensus standard development.

Part of that includes an

interlaboratory study program, so that both precision and bias can be published. Meaning reproducibility and repeatability for these analytical methods.

What makes a method valuable? Everything listed here and more. I would draw your attention to the interlaboratory study, and the fact that with ASTM International, these analytical methods are routinely reviewed and there is a revision process that each of these standards has to undergo.

You may have heard this quotation before about sausages and laws, I would add to that consensus standards, it is not something that the public would want to witness happening, but it is what we have, and what we know works.

D2207 has over 15 of our standards dealing with TEM, PLM, and XRD, over 15 just with TEM. The history of talc and asbestos with D2207 goes back to when USP, the Expert Talc Panel was put together. We were also reproached. I will tell you that just about everyone on that Talc Expert Panel is also helping out with the ASTM side of things in method development.

Of note on this particular slide, we also are in the middle of PLM, XRD, and TEM methods, and another one I'll tell you about as we get going.

One of the things-- challenges that we incurred was certainly the obstacles of good reference materials, which has also been mentioned here today. Regarding analytical prep methods, we have options that we have been exploring, and in some cases have been in and out of some of our draft methods, including some of the concentration methods that we've talked about here today. And that we will hope to continue to promulgate in these methods.

Right now, we can divide those work items into the following categories, TEM, XRD, PLM, and what I like to call the product method, that is for things like cosmetic talc where we are using a combination of PLM and TEM.

The rosters include some of the individuals listed there, and many others not listed. If we look at these basic -- divide these methods up, again, the initial thought was that the -- these methods listed would be for investigating raw or processed ore, but they could have other applications for things like cosmetics.

The product side of things, that work item is exclusively for materials that would need to be gravimetrically reduced and used, other preparation techniques like D5756 when we finally get it down to a powder.

We learned the hard way in ASTM D7521 for asbestos and soil does not include milling. And so that is something that we would not consider unless it was needed to further investigate by TEM. Here is sort of a summation table of where we stand right now with the XRD, PLM, TEM, and what I like to call the product, PLM/TEM combination analytical method.

There we will talk about matrix, the estimated detection limit preparation, we -- the preparation is using existing procedures found in other ASTM methods, ISO, NIOSH, and EPA methods.

With this, we are using the tool and the concept of counting and binning that I was pleased to see in your executive summary. That executive summary I have been calling "The wish list" for FDA, and it is something that we would like to respond to and use as an outline for what can we do to achieve some of these wish list items.

Again, with mass reporting also, perhaps, being an option for a couple of these techniques up here. I will point out to you that with this, countable EMPs, as we discussed earlier and covered minerals would be included. And we should be able to have those in our methods.

So where do we stand right now? By the way, the term "withdrawn" is an ASTM term meaning that it's no longer out there for ballots.

So we have had two ballots with our PLM draft method. It is sort of back to the drawing table with that. TEM has had two ballots, same thing there were a number of persuasive arguments to have that removed, and we have to work on it again before putting it forward. But I will tell you what I've heard here today will be carried into the process of consensus standard development for ASTM. So look for that down the road.

Final note, TEM, the first ballot included size ratios down to 3 to 1 and basically count everything. And count everything is something that you will find throughout some of these methods. And then the other professionals can do what they need to do with that data.

I have 45 seconds left. I wanted to mention for the record that our annual Johnson-Look Conference will be held this summer in July. Talc will certainly be a part of that five-day conference.

I wanted to also mention that there

are plenty of analytical methods that do count less than five microns, including ASTM D6281. FBAS, a fluidized bed. We actually have a work item. So we do have a draft method that is being put together for that-- Ed Cahill, shout out. I think that's about it.

So I'll yield my last five seconds. Thank you very much.

MS. JANESIA ROBBS: Thank you for your remarks.

Next we have Eric Chatfield from Chatfield Technical Consulting Limited.

DR. ERIC CHATFIELD: Thank you for the opportunity to come and say a few words here. I found it very instructive over the last few hours.

My name is Eric Chatfield, and I'm president of Chatfield Technical Consulting, Limited, in Mississauga, Ontario. I'm convener of the working group in ISO that produced these ISO standards on asbestos. I first started doing that in 1978, believe it or not, and it has been going on like that ever since.

Starting out with arguments against the Germans as to whether the SEM was better than TEM for doing asbestos analysis.

I'm the lead author of these various documents. The Analytical Methods of Determination of Asbestos in Water, for EPA, which was published in 1983, I've just mentioned the -- I'm the lead author, the second author is my wife. So I've kept it in the family, so to speak.

With the ISO methods, generally, they've just been updated 10312 and 13794 are both going to be published -- they're published in 2019. They were very much overdue for review, and that's the way it's happened. So I kept control of that.

Now, when I got the Executive Summary, I noted a number of items in it that caught my attention. The first statement was that the published analytical methods for asbestos analysis were only intended to go down to 1 percent. Now that is actually incorrect because ISO 22262-2 and 22262-1 were designed to go down to even the British standard, which is kind of vague, it just says "any asbestos".

So they were designed to go down to trace levels. Now, there are a number of issues regarding the references that we used for whether or not fibers between 0.5 and 0.9 microns should be counted.

The references used seemed to be somewhat selective, because the publications that report zero potency or minimal potency for these shorter fibers, they've been overlooked. Things like Berman and Crump -- well, Berman, et al, Berman and Crump and Roggli in 2015 are not mentioned.

Now, the Suzuki papers, moving on to item B, those fibers were measured on photographic prints, which kind of limits what you can say about the identification of those fibers. They also included many fibers which were less than 0.5.

Now, 0.5 was defined a long time ago. It actually occurred in the drinking water method of 1983. So it wasn't that 0.5 was not known about, the dates of those papers, and we still regard 0.5 as the minimum length for reliable identification and detection.

That supported by work from NIST or NBS, as it was originally. And also a round-robin study we did in ISO in the 1980s. The ANSEs document in 2015 is quoted as supporting the concept of not count -- of counting between 0.5 and 5 micrometers. An actual fact, it says precisely the opposite. With only EMPs having lengths greater than 5, diameter less than 3 be considered in natural materials. That's from the main document, which is only available in French. And the shorter fibers, air and material analysis reports mentioned the presence of. It doesn't say considered them in any kind of regulation or regulatory manner, it says mentioned the presence of.

Now, I can see that being a concern if we only have short fibers. In other words, if you don't see any long ones, not reporting them, I believe would be wrong if we're measuring -- if we are detecting them at all.

The third item is really, if you got the data between 0.5 and 5, what do you intend to do with it. Because there is no basis for quantitative risk assessment for fibers within that size range.

Moving on to -- did I press the wrong thing again? Oh, it's that one.

Okay. Now, I developed a few recommendations here, the first thing is that ISO 22262-2 is being revised to include talc and other mineral fibers. The revised version defers to ISO 13794, the liquid filtration methods, and any other procedures to do with analysis of TEM and analysis of particles on a filter.

Now, if you start out doing a TEM

count for fibers longer than 0.5, it usually means that you never really get to see the long ones, because the counting rules specify that you stop counting at this specific number of fibers, you never see the long ones.

So really you need to define a two-phase strategy where you count all fiber lengths first, and then do a separate count for fibers longer than 5. And that way you get statistical validity at both ends of the size spectrum.

And the other thing is that for the thinner EMPs, magnifications of 10 and 20,000 isn't high enough. You have to go to 60 -- 60,000 or so to get good, reliable width measurements in the thinner fibers.

Now, with respect to mass measurement, it is possible but it requires the specific counting protocol, a different counting protocol. But bear in mind that mass is the only invariant measurement, anything else like fibers per gram is changed by any treatment we give the sample. If you crush it, disperse it, you may break it up into smaller fibers.

And for the numerical EMP concentrations per gram, you really do have to define an analytic sensitivity.

You should take some in what EPA did to define the MCL for drinking water in terms of fibers longer than 10. Somehow, they picked 10 microns, I don't know why. I personally don't. Possible areas of research, while I think we've dealt with those to a point, Bill Longo dealt with that quite adequately. And finishing up with two quick slides, I was restricted to five slides. Determining the size of the EMP to include in the measurements, we should look at the annuals for some guidance.

The next slide shows four population distributions. Two studies, Davis and Aierken, et al in 2014. No tumors through the JAWE 431. 5.6 tumors which it has tremolite. Lots of tumors for the other two --

MS. JANESIA ROBBS: And I would like to say we are at time.

DR. ERIC CHATFIELD: The final slide --

MS. JANESIA ROBBS: Thank you. And I would ask that you submit your presentation and comments to the docket.

DR. ERIC CHATFIELD: Okay.

MS. JANESIA ROBBS: Thank you. Thank you for your remarks.

All right. Next we have Mickey Gunter from the University of Idaho.

DR. MICKEY GUNTER: Thank you, and -- oh, I've lost all that time.

We were asked to list all of the various things we do, so the pointer was -- first and foremost, I'm an Emeritus Professor, that's worse than the biggest bomb. I am also past president of the Mineralogical Society of America, I was the 100th President, which was last year, so our society has been around for 100 years. We know mineralogy, we're a deep field. It's very well understood. I'm not sure anyone can be trained to do many of these things, but I'm sure you can be educated. I'm also a member of the Idaho State Board of Geologists, and they're put in red because I also do consulting, and I'm a defense expert witness.

We've heard some mineral names mentioned earlier today. If you don't know the names of all of these minerals and these lists the percents of them, but I think it would be kind of hard to do a lot of this elongate mineral thing.

So again, I think you need to know a lot of these minerals. We've already mentioned the amphiboles make up 5 percent of the earth's crust, so amphiboles are going to be a very common mineral here.

This happens to be a -- look, I brought this up for a reason. The reason being that this is our textbook, and if you make it up page 515, there's a lot here, that's the chapter on identifying minerals, which I think are going to be pretty important here. If you'd read -- whoops, go back, I don't want to show that yet.

If you read this part it says, one of my smart wisecracks is, when somebody hands me a mineral, I say, do you want me to guess what it is or to tell you? Because we can always tell you. It just may take the knowledge in this, plus four or five other graduate level courses and analytical methods to do that.

I don't think this person should go unmentioned. I would like to dedicate whatever part of my talk to Mac Ross. Mac was the person who got me interested in this whole field a long time ago. This is a picture of Mac and also an article published in the American Mineralogist 1990 where he received our public service award for the work that he had done, and was basically helping, and people realizing there was more than one kind of asbestos.

Okay. Mineralogy, these are essential mineralogical principals, this EMP part. Minerals are classified based on their crystal structure and composition. Thus minerals are identified based on crystal structure and composition. So we need to know these things to clearly identify a mineral.

Also, the physical properties of minerals, things that we could measure. We can scratch talc, right? Those are things that can indirectly help us identify minerals, but we need to know those things to correctly do this.

This is an SEM photograph, we've seen these before. This is an EDS pattern, that's a chrysotile fiber that happens to be out of a gravel parking lot in Vermont. No one would argue that's chrysotile. This is out of the same parking lot. This is probably the mineral antigorite. This is out of the same parking lot again, probably antigorite. And if we consider these things EMPs, we're counting all of these, and just so you know, about 2 percent of the earth's surface is covered with this rock-type serpentinite. In fact, we saw some nice pieces of serpentinite out in the parking lot this morning.

If you continue to look at how you identify minerals this, again, is an EDS pattern. And I see elongate material here, silica and oxygen, probably a lot of you in the room would go, well, that's quartz. It might be, you're not exactly sure. You have to use some diffraction techniques, one is powder X-Ray Diffraction, this is out of our book, the bottom one would be quartz, the top one would be a silica glass or amorphus. You could use single crystal diffraction, or this could be either with x-rays or with electrons, and this one is the mineral quartz, which is common, the other cristobalite. These are electron diffraction patterns. All of those little numbers mean something, and I think electron diffraction patterns without those numbers on them don't mean much.

You could also use one of my favorite things, is Polarized Light Microscopy. You could put minerals into these liquids at different refractive indices. And what actually happens here, you can see the minerals here, you barely can here. So you match the speed of light through the mineral, that's a physical property. A very quick, easy way to identify these things, assuming you know how to do it.

Talc. These are several different images of talc particles. And you can see right here, this would be considered an elongate mineral particle, seen here. In this case, I've rotated the microscope stage, and that talc particle tends to go away.

In the bottom one, you can see it clearly because I've rotated it back. So this is talc, but it's the elongate piece of talc, it has different optical properties in different directions. If someone asks me my major research interest anymore, I'd say it's the orientational dependence of the physical properties and minerals. It's a mouthful, but you have to understand these things to correctly identify them.

This was out of the Reuters, the back image for the Reuters article published about J&J a little while ago. And what it shows here, and this is a piece of chrysotile -- a piece of talc with a scrolled edge that they misidentified as chrysotile. This shows an intergrown, what they're calling intergrown chrysotile and talc, but again scrolled edges. This is the most interesting limits of chrysotile -- they're calling it chrysotile, but it's really a piece of talc, like this is talc, and if you would rotate the stage, you would see that go away.

So again, I'm kind of in this mineral identification thing is my main aspect here. Talc, if you look at its crystal structure, you have the drawing, you can then rotate it in different directions, and this is the way we tend to see it as a nice, flat thing, we can turn it sideways, it looks like this. Its electron diffraction pattern is different, just like the optical property is different. So you get different patterns as a function of the orientation.

We've already mentioned Jim Millette earlier. If you go back to 1990, this is a paper he wrote where he showed this talc particle, talc ribbon that produces an electron diffraction pattern that looks more like an amphibole, and then he goes through -- and I did this, I went through and calculated where the diffraction spot should be, labeled them, assuming this is really a piece of talc.

This is something that we can do easily in 2020. When I was a grad student, it was very difficult to do these kind of calculations. So you can sort of toss all of those together, you can see what the talc particle would look like.

Elongate mineral particle for sure, but again, we also can identify it based and credit interpretation of the electron diffraction pattern.

Again, some of this has been mentioned, this is a chemical formula for anthophyllite. Chemical formula for talc, they're very similar, as there's much in the peaks, the EDS can be difficult to tell apart. Also, they have the repeat length without a lot of details. And this repeat length is often used to identify minerals that would be amphiboles. But they're the same for amphiboles, pyroxenes, and sheet silicates.

So this is the one to memorize or possibly go blind. This is overlain two diffraction patterns, one of anthophyllite and one of talc. And one of the ways some of these identifications are made is by measuring this particular spacing in here. And you can see the spacing for talc and anthophyllite would be the same. And I'm really big into this mineral identification, that's kind of one of my main points in all of this.

Oh math. Math is easy. I like math I have a minor in math. One other thing to do -- again, this is in a sophomore, a sophomore book, right? This is something that we can all do, I hope.

This allows us to do a lot of these cystographic calculations fairly easily. More, math, you know, again, if you like math, you just got to love this stuff. But you can take -- and where this is going is we measure zone axes these directions with these electron diffraction patterns to correctly identify anthophyllite versus talc, and rightly you have to measure two of these zone axes with these numbers on them, and you've tilted your TEM stage a certain amount, and that number right there had better equal the direction you tilted in.

So again, we have ways to check

these things, just like balancing our checkbook, which probably no one does anymore, right?

So back to quiz of gravels, bang, these are feldspar minerals, the most abundant minerals of the earth's crust. Twenty is all elongate mineral particles, more elongate mineral particles. This is a farm field -- and I'm going fast, going fast. This is the important one. If you look at -- we have listings of minerals and how they're classified by IARC. And there were several of these that are classified group three that are really elongate -- oop, going down, going down quick.

MS. JANESIA ROBBS: And you are at time. Thank you so much for your presentation.

DR. MICKEY GUNTER: Gone over?

MS. JANESIA ROBBS: Yes, you were over.

DR. MICKEY GUNTER: So these are group three minerals right here.

MS. JANESIA ROBBS: Thank you.

DR. MICKEY GUNTER: You're welcome.

MS. JANESIA ROBBS: Up next we have Brian Bandli from Matthew -- oh, and Matthew Sanchez from the RJ Lee Group.

DR. BRIAN BANDLI: Good afternoon, and thank you for the opportunity to present comments to the Interagency Working Group on Asbestos in Consumer Products. I'm Dr. Brian Bandli, and I along with Dr. Matthew Sanchez, and Dr. Richard Lee, work for RJ Lee Group in Monroeville, Pennsylvania.

Collectively, we have more than 70 years of experience in the development of analytical methods for asbestos, including EPA, NIOSH, ISO, and USP and in the analysis of a wide range of materials for asbestos. Most importantly is the analysis of talc.

RJ Lee Group has been recognized by EPA for the quality of its data, and for the contributions to the development standard methods. RJ Lee Group scientists have published extensively in the peer-reviewed literature on a wide range of topics, including those related to asbestos analysis, methods, mineralogy, and geology.

While we are all engaged as experts in asbestos litigation, we are not representing any of our clients in our comments here this afternoon.

Dr. Lee has been directly involved in the development and evolution of asbestos analysis methods since the early 1970s. At that time, there was fear the community exposed to possible asbestos and elongate mineral particles resulting from the iron mining operations in Minnesota would result in an epidemic of asbestos related diseases. Methods for the measurement of asbestos and asbestos exposure were in their infancy, and began to evolve to recognize that not all particles with greater than 3 to 1 aspect ratio were, in fact, asbestos.

OSHA and MSHA positions on this have evolved over time to recognize this fact. In the ensuing four decades since the 1970s, other locations where elongate mineral particles are present have been evaluated. Locations include El Dorado Hills, California, Homestake, South Dakota and Enoree, South Carolina.

Investigations performed of these locations and several others have demonstrated that not all elongate mineral particles pose the same risk to human health. Furthermore, studies to assess the potency of particles from these locations have consistently demonstrated that there is a significant difference between potency of elongate mineral particles that are not asbestos, from elongate particles that are asbestos.

The resulting body of evidence has led to clear direction from OSHA and MSHA that only elongate mineral particles from an asbestiform material are to be considered asbestos.

The NIOSH roadmap document cited by

this Working Group in its recommendation also does not indicate a clear correlation between exposure to elongate mineral particles that are not asbestos and increased rates of disease, but that additional studies should be performed.

To be fair, there is ongoing controversy surrounding what constitutes properties of asbestiform fibers that should be used in the enumeration of elongated mineral particles, and more fundamentally, which properties control potency.

Including all elongate mineral particles in the analysis of cosmetic talc products distracts from the actual risks that could be posed if asbestos were, in fact, present in these materials. If all elongate mineral particles are to be counted, recognition is needed that these particles represent a continuum of morphologies, very few which may represent significant risk.

By enumerating all elongate

particles longer than 5 micrometers with an aspect ratio greater than 3 to 1 with no regard to the actual morphology of these particles, significance of the presence of asbestiform particles is reduced. It is well known that grouping separate potential hazards into one measurement dilutes the ability to understand the potency and effect of exposure to them individually.

Microanalysis of individual street particles contained within various materials is relatively straight forward when evaluating components present in a concentration greater than approximately 1 percent by weight. However, the level of complexity steadily increases as the concentration of the particle type of interest decreases to less than 0.1 percent by weight.

Not only does the complexity increase, but the impact of even a single particle from the environment in which the samples are handled is significant. It's impossible to design a test method with an analytical sensitivity of zero. There must always be a detection limit below which it is not possible to differentiate the mean value from zero.

Laboratory practices associated with the preparation of bulk talc samples is at least as important as the recommendations for analysis. Handling bulk powders in a manner that prevents cross-contamination between samples or introduction of particulate from a laboratory environment is not trivial.

Another serious drawback of TEM analysis alone is lack of representativeness of sample size analysis. In a typical TEM analysis of bulk material, hundreds of particles may be included in the analysis. Thus the finding of one particle in any single analysis is in no way significant or representative of the material being analyzed.

Additional analysis using complementary techniques is critical to understanding the composition of the material. Plate microscopy includes, perhaps, hundreds of thousands of particles in a single analysis. An X-ray diffraction includes, perhaps, billions of particles in a single analysis.

Additional context is crucial for a thorough understanding of the findings, and no one analytical technique is a silver bullet.

If all elongate mineral particles are to be counted, and all covered particles are to be discriminated, current asbestos laboratory capabilities and competencies in the United States are inadequate for the task.

Current systems based on NVLAP accreditation are insufficient to determine whether laboratories can confidently identify even the six regulated asbestos fiber types as these diffractions demonstrate.

In this instance one laboratory found two structures and identified them both as chrysotile. However, based on the data presented, only one of them is, in fact, chrysotile. And even the data used by the FDA in its analysis of various talc-based cosmetic products to demonstrate that they contain asbestos is seriously flawed, and does not support the conclusions reached.

If, as a community of analytical laboratories, we are to have any hope of providing accurate and reproducible results that provide the public with data in which there is confidence, we will need to revisit all of the established frameworks, which data -- with data in which there is confidence. We will need to -- which we currently operate.

Methods currently used to measure airborne asbestos concentrations will not provide meaningful answers if the supposition is that any and all elongate mineral particles are of concern. We will need to invest significant time and effort in retraining analytical staff and re-establishing protocols that are demonstrably improved over those currently in use.

The costs to the analytical community will be significant and require a complete paradigm shift of those who operate laboratories, as well as those involved with laboratory accreditation processes.

Our daily group is willing to invest the time, effort, and capital associated with improving our analytical systems, provided that they are representative -- responsive to scientifically established measurements that relate to established risk assessment procedures that follow the public -- that allow the public to make informed decisions.

Thank you for your attention and for your efforts to improve our understanding of the issues surrounding accurate characterizations of talc in cosmetic products. Scientifically accurate characterization of particles in the talc and cosmetic products is our shared goal. Thank you.

MS. JANESIA ROBBS: Thank you for your comments. Next we have David Egliman from Never Again Consulting.

DR. DAVID EGLIMAN: Okay. Back we go. Okay.

So I agree with your report, let me try to help you out with some comments on some of the comments.

First of all, we can never get to zero for something that causes cancer in a product that has no health benefit. A warning is insufficient it should, as Johnson & Johnson said, if there's any question of safety of talc, question of safety of talc, we had a lot of questions here. We've had them for 50 years, they're not going to be resolved today, as you've just heard, it's complicated. This is what Johnson & Johnson told the FDA in '74: "any question of the safety of talc, Johnson & Johnson will not hesitate to take it off the market". I should sit down now.

Okay. Biopersistence. The articles that you cite, in addition to the [inaudible] and Sebastien show that where the cancer occurs, the short fibers are biopersistent. What you heard here from Roggli, which I rebutted, please feel free, I'll send you the paper, okay, is epidemiologic studies which don't look at things less than 5 microns in length because they were never counted in occupational studies, they can't show that those short fibers don't cause effects. So epidemiology does not trump pathology when you find the fibers near the cancer.

In terms of the talc in miners, yes, it looks like that wasn't asbestos. It looks like they got a lot of mesotheliomas there. Same thing with Vanderbilt, some of the folks who have come and spoken today said that Vanderbilt material in talc was not -- was asbestos-free. If so, it's 10 mesotheliomas in those workers. There is mesotheliomas in the Italian, 1 Italian worker at Val Chisone, and probably 2 Vermont talc miners.

Those studies are small, there were only 38 mesotheliomas in all of the Québec mining studies of 38,000 workers studied for 100 years. Studies have to be large to have any importance.

Okay. We pour this stuff on ourselves. It is designed to be used as a powder and to be inhaled. It is inhaled. When inhaled, the asbestos in the lung goes into the lymphatic system, as you heard, and gets carried everywhere.

The best test method has only been discussed once, let me reiterate it. It is the surface area of the lung, and I'm going to show you the lung being the best area to find asbestos from talc.

My estimate was, you heard a half a football field, I was only a tennis court. Again, I gave this in Italy, so that was in Italian. Okay. Who should decide -- you got two issues here, right? How to count, what to count. What to count is a health question as Meeker from USGS said, not a geologic question, okay?

From a health perspective, this is a USG study 1980 is pretty much ignored. The amphibole cleavage fragments have the same size, shape, length, morphology, chemistry and same surface charge, so do winchite, richterite and erionite. And if you don't want to count all of the EMPs, we know there's three EMPs that don't get counted as asbestos. I just named them, there's no question they cause cancer.

I reviewed this for a book chapter in the ASTM publication, you can go to that link at the top, I have the book chapter in question.

From a health perspective, I'm not going to go through these things, but cleavage fibers cause mesothelioma. Vermont talc miners, Vanderbilt, that's the two examples. Some of these things were discussed in '92, of course this discussion started a long time ago. Okay. In '92 NIOSH concluded that cleavage fragments should be counted, because you couldn't in the epidemiologic studies distinguish cleavage fragments from fibers, never happened.

The ATS said the same thing. More importantly, Dr. Chatfield showed you the data from Davis' four animal studies, that was analyzed by NIOSH and they testified in and incorporated in the Federal Register comments that there were NOT zero mesotheliomas in the animal studies, okay.

What happened in -- when OSHA changed -- this is an Imerys document from the head of Health and Safety at the time---OSHA threw in the towel rather than fight with OSHA.

This is a paper from 2019. This is geology. They looked at amosite. Amosite, no question asbestos. They said looking at amosite from the bad, it does not meet the definition of asbestos, it is cleavage fragment. Amosite causes mesothelioma.

This is the -- what do you get from a lung, this is a case series of ovarian cancer cases that I just published. On the right is, see the asbestos in the ovarian cancer tissue. It the middle from the cans of the J&J baby powder, on the left from the NIST standard. Okay. It gets in and it moves, milling breaks talc bundles up. You cannot use a test method that ignores non-asbestiform habit asbestos when you mill the stuff.

This is reason 2,000. Again, this is Dr. Gunter's testimony where he said that the material found in Vanderbilt was cleavage fragments. There is no known safe level, and there is no medical benefit. The stuff, as Johnson & Johnson said, should be taken off the market. Okay. I went fast so -- by the way, in Europe, the CTPA, which is the analoguous organization to the U.S. industry organization, said if the XRD was positive they didn't even look at the thing for fibers, they just wouldn't sell it, use it, all right.

J&J said that -- the same thing early on. Imerys told the FDA the same thing, if

XRD is positive, we just get rid of it, we don't care about fibers, we don't want to take the risk. I agree. Product no health benefit, don't take the risk.

Dr. Berdick said it was not feasible to develop a sampling plan for talc. I think that may be true, if so we're taking a big risk, because there is no way to get to zero.

In terms of -- this is my example of non-homogeneity. On the left, you see we have some chocolate chips, you sample that, you may miss the chips. On the right, that's not talc. Talc is more like what's on the left. In terms of the distribution that you heard from the geologist of asbestos in broad formations, remember this stuff is exploded. The rock formations are exploded and the talc is carried off. It's complete mixing of everything in that area from the rock that's in the sidewall from the head -- from the footwall, everything, okay?

There's been a 50-year campaign to

deregulate cleavage fragments. It should end. That's the history of that. Thanks. It went pretty fast.

MS. JANESIA ROBBS: We appreciate you being here today and offering public comment.

All right. So at this time, we will break for 15 minutes -- for about 20 minutes, I'm sorry. It is 3:06, we will come back at 3:25. Thank you.

(Recess taken.)

MS. JANESIA ROBBS: All right. We will go ahead and get started. And as a reminder for the remaining public commenters, just to state your name and affiliation and speak clearly into the microphone.

First, we have Mark Ellis from Industrial Minerals Association.

MR. MARK ELLIS: Thank you. My name is Mark Ellis. I'm President of the Industrial Minerals Association of North America.

My presentation today will try to

avoid addressing asbestos, talc, geology or mineralogy, but I may not succeed. It will instead focus on customers and consumers.

I want to offer a new conceptual framework for viewing the physical world around you: if it can't be grown, it has to be mined. I ask you to think about that. In the charades analogy the question one typically asks is, is it animal, vegetable, or mineral. And if you think about that, that universe is pretty all-inclusive. Consider food and natural fibers. Examples include, fruits, nuts, vegetables, grains, fish, meat, poultry, cotton, leather, and wool.

If you consider minerals, you're looking at metals, liquid and gaseous petroleum products, examples would include clay, marble, sand, copper, gold, iron, crude oil, and natural gas.

I'd like to ask you to consciously reflect on where the things that you rely on every day come from, including consumer products. Look around the room, where do these things come from. I did that and with the exception of maybe the fabric on the table that's in front of you, the leather on the back of the chairs or the wood that's in front of me, most of this stuff comes out of the ground.

Okay. This may be hard to see, so I'll try to cover it for you. The minerals industry is the beginning of the manufacturing supply chain. Manufacturers are our customers. Consumers are the customers of the manufacturers. Each year, every person in the US consumes roughly 40,000 pounds of new minerals to make the things that we use every day.

Stone, sand, and gravel and cement, about 16 -- or 18,000 pounds or roughly nine tons goes into roads, buildings, sidewalks, landscaping concrete, asphalt, blocks, and bricks. The metals, iron, aluminum, copper, zinc, manganese, and others, roughly 300 pounds a year. It's used in steels, and to make planes, trains, and automobiles. Beverage containers, wire, plumbing, batteries, phones, television, and recreational products.

Minerals including salt, limestone, phosphates, clays, soda ash, and other non-metallic minerals, roughly 1400 pounds a year. It's used to produce chemicals, highway deicing, food, agriculture, animal feed, floor and wall tile, dinnerware, sinks and toilets, paper, plastics, rubber, glass, fiberglass paints, kitty liter, laundry detergent, computers, medicines and water treatments.

Get down to the end we talk about the energy fuel, thousand gallons of petroleum, about 100,000 cubic feet of natural gas. 400 ponds of coal, and roughly two ounces of uranium per year. And that's used to generate power, make electricity, produce heat and lighting. So slide number three address one of the recommendations of the Working Group on elongate mineral particles, principally from pages three and four of the

Executive Summary.

As background, the Working Group agrees with the recommendations and rationale provided in NIOSH current intelligence bulletin 62, the so-called asbestos road map, including defining an EMP as any mineral particle with a minimum aspect ratio of 3 to 1.

Consequentially, the Working Group concludes that an EMP encompasses both asbestiform and non-asbestiform particles that have dimension that enable them to be respirable. The Working Group goes on to endorse the concept of covered minerals, the definition of which is reflected in the first paragraph displayed on this slide.

Covered minerals would include not only the six regulated forms of asbestos, but also their non-asbestiform analogs. Moreover, the Working Group would not necessarily restrict the amphiboles to the five used commercially, but potentially those other amphiboles that are out there, I can give you that list there to make the

Working Group's stated intention clear, they support equating the non-asbestiform amphibole analogs with the asbestiform minerals, one and the same. If you identify a covered mineral, and it meets the new size criteria, count it as an EMP. Asbestos and cleavage fragments are one and the same.

My organization does not support this recommendation. The non-asbestiform analogs may have the same chemical formula as their asbestiform cousins, but they are not asbestiform in their crystal growth habit. Moreover, we do not believe they present the same health affects as asbestos.

The Working Group recommendation is open to including other amphiboles in the covered minerals criterion, even if they do not have an asbestiform growth habit. Some of these are listed in the second paragraph displayed on this slide.

In the next -- is the next step counting any mineral as an EMP if when crushed, it can occur in a 3 to 1 aspect ratio.

So slide 4 primarily addresses geography and a little geology. It identifies the geographic distribution of rocks or ore bodies with the potential to include amphiboles, those are indicated in the gray area. The red and blue dots identify known amphibole asbestos locations.

As you can see, vast areas of the west, east, south, and midwest, not to forget Alaska and Hawaii had the potential to include amphibole-containing rocks.

No mines are indicated on the map. I assure you that there are mines in the U.S. in the areas indicated, producing metals, minerals, and petroleum products. These mine products are being supplied to customers. These customers in turn are manufacturing products for consumers. Is there asbestos in these products, I really don't know.

Are these covered or non-covered EMPs and are there covered or non-covered EMPs and are there covered or non-covered EMPs in these products, again, I don't know.

Does the Working Group know or do agencies represented by the Working Group know? If not, I submit that the recommendations of the Working Group are premature because they have not considered the potential impact of their recommendations.

Finally, slide five. As an extension of the concern expressed in my previous slide, this slide addresses the potential of soils potentially containing amphiboles. As I hope you will recall from your earth science class in grammar school, sand and soil once were rocks and were converted to sand and soil particles by processes of erosion and glaciation.

So to get to the ore that we mine to produced the metals, minerals, and petroleum that are manufactured into products that we use every day, we first must dig through the soil which we call overburden.

What do we do with the soil that we excavate, is it just dirt or EMP-containing material, that's a legitimate question to ask.

Anecdotally, I lived in California, serpentine is the official California state rock. As covered earlier, serpentine can exist as asbestiform chrysotile or as non-asbestiform antigorite. At the time I lived in California, utility companies were asking what they needed to do with the soil they excavated to install a telephone pole, treat it as dirt or as a hazardous waste. I think that question is still relevant today.

In conclusion, the purpose of my presentation was to get the Working Group and the agencies the Working Group members represent to consider the potential unintended consequences of developing convenient counting criteria for EMPs, and the potential unintended consequences of imposing them on the mining industry, or manufacturing customers and ultimately on consumers.

With that, I'll close and thank you for your attention.

MS. ROBB: Thank you for your comment.

Next we'll have Leigh O'Dell, Deborah Giannecchini, Marvin Salter from Beasley Allen Law Firm.

MS. LEIGH O'DELL: Hello, my name is Leigh O'Dell, I represent claimants who have been injured by mesothelioma and ovarian cancer. I serve as co-lead counsel of the ovarian cancer MDL, and I'll be joined in just a moment by two of my clients who have been terribly injured as a result of ovarian cancer.

The emphasis thus far today has been on asbestos in lung disease and mesothelioma, but I want to talk about another elongated mineral particle that's important for these proceedings, and that is fibrous talc. The testing methodology for identifying EMPs should include not only asbestos, but fibrous talc. Fibrous talc should be identified and reported in all reporting requirements. Fibrous talc is another component of talcum powder products besides asbestos that has the potential of causing ovarian cancer, particularly when women apply talcum powder to their genital area for feminine hygiene. This means that talc is applied to the genital area, it enters the vagina, it sends to the ovaries, it's deposited there, sequestered, and that is a biopersistent particle that remains in the ovary. Unlike the lung, it does not have a clearance mechanism, causing carcinogenesis.

Fibrous talc is used in the literature and used synonymously with talc fibers in asbestiform talc. And for purposes of health effects, these terms should be considered the same, should be considered synonymously.

Fibrous talc is a cancer-causing EMP that should be included in all protocols. Fibrous talc, as you've heard previously today, has been determined by IARC to be a group one human carcinogen.

For purposes of illustration today, I took some photographs from the FDA's testing from AMA Analytical. This is a very simple comparison between platy talc on the left, and fibrous talc on the right.

From the FDA's testing also, see the comparison between fibrous talc on the left, and chrysotile on the right.

Just as the FDA required testing for talc fibers and recording talc fibers, all manufacturers should be required to do the same thing.

In addition, as an illustration from Dr. Longo's report on the testing of historical Johnson & Johnson samples, on the left you'll see a talc fiber, on the right you'll see anthophyllite asbestos.

In the FDA's testing, as well as Dr. Longo and Rigler's testing, both the talc and asbestos structures are needle-like. They have substantially parallel sides. They have an aspect ratio of greater than 3 to 1, and they have a particle length of greater than 0.5 microns. This is important and these fibers should be reported.

Also this was talked about earlier today by Dr. Van Gosen. And in regard to transition fibers, the NIOSH Bulletin 62 photograph on the cover shows a transition fiber from anthophyllite asbestos to fibrous talc, making clear the relationship between the two minerals-- a relationship that has been known for decades.

In the testing methodologies, it had been recommended by the working group to use TEM for morphology, EDXA for chrysotile -- I mean, for chemistry, and SAED for crystalline structure. That's the methodology Dr. Longo and Rigler used to test historical samples of Johnson's Baby Powder from the 1960s through the early 2000s for purposes of identifying fibrous talc.

When the structure met each of those criteria, it was counted as a talc fiber. In 98 percent of the samples tested, there was fibrous talc present, that's very important. And when you think of that finding, it's very consistent with the literature. Crowley 1968 reports in the 22 samples of cosmetic talc that he tested, 100 percent of those samples had fibers, including fibrous talc. Why is this important? Because the burden of EMPs contributed through -- fibrous talc is very significant.

Looking at Dr. Longo and Rigler's results for the samples from 1960s to the early 2000s, what you see is a range of a low of 82 million fibers for a ten-ounce bottle to as high as 289 million fibers for a ten-ounce bottle. What does that mean for a woman who is using this for genital hygiene? Many of these women use the product on a daily basis for decades using tens, if not hundreds of bottles. This results in an extraordinary deposit of EMPs in the ovary.

And these calculations were based on an aspect ratio of greater than 5 to 1. If the committee's recommendation of greater than 3 to 1 was used, it would be even greater.

What's the impact? The impact of these fibers are that they have the potential to be directly genotoxic. We've heard today about frustrated phagocytosis, and the potential of a fiber to result in direct genotoxicity in carcinogenesis.

Dr. Weis described also the presence of fibers causing chronic inflammation that results in oxidated stress, resistance to apoptosis, stimulation of self-proliferation, and other cellular changes which can lead to genotoxicity and carcinogenesis. Not only mesothelioma and lung cancer, as dreadful as those diseases are, but also ovarian cancer. And when we're thinking about cosmetics, and the primary users being women, and particularly for talcum powder, the primary users being for women in their genital area, this is critically important.

IARC has long recognized that talc can form into fiber. In 2010, IARC stated that an asbestiform fiber should be understood to mean any mineral particle, including talc. They reiterated this in 2012 and concluded that the monograph for 2012 should apply to talc containing asbestiform fibers to include fibrous talc.

Now, just very briefly I'd like to discuss asbestos. We've heard a lot about the definition, and I would just say this very simply, that companies should no longer be able to say that a fiber is not asbestos because it cannot be proven how it grew into that shape in the ground, as opposed to being milled into that shape and becoming an EMP. The health effects are clear, regardless of how it was formed.

So in sum, all asbestos and fibrous talc fibers that meet the appropriate chemistry, morphology, and crystalline structure should be included in the definition of EMPs, and reported as such by manufacturers.

Thank you. Let me introduce my clients, Mr. Marvin Salter and Deborah Giannecchini who have brief remarks.

MR. MARVIN SALTER: Thank you, Leigh.

Hello, my name is Martin Salter and I am the son of the late Jackie Fox. In 2013, my mother was diagnosed with ovarian cancer and went through chemotherapy along with multiple surgeries before I watched her die of that disease in 2015.

After learning of the relationship between talc and ovarian cancer, she filed a lawsuit. In 2016, the jury returned a verdict against Johnson & Johnson for failing to warn of the dangers of baby powder and Shower to Shower. My mother did not live to attend the trial, but the jury heard evidence that she had absolutely no family history of ovarian cancer, a negative genetic test, 50 years of daily talc use, and substantial burden of talc found in her ovaries.

Consumers like my mother were unaware that fibrous talc and asbestos had been found in Johnson's Baby Powder. Had proper testing methods been used, my mother and thousands of others could have avoided cancer.

Thank you for considering this matter, and I urge you to require adequate testing, although it won't bring my mother back, it will save thousands of others. Thank you.

MS. DEBORAH GIANNECCHINI: Hello, my name is Deborah Giannecchini. In 2012, I was diagnosed with metastatic ovarian cancer after having used baby powder for 46-plus years.

I can't tell you how it's altered the course of my life, and I would urge you strongly to require adequate testing to provide -- prevent this from happening to any other woman. Thank you.

MS. JANESIA ROBBS: Thank you so much for taking time to give your personal testimony and public comment.

At this time, I would like to turn it over to Kari Barrett.

MS. KARI BARRETT: Thank you, again. We will continue with our listing, and our next commenter is Laura Plunkett, Integrative Biostrategies, LLC.

MS. LAURA PLUNKETT: Yes, hello. Thank you for allowing me to speak today. My name is Laura Plunkett, I own my own consulting company known as Integrative Biostrategies.

Just very briefly, I provided a slide to let you know who I am. I'm a little different than some of the other people that have spoken today, I am a toxicologist like Dr. Weis, but I'm also someone who deals with clients that have to operate within the regulatory world, finding ways to comply with regulations, understanding the differences between how different products are regulated by the FDA, and that's an important distinction here that I want to talk about at the very end. These are not drugs.

These are not something that have a benefit. These are something where risks should be what is considered when you're talking about what to tell a consumer about the product. They need to understand what the risks are when this product is not something that's going to save their life, provide them with a benefit like a drug, for example, that might be formulated with talc as an excipient. I have worked in the plaintiff's litigation, you'll see down here under my current company, I'm working on behalf of women who have been -- either died of an injury due to ovarian cancer and their long-term talc exposure.

I would also point out however when I worked in 1989 to 1997 at Environ Corporation, it's interesting one of the products that I worked on had to do with whether or not talc could be safely used as a dusty powder on medical condoms -- on medical devices known as condoms.

It's interesting that those medical devices no longer allow the use or are not being used, that company actually voluntarily took that out of what they were dusting their condoms with in the early '90s. So I think that's something to understand. This is not a new issue, it's been something that on the issue of talc safety, has gone back to the '70s, came out in the '90s, it's still around today.

So we've heard a lot today about -- I'm not going to repeat some of these things that I actually have bulleted on my slide, but I wanted you to understand that I agree it's not just asbestos. As Ms. O'Dell just said, fibrous talc is indeed a hazard, talc powders, generally, when they've been administered to animals, when they've been found in tissues of humans, those particles injure tissue.

So when you talk about talc fibers, you're not just talking about whether it is asbestos itself, but whether or not, indeed it's a fiber or the type of particle that has a toxic effect on tissues.

So my third bullet there that fibers, including talc have toxic properties, I have a slide in a minute, and I'm going to provide a bibliography for you that shows that we've known, again, for many, many decades, 50 or 60 years, that these particles, these fibers, when they get into tissue, and that's what we're talking about here, we've been using it for years, the particles migrate internally. When you contact tissue, it doesn't -- it can't be handled by the body, it's not absorbed and disposed of, but indeed it deposits and when it contacts the tissues, it causes a toxic effect. And some of those individuals with long-term exposure, set up a process that can lead to cancer.

Very quickly, I think you've already seen what the powder bottles look like. I put this slide for two reasons. First, I wanted you to understand, which I think has already been said, that the talc body powder is a mixture, it's not just platy talc. It has other things in it.

I have a yellow-red listing on my slide here to show you that in this bottle, there are constituents that have been identified by IARC as either possible or known human carcinogens.

Again coming back to the fact that it's a cosmetic. If you're delivering something with possible known human carcinogens, don't you think consumers should know that? I don't believe consumers understand that that is what is necessarily in the talc, especially when you come up here and look at the bottle and it says talc and fragrance. And then you see this little leaf about the fact that what we have here are naturally-derived ingredients.

I believe if you read the published literature on risk communication, you'll find that many people believe "natural" means safer, and that's not the -- that's not the issue here. I don't think that we should be letting people think that because it's natural, it's something that they should assume is safe.

This has also been covered a bit today, but I actually have providing -- I have a published -- I have a list of all of the publications I cite on my slides that I've listed. It's a two-page, one-page handout. I encourage anybody to take it home with you, you can get the full citations.

I just wanted to show here that, again, since the 1970s, there have been published studies, publicly available information to show that not only is asbestos being repeatedly found in talc body powders, but also fibrous talc.

I wanted to touch on a point that I think has been talked about a bit today, but I believe there has been some people who have raised the issue of whether or not the animal studies actually showed cancer with exposure to talc, or whether or not there is some concern over whether or not it's the whole, just the asbestos issue, or is fibrous talc, or is it the whole talc powder that's the issue.

I would encourage you to look at the literature, and I'm going to talk about a little bit more in a minute, but to understand that fiber toxicity, I think a lot of speakers have said that, is indeed a function of the chemical nature of the fiber, as well as its physical form.

So I don't believe that there is a lot of controversy in the scientific literature over the fact that these elongated mineral particles, the form of it is extremely important to the toxic insult that you get when you leave in the tissue for a long period of time. Both fibrous talc and fibers of asbestos have been shown to trigger the responses that are consistent with a carcinogenic process and tissues. And again, I'll have a slide on that in a minute, and I have a -- in my bibliography listed for you papers that show the kind of molecular mechanism, the studies that support that you're getting these preneoplastic changes in tissues, or you're getting changes in the cellular mechanism that are related to oxidive stress, inflammation. And those are all the types of processes that have been linked with the risk of cancer or the carcinogenic process, not only in animals, but also in humans.

As Ms. O'Dell pointed out, indeed IARC has classified fibrous talc, as well, as a known human carcinogen. I'm going to skip over this, because I believe the previous speaker just covered this, but again, I think it's really important to go back and look at those IARC documents and understand that they're talking about fibrous talc, not always about asbestos.

This slide is also one I think is also similar, I noticed. Although, it's one that I've used before when I've discussed this -- I'm sorry.

This is the important end points I wanted to point out as a toxicologist, we know that fibers, particles in fibers of the powder itself can lead to a chronic inflammatory response in tissues, there is studies that show this in isolated cells, as well as in animals, and also in human cells, as well as in humans.

The genotoxic events can occur due to direct interactions with the fibers, these direct effects of the -- of the exposure, but also this inflammatory process develops and produces these indirect changes in the cells that can also produce genotoxic events.

Genotoxicity is damage to the DNA in the cell. These things lead to these preneoplastic cells. Again, there are studies in the literature that show this in animals, that if you just go from the inflammatory response, you can actually see these preneoplastic lesions, and I think the toxicological sciences have shown that when you start along this process, the tumors can form.

So what do we also know about talc is that there are numerous studies out there that can document this, that's why I'm providing the bibliography for you. That the focus should be on more than asbestos, but also on this issue of fibrous talc. And just really briefly on this issue of regulatory issues, I'd like to point out that a warning is something a consumer can see. So by even if there is controversy over what we're going to test for and what we see, what is the reason for not providing the consumer with the information to say that there is a potential, because that's what the cosmetic standard is. It's a potential for whether or not there can be a risk to your health. Thank you.

MS. KARI BARRETT: Thank you for your comments. Our next commenter is John Godleski. John Godleski, MD, PLLC.

DR. JOHN GODLESKI: Thank you very much.

I'm going to talk about the identification of the talc and fibers in the female genital tract. I'm Professor of Pathology Emeritus at Harvard Medical School, and CEO of my company, John Godleski, M.D.

My disclosures include that I've been an expert witness for both plaintiffs and defendants in environmental disclosure and product liability litigation. I've been an expert witness for plaintiffs in talc litigations.

Why identify foreign material in human tissue? The specific identification of foreign particulate material in human tissue confirms exposure to materials associated with the development of malignant tumors and other diseases.

So finding it in the tissue is important. Okay. Let me talk about the preparation techniques that we use to find particulate material in the tissue. It was mentioned in one of the other talks that you can use tissue digestion with strong acid, Clorox, or incineration. Isolate the inorganic particulate and chemical characterization by TEM, SEM, EDX in electron diffraction.

What I'm going to talk about today is the in situ identification of particles with SEM and characterized by EDS. This shows you that the particles are truly in the tissues.

Now, the advantages of having it in the tissues is that the tissue context remains, and there is much less preparation when you use variable pressure Scanning Electron Microscopy and EDS, because you can actually look at the face of the paraffin block tissue.

Disadvantages is that you are looking at a very small volume of this tissue. Now, here is our approach. We first do Polarized Light on the tissue sections that are taking that pathology when the -- there is surgery on the patient.

We look at that, and what we're able to see is that by Polarized Light, and many of the tissues we can see large numbers of both particles as well as fibers. This is a very important step because there is a distribution among the tissues that you'll see, and so we have to follow that identification.

So we get the block of tissue, and the first thing we do is take some sections off of it. This is important because pathology departments where people wear gloves that have talc on the surface of the gloves. So you have to assume that these have been touched by all sorts of things with all sorts of contamination.

So you take the surface off by cutting a few sections. You can also cut additional sections for other kinds of microscopy and then you can also do Scanning Electron Microscopy directly on the block.

So we do this, and what we are able to find is that we can then see the particles within the tissue. And here you can see some of these particles, you can see that they're clearly inside cells, we can do -- and do electron Energy Dispersive analysis, and we can see these in this picture. This is the same picture a lower magnification than this one, and when we do the EDX spectrum, we can see it has the chemical nature of talc.

So how much tissue do we really examine with this? It's actually a very small amount. The area of tissue and paraffin blocks from resection is at the most 20 by 20 by two millimeters deep.

The length and width can depend on the tissue, but the depth is almost always two millimeters. SEM, EDX in this setting assesses a depth of about two microns. So one millimeter equals 100 microns we're actually looking at 1,000 of the paper -- the surface.

So that if we look at the analogy, if we have 1,000 sheets, two reams of paper, and we take out one sheet, we're essentially looking at what would be comparable to one sheet or one one thousandth of a tissue.

Now, we studied this back in 2007 where we looked at talc in the pelvic lymph nodes of a woman with ovarian cancer and long-term genital exposure to cosmetic talc.

What we're able to see, this was a woman who was 68-years-old. She had stage 3 ovarian papillitic carcinoma. She had used talc daily for 30 years. Examination of her lymph nodes under Polarized Light Microscopy showed diffuse areas of birefringence compatible with talc, and confirmed by Scanning Electron Microscopy and X-ray spectroscopy.

In 2018, we reported on a case of accumulation of talc in the ovary. We're looking to identify foreign particles in human tissue using both Scanning Electron Microscopy and Raman spectroscopy as a way of doing this.

You can see how much birefringence is in this ovarian tissue in this particular patient. This is all intracellular, and you can see here that it's also intercellular, here it is by Scanning EM. And you can also appreciate that these are all small particles less than 5 microns, and by Scanning EM, we're able to show that this is talc.

We more recently, in this past year, have described migration of talc from the peritoneum to multiple pelvic organ sites. And this is taken from the paper, and it's actually Table 3 in this paper, and it's a bridge to show all of the total numbers.

The number in parentheses is the number of blocks that we studied. The number ND is "not done", NS is "not sampled". Note how much we can find by this method in the ovaries, we can also find it in the cervix, uterus, fallopian tubes and lymph nodes.

Here is pictures of this where you can see what it looks like. Here is another one where looking at the microscopy, you can see macrophages by Polarized Light are filled with particles and by SEM, we can identify these as talc. We can also find fibers, and here you can see some of those fibers.

Now, here's our total experience. We start out with 196 cases. Of those, 180 were positive by polarized light, 16 were negative. On those that we've done SEM, EDX. We have 82 positive, nine negatives. So we don't always confirm that these are talc.

When we look at the average number, we have 40, average number of talc particles per patient. Number of patients with greater than 50, out of this group, 24.

But here is the important piece, the number of patients with fibers by this in situ analysis, we have 21 talc, nine asbestos, two patients had both talc and asbestos. Here is our examples of tremolite asbestos --

MS. KARI BARRETT: We do need to wrap up.

DR. JOHN GODLESKI: -- and these are my summary. Thank you very much.

MS. KARI BARRETT: Thank you. Thank you for your comments today. We'll go to our last public commenter, Jeniffer Carson, CMBG3, Law, LLC.

MR. JENIFFER CARSON: Thank you. I am Jeniffer Carson, the managing partner of CMBG3 Law in Boston and California. We represent individuals and corporations in litigation, compliance, and government's affairs.

I'm here to talk today, I'm a non-scientist, about the impact of these decisions that you're about to -- that you're going to be making and how they impact the litigation.

I want to set the stage, because I don't think everybody always understands what the litigation actually looks like for both sides of the equation. There are judicial resources dedicated exclusively to asbestos litigation and now talc in many states.

It consumes lots of man-hours, takes away jury pools and other things from other cases that also need to be attended to. There are hundreds of individuals who have been diagnosed with diseases that cause them concern, and then there is also an extensive amount of social medial presence and media attention on this issue that's causing fear in individuals who are not harmed, but who have concerns that they may have harmed their children or others by using talc products.

It's an important piece to not forget, that the information that's circulating out there can cause undue harm when it's not matched with education and proper science. There are also hundreds of companies impacted by both asbestos and talc litigation. These are not all large corporations. I personally have represented in the last 20 years everything from small Mom and Pop companies to Fortune 500 and 100 companies.

The bulk of the clients that I represent usually are the smaller entities that did their best to be in compliance, to following the rules, to do what they were told. And those companies are impacted just the same as everybody else. And there are no real metrics for people to look at how that's actually impacting the industry and the court system. There are multiple jury verdicts as everyone has read about, and there is mixed results in those jury verdicts.

It's important to think about all aspects of this. We've heard today from a number of different, I want to say factions. We should all be here to try and reach good decisions together, collectively and let true science come through, but there are different entities involved and it's important to recognize that there are both interests in play, and money to be made on all aspects of this, both from the lawyers, from the judiciary, from the individuals who are being injured, and from the corporations. It's not a one-sided story.

There are a number of things that we could talk about, and I'm not going to speak to the science, because I'm not a scientist. But I can tell you that I lived for the last 20 years trying to manage the impact of the decisions that are made by governing bodies in the court systems.

Regulations and testing, I will talk very briefly about my attitude towards it. Regulations and testing requirements should focus on fibers that are respirable and actually transmigratable through the body. That's an important piece. We talk about counting everything, you're not focusing on the real harm, and that's what everybody wants us to do, is focus on the real harm, the things that actually cause problems.

If you count everything, you are not recognizing that some things are not respirable in human beings. Some particles are not able to be transmigrated through the body, and that's important to speak to scientists, biologists, people who focus in exclusively toxicology and actually understand the impact of the particles on the body, and not just talk about counting particles in the abstract.

You want to count the particles, all

of us want you to count the particles, regardless of what side of the coin everyone is on, we want to focus on things that impact cellular development negatively, not things that have no impact. Creating a system that counts everything causes more confusion. It does not fix the problem. Testing methods should be clear and follow objective science as appropriate for the circumstance.

Science created in litigation or for litigation purposes is not true science. It's not objective. It's subjective. It's desires to feed and approp a win, that's not what we should be trying to do in our government. Regulatory requirements should be documented using clear and plain language. How does that play out in the courtroom? We used a lot of terminology here today, and there are some very bright minds in this room. The people in this room understand the science better than your average citizen. Try explaining that to an average person who has never gone, looked at any of the scientific issues, who doesn't understand what an EMP is, or asbestos, or asbestiform. Most of the juries I've ever interviewed think asbestos is a chemical. They think it's made. They don't understand it is a rock mined from the earth.

So when you get into these types of issues, and you're making decisions about the language, and the process, and the methods used, remember that average people need to interpret this information, and these decision every day that impact both individuals who are harmed who want to be heard, have a right to have their cases heard, but also the companies have a right to be heard and judged fairly by a process that exists in today, and applying knowledge that we know today to cases that occurred 20 years ago.

Most of our cases and our clients involve incidences of use of a product that occurred upwards of 60 years ago. Based on science and technology, today's companies are judged by that information, and what we know now, as opposed to what was known then.

When the regulations, whatever, ultimately is decided here, you have to remember that there is an impact, and that the knowledge we have now is seen through a lens of today. Hindsight is always 20/20. And when you're making regulations, that's not your focus what happened 60 years ago, you're trying to make good decisions about what we know now. But the cases in the courthouses are not being judged fairly.

Consider creating a mechanism to educate the judiciary who also wrestles with very complicated complex issues in this litigation. And very few of the judges have any science background, no anatomy background, no biology background, no toxicology background, and yet they are being held to hold their one responsibility which is to create an unbiassed forum, a fair forum for decision making. Under very high stress moments, with no time, no unbiased educator at their disposal and those decisions have real implications.

A procedural mechanism should be created to allow for companies whose products have cleared the governing bodies, the Consumer Product Safety Commission, for example. Those products have been cleared by them, they shouldn't have to go all the way through litigation for years, paying for something that they know and have been told was fine. It's an important thing and there are more than one aspect of this, and I really implore the governing body, the Work Group to think about all aspects of it, not just what we do from here going forward, but also the implications in the courthouses. Thank you.

MS. KARI BARRETT: Thank you. Thank you for your comments. At this time, I just really want to thank collectively everyone who offered public comment today, I recognize, as you all do, that there are a number of different perspectives in the room and really do want to thank all of you for taking the time to give a comment, and to remind you to consider any additional materials that you would like to submit to the docket, further thinking that you have on these important topics.

So with that, I am now going to turn the podium over to Dr. Linda Katz, who will give some closing remarks and wrap us up for the day.

DR. LINDA KATZ: Good afternoon, again. I'm Dr. Linda Katz. I'm the Director for the Office of Cosmetics and Colors. I appreciate everybody staying here, being as engaged as they have for the entire day. So my remarks actually will not be all that long. So that we'll try to get through this relatively quickly. But what I'd like to do is just to identify some of the discussion points that we've heard today. Talking about mineral fibers of potential concern in talc. Mineral fibers that we heard about and what they can do to the lungs regarding exposure and toxicity. Talk about some, again, the preliminary recommendations from the Interagency Work Group, identifying the mineral fiber terminology and definitions, analytic approach, the content and format of the report, again, which you've heard earlier. And once again thank the public for their comments. And I will put a plug in at the end with our Federal Register notice for the docket number to have all of those comments get taken, and if you have additional comments that you would like to make to submit them to us.

So let me begin and just briefly summarize. With regard to mineral fibers of potential concern in talc, we heard a lot about the geology. We heard about how talc is formed, how it's mined, where the different mines are, some of the problems that can be seen, but basically because of some specific geologic conditions that do form talc, it can result in some internal variation, even within the prospect of a mine itself. So even within a mine, there is some variability.

Talc ore is used for cosmetic raw material talc would benefit from a comprehensive mineralogic assessment, and we heard about that earlier today.

With regard to mineral fibers in the lung, we've heard about exposures and toxicities. We heard about asbestos and EMPs that can cause both cancers and non-cancer health effects. The proposed mechanism of action appears to be an inflammatory response, and we heard a lot about the details, again, specifically with reference to the lung.

The EMP characteristics that potentially influence this process appear to be probably length and width, the mineral type, the persistence in biologic tissue, the surface area, surface reactivity, and the surface charge.

With regard to our preliminary recommendations, I'm not going to belabor the next two slides, but I'd like to go through them one more time again, because not only have you heard them from the Work Group, but you've heard them from others referencing the Work Group's preliminary recommendations.

The first was to adopt the term EMP as in a mineral particle with a minimum aspect ratio of 3 to 1. As we listen to the comments, the public comments, we realize that there may be more things that we need to consider there as well. That the testing laboratories should report all EMPs having length greater or equal to 0.5 microns.

The test method should specify reportable EMPs identified as amphibole or chrysotile particles as covered minerals. And test methods should include directions in enabling reporting and counting of primary and secondary structures. That is examples with bundles clusters and fibers of covered EMPs as a function of sample mass.

We heard that Polarized Light

Microscopy may be required analysis of each sample using established guideline methods. X-Ray Diffraction is also a useful method for detecting asbestos. However, it may be limited due to some sensitivity issues. The use of TEM with EDS and SAED to address deficiencies and sensitivity that cause false negatives by PLM also need to be looked at.

We heard that Scanning Electron Microscopy might be useful as a complementary method, but currently has significant shortcomings for identifying chrysotile.

And finally, we heard that the mass percent, a unit is frequently -- that a unit is frequently used to express the content of asbestos in commercial bulk material is not appropriate for measurement of EMPs in talc, and products containing talc.

The reasons for this, again, we heard earlier is that mass percent does not correlate with the number of fibers, and that a single atypical EMP could dominate and skew the conclusions of the mass percent, making it appear larger than what it is.

Also, with today, identified were additional needs, and additional research needs that need to happen as we try to go through and address most of these issues.

That research is needed to minimize false negative or positive rates, improve sensitivity and accuracy of counting, to determine the sources of variation in the sampling, to improve sample preparation methods, such as with concentration methods, and reference standards specific to talc and talc-containing products.

We also need more research regarding the validation of analytical methods, such as X-Ray Diffraction, Polarized Light Microscopy, and Transmission Electron Microscopy. Specific to talc and cosmetic containing talc products, we need to go back to look at ways to try to increase laboratory and analyst proficiencies, and we need to increase interlaboratory concurrence of results that are seen when products are analyzed.

So what are our next steps? The Interagency Work Group will continue its work on these and other topics, specifically related to health and health concerns. That it will review the information that was presented at this meeting, as well as the information that's submitted to the docket.

I've included the docket here so that for reference in case people can't find it readily, and to let you know that the docket closes on March 4th. So that if you have comments that you'd like to consider, they need to be in by then.

What our ultimate goal would be is to complete and post a white paper that addresses these issues presented in our Executive Summary, the issues that were described today, and issues that come into the document and that we -- so that we can move forward.

The final slide that I have is really with a special thanks. This was a tremendous undertaking by the Agency, as we heard earlier from -- with a relatively short period of time to try to get this public meeting together.

I'd like to thank the following individuals from CFSAN specifically, Debbie Smegal, Steve Wolfgang, Susan Spence, Denise Hodge, Caroline Linder, Janesia Robbs, Kari Barrett, Juanita Yates, Lindsey Haake, Jessica Larkin, Phil Chao, Doug Ticker. And I'd also like to thank, the Work Group members who you see up here, Paul Howard, Brad Van Gosen, Chris Weis and others such as Dayle Cristinzio, Beth Fritsch, Steve Morin, Monique Richards, Alyssa Polovoy, and all of our federal partners and other Work Group members, who without their help and assistance, could not have made this day a success.

So with that, I would like to thank everyone again for all of their attention, and for coming, and we will adjourn the meeting. Thank you.

(At 4:21 p.m., the meeting concluded.)

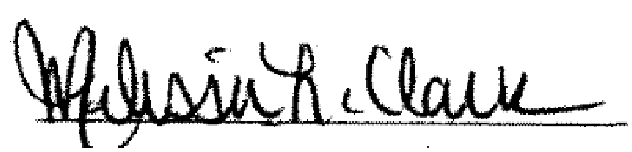
CERTIFICATION

I HEREBY CERTIFY that I am a Court Reporter and Notary Public.

I FURTHER CERTIFY that the witness was sworn to testify to the truth.

I FURTHER CERTIFY that the following is, to the best of my ability, a true and accurate transcription of the testimony taken stenographically by me at the time, place, and date herein before set forth.

I FURTHER CERTIFY that I am neither a relative, employee, attorney nor counsel to any of the parties to the action, and that I am neither a relative nor employee of such attorney or counsel and that I am not financially interested in the action.



Court Reporter

Melissa L. Clark

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