

1 U.S. FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC
2 MEETING: TESTING METHODS FOR ASBESTOS IN TALC AND
3 COSMETIC PRODUCTS CONTAINING TALC
4

5 Moderators: Ms. Kari Barrett
6 Ms. Janesia Robbs

7 Panelists: Dr. Kristina Hatlelid Dr. David Berry
8 Mr. Frank Hearl Ms. Deborah Smegal
9 Mr. Bradley Van Gosen Dr. Linda Katz
10 Dr. Steven Wolfgang Dr. Christopher Weis
11

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18 Silver Spring, Maryland 20993
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Moderated by Kari Barrett

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Afternoon session

Moderated by Janesia Robbs

Kari Barrett

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

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

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

15 The purpose of today's public
16 meeting is to discuss and obtain scientific
17 information on topics related to testing methods
18 for asbestos in talc and cosmetic products
19 containing talc. We expect this meeting to be an
20 important step in our continued efforts to gather
21 information on this topic, and we thank all of you

1 in the room and online for joining us today.

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

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

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

18 I should note that today's meeting
19 is being webcast. It will be recorded and posted
20 on our website. We also will have a transcription
21 of the proceedings today. All of that will be

1 available. Also the PowerPoints, but give us a
2 little time. The PowerPoints take about a week to
3 get up and then the transcript and the recording
4 -- the recording, I'm not sure of the exact
5 timing, but the transcript could take up to a
6 month. So I just want to forewarn you in that
7 regard, but do check back to the meeting website
8 for updates in that regard.

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

13 MS. RICHARDS: Good morning.

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

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

1 you need to.

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

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

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

17 The restrooms are located past the
18 registration area. If you need any help in that
19 regard, just ask the registration staff. And I do
20 want to remind people who are offering public
21 comment this afternoon -- we're going to talk

1 about this later today, but do keep in mind that
2 we are going to really be strictly adhering to the
3 time limits that have been given. We do have, for
4 those who are speaking, a light system, a green,
5 yellow, red light system. And we will, again, be
6 adhering to that. So If you have a chance this
7 morning just to kind of revisit your talk and be
8 sure you're within your time limits, that would be
9 greatly appreciated.

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

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

1 presence of asbestos.

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

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

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

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

21 Today, we are going to hear

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

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

20 In closing, I want -- I would like
21 to especially thank our partner federal agencies

1 and their Subject Matter Experts for their work
2 on this issue, along with all who helped to put
3 this meeting together today.

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

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

17
18 (Technical difficulties.)

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

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

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

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

18 So let me begin with FDA's authority
19 over cosmetics. FDA regulates cosmetics under the
20 Federal Food Drug and Cosmetic Act, where it's
21 described -- a cosmetic is described as an

1 article, other than soap, that's intended for
2 cleansing, beautifying, promoting attractiveness,
3 or altering appearance.

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

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

21 So what -- why is talc used in

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

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

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

14 So let me shift a little bit and
15 talk about some of the historical testing. And I'm
16 going to go back to the 1960s to '70s, because this is
17 basically when we began to talk about or get reports
18 on problems with testing from a variety of
19 laboratories in the U.S. that raise
20
21

1 concerns about asbestos-contaminated cosmetic talc.

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

13 The FDA realized that there was an
14 issue and began to grapple with what would be the
15 best approach and proposed a mandatory optical
16 microscopy method. But at the same time, in around
17 1976, the cosmetic and toiletry -- Cosmetic
18 Toiletry, Fragrance Association, CTFA, now known as
19 the Personal Care Products Council, also began
20
21

1 developing a new method. And that method was
2 referred to as the CTFA Method J4-1.

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

10
11 The detection limit is low. It's
12 greater than or equal to 0.5 percent, and it only
13 really is useful completely for identifying
14 amphiboles, and we will talk a little bit more
15 about that. But that in terms of being able to
16 identify chrysotile fibers, that its sensitivity
17 is not really very good.

18 In 1994, FDA also held a workshop to
19 address talc consumer uses and health
20 perspectives. The proceedings were published in
21 the Regulatory Toxicology and Pharmacology Journal

1 in 1995. And as the title would imply, that
2 basically, the premise was to look at the variety
3 of different reports, the epidemiologic and
4 toxicologic data that was available at the time
5 related to talc.

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

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

15 However, in 2009, a news report from
16 South Korea indicated that asbestos was detected
17 in pharmaceutical and cosmetic products traced to
18 talc imported from China. The Korean FDA at that
19 time ordered that products that might contain
20 asbestos to be removed from the marketplace, and
21 FDA, as a response related to this concern,

1 commissioned a survey analyzing 34 talc-containing
2 cosmetic products.

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

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

17 That, again, because FDA has still
18 no established labs to conduct this testing, we
19 sought the services, primarily of a contract lab
20 to implement a suitable approach to do some
21 testing for us that would enable the FDA to test

1 the products of concern, to test additional
2 products that contain talc, and to communicate
3 findings, both with industry and consumers.

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

9 While this was ongoing, we were
10 still awarded a contract to AMA in the fall of
11 2018 that AMA began to actually do some of the
12 testing of talc-containing cosmetic products in
13 2019 using Polarized Light Microscopy and
14 Transmission Electron Microscopy.

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

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

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

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

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

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

13 In addition, the FDA realized that
14 we need to go ahead and to think about how to
15 develop these approaches. So as you've heard,
16 we've formed an Interagency Work Group that I
17 will talk more about as we go further, but to try
18 to deal with some of these issues, and to develop
19 suitable analytical approaches to look at ways to
20 develop a definition of asbestos, to reference the
21 properties, including appearance of commercial

1 types of asbestos used in finished products, to
2 evaluate counting criteria for the asbestos
3 fibers, to realize -- to look for a suitable
4 reference and sample of preparation and test
5 methods.

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

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

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

21 In 2010, FDA proposed the formation

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

4 The Joint Institute for Food Safety
5 and Applied Nutrition (JIFSAN) Scientific and
6 Technical Symposium, which was held in November of
7 2018, was an attempt to address the need for
8 standardization of definitions and methods
9 necessary to detect asbestos in talc-containing
10 products.

11 And we will hear more from the
12 Interagency Work Group on asbestos in Consumer
13 Products today, but this was formed in the fall of
14 2018 as a federal government-wide with eight
15 different partner agencies to be able to address
16 and grapple with some of the issues to try to
17 further look at definitions and methods that might
18 be useful to help us to detect asbestos in
19 cosmetic and other products that the FDA -- that
20 the government regulates.

21 In going forward, we realize that

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

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

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

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

21 MR. BRADLEY VAN GOSEN: Thank you.

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

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

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

13 So during -- in 2018, total domestic
14 sales and export from domestic operations of talc
15 by U.S. producers was estimated to be about
16 540,000 metric tons, with a value of about
17 \$117 million. So again, during 2018, talc
18 produced and sold in the U.S. was used mainly in
19 ceramics, paint, paper, and a lesser amount in
20 plastics, rubber, and roofing. And you can see
21 that cosmetics represent a relatively small amount

1 of the talc uses in the talc market.

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

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

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

20 Talc is usually platy -- a sheet
21 silicate, but as I'll show, fibrous varieties of

1 talc can occur. There are weak bonds between the
2 layers of talc, so they easily slide past each
3 other, which gives talc its greasy and slippery
4 feel, and it's very low hardness. Well-developed
5 crystals of talc that are invisible to the naked
6 eye extremely rare. Rock that is described as
7 talc and is the least bit hard means it also
8 contains other minerals such as quartz or calcite.

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

21

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

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

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

16 This variation and amphibole shape
17 is not specific to talc deposits, but can occur in
18 all deposits of asbestos. The most common forms
19 of amphiboles are the blocky to prismatic forms.
20 The asbestiform varieties are much less common.
21 Acicular, the example in the lower left is another

1 word for needle-like.

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

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

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

18 The cleavage for amphiboles is
19 preferentially along their long axis, forming
20 elongate minerals such as this example of
21 actinolite in the upper left. For amphiboles, the

1 elongate particles that are produced are often
2 referred to as cleavage fragments.

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

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

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

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

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

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

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

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

20 Platy fibrous talc formed amongst
21 the tremolite and anthophyllite as the pressure

1 released in the region and the fluids began to
2 cool. These are the mineral reactions that
3 occurred in these systems. First, under high heat
4 and pressure, dolomite in the presence of silica
5 and heated waters formed large bodies of tremolite
6 replacing part of the dolomite marble.

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

15 This is fibrous talc -- whoops,
16 sorry. This is fibrous talc accompanied by platy
17 talc in one of the deposits in which talc has
18 replaced pre-existing fibrous anthophyllite. The
19 talc deposits of upstate New York are classic
20 examples of fibrous talc, and these were used in
21 the manufacture of paints, ceramics, and plastic

1 molding compounds, but not suited for cosmetics.

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

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

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

20 This view shows the relationship
21 well. A pre-existing cherty dolomite, a silica

1 magnesium rich carbonate was intruded by the magma
2 represented by the gabbro sill. This reaction
3 caused by the heat of the magma, and its heating
4 of the waters in this sytem formed a talc
5 tremolite rock, which became the talc ore body.

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

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

19 This is a closer view of the type of
20 talc deposit that was formed in the Death Valley
21 type deposits. You can put your finger on the

1 contact between the gabbro, which was the invading
2 magma. And your reaction to them that became the
3 layered talc tremolite rock.

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

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

20 So even under high magnification, it
21 may not be clear that in an individual elongate

1 particle within a dust or in a milled product were
2 the result of an asbestos bundle that was crushed,
3 or instead began as a thin, elongate cleavage
4 fragment.

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

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

17 Serpentinite can contain chrysotile
18 and amphibole asbestos, and in some settings can
19 contain talc deposits. The very presence of
20 serpentinite indicates that the chemical
21

1 components needed to form asbestos are present.

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

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

19 Rick determined that between the
20 ultramafic rock shown on the left and the country
21 rock on the far right, that there are a series of

1 distinct zones formed by metasomatism due to the
2 movement of waters through the pores during
3 regional metamorphism. Rick can determine these
4 involved temperatures in the range of 590 to 645
5 degrees centigrade, and pressures of seven and a
6 half to eight and a half kilobars. This occurred
7 during the Acadian orogeny, which was about 430 to
8 390 million years ago affecting the northern
9 Appalachian Mountains.

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

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

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

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

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

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

1 perhaps, tremolite.

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

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

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

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

20 The heat and pressure conditions
21 were high enough to form talc, but did not reach

1 the higher temperature pressure conditions needed
2 to form amphiboles or chrysotile. Instead,
3 dolomite simply converted to talc and the
4 amphiboles, Alton ore or serpentine were created
5 in these types of deposits.

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

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

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

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

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

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

19 So while considered to be a high
20 purity talc, because it is at least 90 percent
21 talc, only pockets of the deposit are considered

1 suitable as cosmetic talc, mainly because of its
2 darker color.

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

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

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

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

21 And one last point, I'll suggest

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

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

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

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

1 Working Group, for inviting me here today.

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

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

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

19 Over the next several minutes, I'd
20 like to give you some background regarding our
21

1 thoughts about the exposure and toxicity of the
2 elongate mineral particles. I'll refer to these
3 sometimes as EMPs, and these include asbestos.

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

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

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

19 Finally, I'll show you some examples
20 of how EMPs that are below the resolution of light
21 microscopy contribute to exposure. And why the

1 characterization of all EMPs are vital for an
2 understanding of disease.

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

13 This is why measurement of fiber
14 size and shape is so important to the path of
15 physiology of EMP exposure. Particles that impact
16 on the surface of the upper reaches of the
17 respiratory tract prior to reaching the alveoli of
18 the lung, can be removed by mucous-coated cilia or
19 little hairs on the surface of the trachea or
20 bronchus that push them up to the esophagus then
21

1 they're swallowed into the digestive tract.

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

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

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

20
21 Damage caused by the EMP is not

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

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

8 This cartoon represents a typical
9 alveolus. I'd like you to take -- I'd like you to
10 take note of a couple of interesting aspects of
11 the physiology here. One, note that the thickness
12 of the alveolar membrane is only about
13 0.2 microns. That's approximately 5,000 times
14 thinner than a human hair.

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

20 The other thing that I want to point
21 out, and which we'll talk about on the next few

1 slides, is the alveolar macrophage, this subtle
2 color green here down in the lower right. The
3 macrophages are a type of monocyte or a white blood
4 cell that course through the body identifying and
5 removing foreign material, and recycling old
6 diseased or dead cells. They do this by engulfing
7 these particles, treating them with acids and
8 hydrolytic enzymes that reside within the
9 macrophage cell.

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

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

19 All EMP, regard -- all EMP,
20 regardless of their mineral makeup or size, are
21 clearly foreign and potential targets for these

1 macrophage. The green particle here -- the green
2 particles here are bacteria and the red circular
3 object is a red blood cell for scale. The
4 macrophage uses surface ligands, as well as other
5 characteristics to identify target particles that will
6 be engulfed, and recycled through the lymph ducts and
7 eventually excreted in the urine.

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

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

19 Here we see a variety of different
20 shaped particles, some obviously manufactured,
21

1 others naturally occurring, such as the panel on
2 the lower right. All are potential targets for
3 removal by the macrophage cells if they were to be
4 inhaled.

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

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

21 This work by Ji et al. -- and one of the

1 authors, by the way, is with us in the audience
2 today, and we may hear from him later this
3 afternoon -- was funded by NIEHS, and depicts the
4 use of engineered elongate mineral particles to
5 measure the release of cytokines as a function of
6 aspect ratio or length-to-width ratio labeled AR
7 on the right side of the graph here.

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

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

17 Dr. Paul Howard will give us several
18 examples of this later today. Stimulated release
19 of cytokines, proteolytic enzymes, and the
20 production of reactive oxygen species is clearly
21 an adverse outcome pathway associated with the

1 inflammatory processes in disease progression.

2 All EMP have the ability to trigger this adverse
3 outcome pathway.

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

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

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

18 And malignant mesothelioma. This very
19 lethal disease usually arises in the pleural and the
20 peritoneum, but sometimes the pericardium, the larynx,
21 and the

1 kidney. It's strongly associated with a cumulative
2 burden of EMP exposure, and has a latency of 35 to 40
3 years. This disease is aggressive, most die within
4 one year of diagnosis.

5 And bronchogenic carcinoma, develops in 20 to 25
6 percent of asbestos workers, or others who are
7 chronically exposed to EMPs, usually after 10 to 30
8 years of latency, and the prognosis is poor.

9 Amphiboles are 10 to 50 times more potent than
10 chrysotile as an inducer. And smoking, coupled with
11 EMP exposure, greatly magnifies the risk.

12 This and the following slide shows some of the
13 consequences of chronic inflammation due to EMPs.
14 These apical diseases are progressive. All can be
15 fatal. The left two panels show asbestos bodies
16 viewed under light microscopy following autopsy. The
17 upper right photo shows severe diffuse pleural
18 thickening and bilateral fibrosis. The bottom right
19 photo is the diaphragmatic view of the lungs of an
20 individual
21

1 who died with pleural plaques.

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

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

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

20 EMP-related respiratory diseases are
21 initiated by chronic inflammation, and typically

1 develop over a long period of time.

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

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

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

19 Bundles similar to this can be
20 inhaled and might be expected to disaggregate into
21 hundreds of individual EMPs. This

1 mischaracterization by light microscopy was common
2 during the early stages of the Libby response.
3 And as the science advisor for the response, I
4 requested that we turn to more powerful analytical
5 techniques.

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

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

18 Under certain analytical protocols,
19 it's common convention when addressing exposure to
20 EMP, that the microscopist exclude fibers less
21

1 than five microns in length. While this practice
2 may have been useful for screening occupational
3 exposures, it places an undue burden on the
4 analysts, and limits the information that
5 toxicologists and epidemiologists critically need
6 to understand the pathology and pathological
7 effects of the overall dose.

8 This graphic -- this graphic shows
9 the length distribution of EMPs collected during
10 the federal response action in Libby, Montana.

11 During that action, the EPA collected and counted
12 all fiber sizes visible by electron microscopy.

13 This frequency distribution graph shows the
14 cumulative length fibers counted in more than 29,000
15 Libby air samples. Nearly half of the fibers were
16 found to be less than five microns in length. So
17 nearly half the EMP exposure in Libby would have
18 been excluded from reporting under conventional
19 laboratory reporting methods.

20 Here are a couple of fiber length
21 distributions of tremolite EMP collected from two

1 cosmetic talc samples. Yet again, we see this
2 dominance of short EMPs that are not usually
3 counted. EMPs to the left of the red mark in both
4 panels are shorter than five microns in length,
5 and would not conventionally have been included in
6 the laboratory report.

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

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

20 The boxes shaded gray at the tops,
21 even though they represent most of the exposure to

1 these workers, were not originally counted.

2 Stayner's team reanalyzed the data using a
3 transmission electron microscope to obtain a full
4 characterization of the fibrous sized
5 distribution.

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

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

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

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

1 asbestosis mortality."

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

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

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

21 Thank you very much, and thanks

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

3 MS. KARI BARRETT: So I do see we
4 are ahead of schedule. I think what we'll do is
5 we will go ahead and take our break, and we'll
6 start up again at 10:10. So we'll come back at
7 10:10 and go to our next session.

8 (Short recess taken.)

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

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

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

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

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

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

20 When we refer to consumer products,
21 we are referring to products used by consumers,

1 which are regulated by a variety of federal
2 agencies. This includes, but is not limited to,
3 consumer products defined under the Consumer
4 Product Safety Act.

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

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

12 The Work Group consists currently of 38
13 Subject Matter Experts from eight federal agencies shown
14 on this slide. That includes the Food and Drug
15 Administration. The National Institute of Occupational
16 Safety and Health. The National Institutes of Health/
17 National Institute of Environmental Health Sciences.
18 The Occupational Safety and Health Administration. The
19 Environmental Protection Agency. The Consumer
20
21

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

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

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

19
20 testing methods for analysis of talc, developing
21 criterion used for fiber identification, and

1 interpreting data.

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

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

19 Question one was, considering the
20 characteristics of fibers, including length, width,
21 aspect ratio, morphology, what criteria

1 should be used in assessing if talc or a
2 talc-containing product tests positive for
3 asbestos fibers?

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

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

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

19 And five, what standards should be
20 developed for use to assess the presence of
21 asbestos in talc-containing products? And this

1 can also include reference materials, as well as
2 methodology.

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

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

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

21 The IWGACP held ten monthly meetings

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

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

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

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

20 And our goal is to develop a white
21 paper with the final recommendations after this

1 meeting.

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

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

21 Subgroup formation was decided based

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

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

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

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

20 Each subgroup was provided a problem
21 statement and a series of charge questions that

1 built upon the questions discussed at the JIFSAN
2 symposium.

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

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

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

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

20
21 They deliberated on a long list of

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

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

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

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

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

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

17 In addition, Steve will present a
18 summary of research needs, and a recap of the
19 IWGACP preliminary recommendations. This
20 concludes my overview of the Interagency Work
21 Group on Asbestos and Consumer Products. Thank

1 you for your attention.

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

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

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

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

21 These preliminary recommendations

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

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

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

18 Well, the goal of the Working Group
19 Subgroup 1 was to establish consensus on
20 terminology and definitions for mineral fibers of
21

1 concern in talc and talc-containing consumer
2 products. So in other words, the goal was to
3 define consistent language of what should be
4 analyzed in talc and talc-containing consumer
5 products.

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

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

14 As a quick review of the talk that
15 was given by Brad Van Gosen of the U.S. Geological
16 Survey, greater than 90 percent of the earth's
17 crust is composed of silicates. These minerals are
18 classified into seven groups depending on the
19 chemical content and mineral structure. We will
20 not delve into each group and the minerals
21

1 contained in those groups, except to say that the
2 asbestiform minerals anthophyllite, amosite,
3 tremolite, actinolite, and crocidolite are members
4 of the amphibole group in the double chain ino-
5 silicates.

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

18 An example of the growth of minerals
19 into non-asbestiform or asbestiform space shown on
20 this slide are examples of non-asbestiform
21 grunerite-cummingtonite, as shown on the left here,

1 and amosite, which is the commercial term for the
2 asbestiform mineral grunerite-cummingtonite. So
3 the same minerals can result in two different
4 formations: asbestiform and non-asbestiform fibers.

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

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

18
19
20
21 Second, this document has stood the

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

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

7 Subgroup 1 of the Working Group
8 agreed with the recommendation in the NIOSH
9 Current Bulletin 62 regarding adoption of the
10 term, elongate mineral particle, or EMP that is
11 defined as any mineral particle with a minimum
12 aspect ratio that is linked with a ratio of 3 to
13 1.

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

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

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

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

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

18 Thus any EMP, according to Subgroup
19 1's recommendation, any EMP that is greater than
20 one-half micron in length, should be recorded and
21

1 reported by an analyst.

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

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

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

19 Now, we do not have time today to
20 cover all of the publications that support this
21 position. However, we will look briefly at the

1 conclusions of a few representative publications
2 that were identified by Working Group and Subgroup
3 1, and are listed in the executive summary.

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

12 The authors obtained tissues from
13 168 patients that had mesothelioma, and used high
14 resolution transmission electron microscopy to
15 determine the asbestos particle type, the number,
16 and dimensions in lung and mesothelial tissues.

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

1 presentation.

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

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

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

19 The yellow highlights that are
20 placed on this slide point out some things that I
21 want to draw your attention to. First is GM,

1 which is geometric mean of the particles that they
2 detected. It's highlighted in this column. And
3 then also GSD is the standard deviation of the
4 geometric mean, which is shown and I'll highlight
5 here for amosite particles.

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

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

21 So based on this, a significant

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

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

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

20 Continuing with Table 4, with Suzuki
21 and Yuen tremolite and anthophyllite asbestos

1 particles that were detected in the human lung
2 tissue had somewhat similar distributions. In the
3 lung tissue, around 5.8, plus or minus 2.75
4 microns. In the tumor tissue smaller, but still
5 with a pretty good distribution. And for the
6 anthophyllite, also a distribution around five
7 microns.

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

13 Suzuki and Yuen summarized the size
14 of asbestos particles detected in all tissues from
15 the 168 patients, whose data is shown in their
16 Table 5A, which is on this slide. Now, with the
17 exception of the chrysotile asbestos,
18 approximately one half of the asbestos particles
19 that are detected in these human tissues were less
20 than 5 microns in length. And approximately more
21 than half were greater than five microns in

1 length. With the chrysotile asbestos particles
2 greater than 99 percent of the minerals were less
3 than five microns in length. When summarizing for
4 all of the asbestos particles that were detected
5 in all of the human tissues in those studies,
6 89.4 percent of the particles were less than 5
7 microns in length.

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

18 The second publication that the
19 Subgroup cited in support of recommending that
20 particles greater than 0.5 or one-half micron be
21 reported, recorded and reported, is further work

1 that came from the Mount Sinai Medical College
2 researchers. They updated their work in 2005.
3 But we don't have time to review all of the data.
4 This -- I mean, I'd love to spend all day talking
5 about the data, but we don't have time. We can
6 focus on a couple of the conclusions from the
7 authors that support Subgroup 1's recommendation
8 that EMPs greater than one-half micron should be
9 recorded and reported.

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

14 Secondly, the majority, that is 89
15 -- over 89 percent of the fibers in the examined
16 tissues were less than five micrometers in length.

17 And approximately 93 percent were smaller than or
18 equal to 0.25 microns in width. This reinforces
19 the recommendations of Subgroup 1 that EMPs greater
20 than or equal to one-half micron should be recorded
21 and reported.

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

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

16 Again, we don't have time in this
17 presentation to thoroughly examine the data in
18 this publication, However, we highlight some of
19 the conclusions as justification for Subgroup 1's
20 recommendation that EMPs greater than one-half micron
21 in talc, talc-containing cosmetics

1 be recorded and reported.

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

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

16 Boulanger and colleagues concluded
17 first that a view of experimental and
18 epidemiological studies, toxicity of small fibers
19 below 0.5 -- excuse me, below 5 microns cannot be
20 dismissed. The potential toxicity of small
21 asbestos fibers remains widely debated in the

1 scientific community, but they can't be dismissed.

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

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

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

21 Finally, as discussed by Chris Weis,

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

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

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

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

17 Subgroup 1 recommends that any
18 EMP, that is particles with aspect ratios of 3 to
19 1 or greater, and also greater than one-half
20 micron in length, be considered a countable EMP.
21 All effort should be made to identify the

1 dimensions, the composition, and mineral content or
2 identity of all countable EMPs.

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

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

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

20 That these EMPs greater than
21 one-half micron in length be recorded and

1 reported, or in other words, the countable EMPs.
2 That EMPs have no maximum length, and no maximum
3 aspect ratio. And most importantly, for counting
4 and reporting purposes, that every effort should
5 be made to obtain the chemistry and mineral
6 identity of every countable EMP.

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

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

17 Now, while the Working Group and
18 Subgroup charge was broad, we'll focus today on
19 cosmetic products as an example of consumer
20 products that contain talc.
21

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

10 In addition, any mention of
11 organizations, manufacturers or products should not be
12 considered as an endorsement. And the following are
13 preliminary recommendations from the Working Group
14 Subject Matter Experts regarding analytical methods to
15 consider in using, detecting asbestos in talc and
16 talc-containing consumer products, including
17 cosmetics. The deliberations of the Subgroup and
18 Working Group focused on specific methods required for
19 consistent identification in measuring mineral
20 particles in
21

1 talc and talc-containing consumer products.

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

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

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

18 The charge questions that were posed
19 to Subgroup 2 were the following. First, what
20 general techniques of published test methods
21 should be considered for the identification of

1 asbestos fibers in talc-containing products? With
2 example methods for sample preparation, as well as
3 instrumentation needed to make an assessment.

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

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

1 issues that alter the property of the fibers?

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

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

16 First, sampling and handling.
17 Well, Subgroup 2 did not submit specific
18 recommendations regarding sampling size and
19 frequency. The FDA and other agencies have existing
20 guidelines regarding sampling size and
21

1 frequency for many different products. And these
2 should be considered when a sampling plan is
3 established. Examples of this are publications
4 and guidelines from other organizations such as
5 the USP General Chapter 1097. ISO guidelines, ISO
6 10725. ISO 11648 and ISO 14488. And the EPA's
7 approach to incremental sampling of soils.

8 Sampling plan issues that were
9 identified by Subgroup 2 to be considered are the
10 following: First is the batch size, the talc or
11 cosmetic product batch size. That is, the size of the
12 batch that is being considered, does it or does it not
13 contain EMPs? And, you know, is it 20 liters, is it
14 200 liters, is it 2,000 liters, what is the size of
15 the batch? Because this sometimes will dictate the
16 size and number of representative samples that should
17 be taken according to rules for many other products.

18 The second thing that should be
19 considered in the sampling plan is homogeneity.
20 More data is needed regarding the homogeneity and
21

1 concentration of asbestos in talc, and this will
2 inform regarding a recommended sampling plan. The
3 more non-homogenous, the more sampling is required
4 to get a good representative composite sample of
5 that product.

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

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

17 Next, handling considerations. The
18 subgroup noted that standards and guidelines are
19 currently in place for the sampling and handling
20 of many commodities, and that these approaches
21 might be appropriate for the sampling and handling

1 of talc and talc-containing products. Common
2 considerations that the Subgroup identified that
3 should be in place are the issues of chain of
4 custody. Documentation to verify chain of custody
5 of the sample, including any and all subsampling
6 for analysis should be part of the handling
7 considerations.

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

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

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

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

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

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

19 Nonetheless, the concern is that
20 asbestos and other non-talc minerals in talc or
21 cosmetics are non-homogeneous. This could result in
small,

1 non-representative samples being taken for
2 analytical measurements, leading to erroneous
3 determinations of the true asbestos level in the
4 talc or talc-containing cosmetic.

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

15 Finally milling, either ball milling
16 or jet milling has been used to produce particle
17 size and achieve mixing in the industry. Subject
18 matter experts caution against the use of milling as
19 a way of achieving homogeneity of a sample and do not
20 recommend this use in sample preparation. Since
21 milling can

1 result in particle size reduction in the sample,
2 which will not be representative of the particle
3 size in the original lot of talc or cosmetics.

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

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

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

21 Next, one of the most wildly used

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

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

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

17 This approach is described in
18 several published methods including, for example,
19 the New York PM-21 Environmental Laboratory
20 Approval Program Certification Manual 198 and
21 subsections. EPA's document, EPA slash -- I don't

1 know how else to say that other than
2 EPA/600/RN3/116, which was published in 1993.

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

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

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

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

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

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

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

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

3 The Fluidized Bed Asbestos

4 Segregator or FBAS, is being used to separate and
5 concentrate asbestos minerals from soil samples.

6 With this method, the dried sample is diluted
7 with sand, and air is drawn through the
8 circulating vibrating mixture to separate fibrous
9 minerals with the air flow, and to collect
10 asbestos and other fibrous minerals on filters.

11 There is no standard protocol or
12 guideline regarding the use of this method with
13 talc or talc-containing cosmetics. Publications
14 regarding the use of the fluidized bed asbestos
15 segregator with soils are shown on this slide and
16 include a quote from Jed Januch, David Berry and
17 colleagues in the Analytical Methods published in
18 2013. Daniel Farcas, Martin Harper, Jed Januch and two
19 colleagues in the Environmental Earth Sciences in
20 2017. And lastly, Julie Wroble

21

1 and colleagues published in PLOS-ONE in 2017
2 regarding the Fluidized Bed Asbestos Segregator.

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

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

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

21 Analysis. Now, turning from

1 handling of sampling and sample preparation to the
2 analytical methods. Well, powder X-Ray Diffraction (or
3 XRD) is a well-established technique used for the
4 identification and quantification of powdered minerals
5 based on X-Ray Diffraction patterns. When
6 monochromatic x-rays irradiate a crystal, some energy
7 is diffracted along planes. This diffraction is
8 characteristic for each crystal, and can be diagnostic
9 of mineral types in

10 a sample as shown in the figure for chrysotile
11 asbestos, amosite, and crocidolite. Standards
12 exist, and the advantages of XRD are: 1) that
13 it's a proven method for mineral powders, and 2),
14 that there is availability of a wide range of
15 standards for this method.

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

21 There are several guidelines

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

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

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

21

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

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

14 The limitations are exacerbated when
15 the EMP are small, that is less than one micron,
16 and especially those with higher aspect ratios,
17 greater than, for instance, 5 to 1 aspect ratio
18 that are present in low concentrations. There are
19 several established methods for the analysis of
20 samples with Polarized Light Microscopy for the
21

1 presence of asbestos minerals, for which some are
2 shown on this slide, including established methods
3 from NIOSH, OSHA, CTFA, EPA, and ISO.

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

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

18 Well, there are two reasons why the
19 Subject Matter Experts recommended electron
20 microscopy. The first reason electron
21 microscopy is recommended is due to the
limitations of

1 visible light microscopy. The theoretical limit
2 of resolution, that is the minimum separation
3 between two objects can be seen for all
4 microscopes is defined by this equation shown
5 here, for which there will be a test afterwards.

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

16 In a case of Polarized Light

17 Microscopy where the shortest wavelength of the
18 visible light is approximately 0.4 microns or 400
19 nanometers, the limit of resolution should be
20 approximately 0.2 microns.

21 In fact, limitation PLM resolution

1 is described as around 0.2 microns or greater by
2 several documents, including OSHA Internal Document
3 160. NIOSH Publication 9002. NIOSH Internal Document
4 191, and EPA Publication 600/R-93/116. This is
5 important, since small EMPs, let's say one micron or
6 less with an aspect ratio of 5 to 1, would have a
7 particle width of 0.2 microns, which is at or beyond
8 the limit of resolution of the visible (light)
9 microscope techniques.

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

16 In reality, the limit of resolution
17 of a 100 to 200 kilovolt electron microscope is
18 considered to be approximately 0.2 nanometers, or
19 two thousandths of a micron. The limitation is due to
20 aberrations in the magnetic lenses, not the incident
21

1 wavelength.

2 This observation that an electron microscope can
3 resolve EMPs with at least 1,000 times better
4 resolution begs the question: Is there a situation
5 where EMPs were not detected by visible light
6 microscopic methods such as PLM, however,
7 examination by electron microscopy, such as
8 Transmission Electron Microscopy did detect EMPs?

9 Well, the short answer is yes. There are several
10 examples on the FDA talc and cosmetics website where
11 samples that contain EMPs detected by TEM, were not
12 detected by Polarized Light Microscopy.

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

18 The Polarized Light Microscopic
19 analysis resulted in the conclusion that asbestos
20 was not present. However, when the same examples
21

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

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

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

13 The Subject Matter Experts of
14 Subgroup 2 had three general recommendations for
15 Transmission Electron Microscopy. First, the

16 Subject Matter Experts recommend that the
17 Transmission Electron Microscope have the
18 capability of operating at 200 kilovolts.

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

1 I happen to say that.

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

7 Let's look briefly at these three
8 specific recommendations.

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

17 Electron penetration is required to
18 generate diffraction patterns that can be
19 diagnostic of the mineral. While this
20 recommendation is not consistent with the AHERA
21

1 protocol which recommends 100 to 120 kilovolt
2 Transmission Electron Microscope analysis, the
3 Subject Matter Experts consider this an important
4 criterion to recommend.

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

14 For instance, as shown in this
15 figure, following electron imaging of a single
16 particle, you can capture x-rays that are
17 diagnostic of that particle having magnesium,
18 silicon, and calcium, suggesting that the
19 irradiated particle was a calcium amphibole, and
20 probably tremolite or actinolite. Further
21 examination would be required to confirm or refute

1 this diagnosis, but this is very critical
2 information.

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

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

16 Subgroup 2 Subject Matter Experts
17 noted their established methods for the detection
18 of asbestos using TEM, such as the examples shown
19 here listed for ISO, ISO 10312. For EPA, the
20 EPA/600/R-94/134, NIOSH Bulletin 7402 and also
21

1 the AHERA Protocol.

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

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

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

20
21 The Subgroup 2 Subject Matter

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

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

14 However, the Subject Matter Experts
15 noted that despite some scanning electron microscopes
16 having Electron Back-Scatter Diffraction, or EBSD
17 capability, there are currently no validated methods
18 at ISO or ASTM or any other agency or organization for
19 the use of Electron Back Scatter Diffraction of
20 individual
21

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.

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

4 However, any protocol should be one
5 that results in confidence that the sample is
6 representative of the distribution of asbestos in
7 the overall batch of talc for talc-containing
8 cosmetics.

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

17 The Subject Matter Experts recommend
18 that XRD and PLM are appropriate for the beginning
19 analysis. The Subject Matter Experts recommend
20 Polarized Light Microscopy as a required analysis
21 being sampled using established guideline methods

1 for asbestos by an analyst that's trained in this
2 method.

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

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

14 If a sample has been analyzed XRD
15 and PLM and EMP -- asbestos EMPs are detected in
16 the talc for talc-containing cosmetics, that could
17 be recorded and reported. If, however, using X-Ray
18 Diffraction or Polarized Light Microscopy, there were
19 no EMPs greater than one-half micron detected, then it
20 is obligatory to then conduct Transmission Electron
21 Microscopy analysis. This

1 should be conducted by a trained and experienced
2 analyst. And in this way the TEM, the
3 transmission electron microscope becomes the key
4 analytical tool in the analysis of talc or
5 talc-containing cosmetic samples for asbestos
6 mineral EMPs.

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

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

15 MS. KARI BARRETT: Thank you so much
16 for two very good presentations. We will now
17 bring up Dr. Steven Wolfgang who is the Consumer
18 Safety Officer of Cosmetics and Colors at FDA's
19 Center for Food Safety and Applied Nutrition. He
20 will close this section of the agenda with
21 recommendations from the Work Group on content and

1 format of the analytical reports, and then provide
2 a recap of the overall preliminary Work Group
3 recommendations.

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

9
10 Okay. As the Chair of Subgroup 3, I
11 will first speak on the deliberations on data
12 reporting and analysis, and the recommendations on
13 content and format of analytical reports coming from
14 asbestos-testing laboratories.

15 Secondly, I will recap the IWGACP's
16 overall recommendations on analysis of talc and
17 talc-containing products, including thoughts from
18 the Work Group toward further development of
19 analytical methods worthy of being recognized as
20
21

1 public standards.

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

7 I make this disclaimer on behalf of
8 the IWGACP, a group of dedicated scientists whom
9 I'm honored to have had the opportunity to
10 collaborate with. This is the same statement that
11 was made earlier by Paul, specifically that the
12 IWGACP preliminary recommendations are from
13 individual scientists functioning as Subject Matter
14 Experts in their respective scientific fields, are
15 participating in a Work Group striving for consensus
16 recommendations and do not necessarily reflect the
17 opinions or policies of their agencies or represent
18 proposed changes to any regulations of the U.S.
19 Government. Any mention of organizations,
20 manufacturers or products should not be considered
21

1 as an endorsement.

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

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

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

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

1 irrefutable evidence.

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

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

19 Secondly, how should lab report
20 EMPs that might be regarded as either asbestiform or

21

1 non-asbestiform mineral analog? --Since we recognize
2 there is ambiguity in what is regarded as
3 asbestiform versus non-asbestiform.

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

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

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

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

21

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

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

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

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

20 Subgroup 3 working in
21 conjunction with the IWGACP at large, focused on

1 the covered minerals, that is amphibole and
2 chrysotile and high level classifications of --
3 these are high level classifications for EMPs.
4 However, these -- the Work Group recognized that
5 labs are often more specific in their attempts to
6 classify minerals.

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

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

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

1 products.

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

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

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

20 The IWGACP concluded that it would
21 be difficult to determine, if a particle, such as

1 the one in the lower left quadrant, this one here,
2 is derived from an asbestiform bundle such as the one
3 shown on the lower right---or alternatively, from
4 the prismatic particle that appears in the upper
5 right quadrant.

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

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

18 When talc ores that contain
19 amphiboles are processed, such as in the
20 manufacturing of raw material talc, it would not
21 be unexpected to find tremolite particles such as

1 the one shown on this slide.

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

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

21

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

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

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

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

1 amphibole or and chrysotile.

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

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

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

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

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

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

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

18 The penultimate recommendation on
19 this slide is to use TEM with EDS and SAED when
20 analyzing products that contain talc, noting that
21 the EMPs which are present are often extremely

1 fine, and rest below the resolution capability of
2 the light microscope.

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

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

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

21 The development of reference

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

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

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

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

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

1 please make use of it.

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

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

11 (Lunch recess.)

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

16 So now with our public comment
17 session, we're here and ready to listen. Before
18 we do begin, I do want to turn to our
19 distinguished panel members. And we're going to
20 start down the table and have folks just introduce
21 themselves. Then I'll take just a few minutes to

1 talk about our process. I appreciate you being
2 ready to go, and then we'll kick off.

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

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

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

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

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

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

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

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

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

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

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

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

20 For the second group, they will have
21 nine minutes, and they will also have slides. And

1 so again, we'll ask for the same protocol of being
2 mindful of the time.

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

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

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

18 Listening to all of the different
19 talks this morning, there was much of it that I had
20 heard before. A few things I hadn't heard, and so
21 I really enjoyed the topics. One of the things

1 that I'd like to say, and I agree with Dr. Katz is
2 that standard terminology between microscopists,
3 industrial hygienists, and toxicologists does need
4 to happen.

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

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

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

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

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

20 The general consensus there was that
21 at least for mesothelioma, fibers less than five

1 microns really did not cause mesothelioma. That
2 certainly could be debated, but I would also point
3 to the Italian talc. I've been to the Italian
4 mine, I did not see any indications of asbestos in
5 that talc mine. And look at the epidemiological
6 studies over a 72-year period for that talc, and
7 you'll find no mesotheliomas was there as well.

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

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

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

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

21

-- 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

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

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

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

19 USP wishes to clarify that the
20 revision bulletin does not represent the language
21

1 and the currently official version of the USP talc
2 monograph, which was published in 2013 and can be
3 found in the current USP&F.

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

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

1 Scanning Electron Microscopy methods.

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

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

17 Thereafter, we intend to publish
18 proposed revisions to the USP talc monograph and
19 stimulate article for public comment. We look
20 forward to continuing our engagement with FDA and
21 other stakeholders in this important topic. Thank

1 you for your time and for this opportunity to
2 clarify the record and the work of USP. Thank
3 you.

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

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

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

19 PCPC has reviewed the preliminary
20 recommendations of the Interagency Working Group
21 on Asbestos in Consumer Products, and offers these

1 brief initial comments.

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

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

18 Time does not permit me to address
19 each of the preliminary recommendations.

20 Accordingly, I will identify an example that
21 highlights the need for some full analysis,

1 scientific support, and industry input.

2 The Working Group's Executive

3 Summary offers several preliminary recommendations
4 regarding elongate mineral particles or EMPs.

5 However, the summary does not support the
6 supposition that all EMPs are biologically harmful, or
7 that a change in the long-standing and well-considered
8 definition of asbestos is necessary.

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

18 The summary recommends counting all
19 EMP's under a single classification, but then
20
21

1 reporting additional information that would allow
2 further classification based on measurements such
3 as mineral type and dimensions in the future.

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

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

16 PCPC recognizes that these are
17 preliminary recommendations, and that any change
18 to existing regulations or the promulgation of any
19 new regulation will provide an opportunity for
20 interested stakeholder input. Nevertheless, we
21 would encourage greater transparency into the

1 processes and work during this preliminary stage.

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

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

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

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

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

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

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

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

19 Exposures to talc has been suggested
20 as a causative factor in the development of
21 ovarian carcinomas, gynecological tumors, and

1 mesothelioma. Over the past several years, case
2 control and cohort studies examining the link
3 between talcum powder use and incidences of ovarian
4 cancer have been carried out.

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

10 Researchers found that regular,
11 perineal talc use increased the risk of developing
12 both serous and endometrial ovarian cancer.

13 Researchers also found that post menopausal women
14 who regularly use talc-based powders and who had
15 taken or were currently taking hormone therapy,
16 were at a greater risk of developing ovarian
17 cancer.

18 The FDA has deferred to
19 manufacturers for over 50 years when assessing the
20 safety of talc powders and cosmetics. This
21

1 practice is dangerous and has the consumer's
2 health at risk.

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

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

16 Although the FDA considers
17 asbestos-contaminated talc unacceptable for use in
18 cosmetics, there are currently no laws prohibiting
19 its use in cosmetics. We hope that Congress will
20 take action to give the FDA authority to regulate
21 cosmetics, including ingredients used in cosmetics

1 in a meaningful way. And while we are delighted
2 that the FDA is using its powers, the powers that
3 it has, to take measures to regulate these testing
4 methods, the reconsideration of testing standards
5 and safety parameters for the talc use in
6 cosmetics used by millions of people is a positive
7 step --

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

11 Linda Reinstein, Asbestos Disease
12 Awareness Organization.

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

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

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

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

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

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

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

5 It took us about 18 months to test
6 200 products. I understand testing methods. We
7 released our testing results, which confirmed by
8 three labs, that asbestos was found in four
9 consumer products and a kid's toy; nothing was
10 done.

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

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

20 The testing standards and the agency
21 recalls, when there is a delay, it compromises the

1 public health. I have to be honest, I've seen it
2 all in 15 years. Corporations, often knowingly,
3 use archaic, low-level equipment, and methods to
4 get the results that they want. This meeting is
5 important to advance the science and the
6 methodology.

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

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

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

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

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

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

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

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

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

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

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

My first statement is that the fiber

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

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

1 access to the pleural space.

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

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

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

20
21 And though non-asbestiform

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

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

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

19 In line with that comment, my second
20 statement is that it is not definite in light of
21 cellular and animal experimentation studies to

1 state that asbestos fibers and non-asbestiform
2 amphiboles have similar pathological outcomes, and
3 that the distinction is irrelevant.

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

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

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

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

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

16 The tenets of the importance of the
17 feature of fiber length width and biopersistence
18 have been confirmed by research on asbestos fibers
19 in humans. In fact, the documentation of
20 pathogenic fiber features have been used for the
21 safer design of vitreous fiber products through

1 the tuning and adaptation of fiber length,
2 diameter, and biopersistence properties.

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

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

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

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

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

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

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

19 I would like to comment today on the
20 research that we have done using heavy liquid
21 separation for both amphibole asbestos, as well as

1 our chrysotile asbestos that we have recently
2 cracked the code, so to speak, where we can now do
3 both. Next slide -- oh, I have my thing here --
4 never mind. Nope. There we go. Thank you for
5 the help.

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

21 Why? The standard TEM bulk

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

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

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

19 Depending if it is 10 or 20 grid
20 openings, they have a detection limit of between 7
21 -- 2 million up to about 14 million. When I say

1 detection limit, obviously, this is the
2 concentration that you must have in your cosmetic
3 talc to statistically define one fiber.

4 So how can we improve that -- oh,
5 skipped one here. Sometimes some of these methods
6 have that you have to find 3 to 5 of any one
7 species of type of asbestos before you can call it
8 quantifiable. This was a lot of work in the 1970s
9 and '80s by McCrone. So if you have to have, say
10 for tremolite fibers or you find the four that
11 should be actinolite fibers, anthophyllite fibers,
12 28,000 asbestos fibers would still be
13 non-quantifiable.

14 This is because of background
15 contamination. And in my view, if you have a
16 professional lab, you should not have background
17 contamination in your samples. You should be
18 running process blanks, meaning everything but the
19 talc, and it should be below your detection limit.
20 And there is no background contamination in the
21 outside environment, in my opinion, of tremolite

1 and anthophyllite unless you have a source.

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

5 So how do you increase the
6 sensitivity? You can remove some of the material,
7 such as acid dissolution for calcite. If you want
8 to get rid of the pigments out of the face
9 powders, which have things like TiO₂ or aquamarine
10 or liposomes particles, you got to go to something
11 like an aqua regence to get rid of those. And the
12 organics you want to get rid of, or you can
13 increase the amount of grid openings. So 20 grid
14 openings for a typical analysis, 7 million. If you
15 jump that to 500 grid openings, you can reduce that to
16 280,000. If you jump that to 1,000 grid openings, you
17 can reduce that to 140 fibers per gram. 500 to 1,000
18 grid openings, a lab that is going to really
19 investigate this should take anywhere from three to
20 five days, eight hours a day.

21

1 We chose not to do that, and decided
2 to go to heavy liquid density separation. Wow
3 here is an interesting one from Dr. Hutchinson. He
4 is from the University of Minnesota. He was a
5 Johnson & Johnson consultant. And he was asked to
6 analyze Dr. Lewin's sample from that 1971, '72 XRD
7 work where Dr. Lewin said there was 3 to 4 percent
8 chrysotile. In reality, it was probably chlorite.

9 But Dr. Hutchinson did something in 1972 that I
10 have not seen until the late -- mid to late 2000 --

11 2015, 2016. He looked at TEM. He looked at
12 Lewin's sample, and he used 900 grid openings on a
13 200 mesh grid. He looked at the Shower to Shower
14 Johnson sample that Lewin looked at, another split.

15 He looked at 2100 grid openings. He found
16 chrysotile asbestos in both of those samples, and
17 estimated that it was 0.1 percent by weight. I
18 could find no record that Johnson & Johnson ever
19 informed the FDA that those samples were indeed
20 positive on this one for chrysotile. That
21 shouldn't be there.

1 So let's look at a brief history.

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

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

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

18 Using heavy liquid density
19 separation for amphiboles, we analyzed 72
20 historical Johnson & Johnson cosmetic talcs. And

21

1 for -- we used the Blount method published in 1991.
2 And out of the 72 samples that Johnson & Johnson
3 provided, from approximately 1960, all the way up
4 to 1996, as well as Imerys, we had 41 positives or 57
5 percent.

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

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

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

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

5 DR. WILLIAM LONGO: Real quick.

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

9 DR. WILLIAM LONGO: Thank you. MS.

10 KARI BARRETT: Yes, thank you. MR.

11 WILLIAM LONGO: Thank you,
12 everybody.

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

15 MR. SCOTT FABER: Hello my name is
16 Scott Faber. I'm the Vice President of Government
17 Affairs for the Environmental Working Group. Some
18 of you may recognize this statement. It was taken
19 from FDA's 2014 response to petitions seeking a
20 warning on cosmetics made with talc. And for
21 those of you who are watching at home it reads,

1 "You have not provided evidence that asbestos
2 contaminated talc-containing cosmetic products are
3 currently being marketed."

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

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

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

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

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

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

18 I'm not the only person who thinks
19 that it is long past time for FDA to act. Today's
20 meeting is important, but conducting testing or
21 defining the state of the art for testing is not

1 enough. That's why nearly 25,000 Americans, just
2 in the last few days, have joined a petition
3 calling on FDA to require companies to use the
4 most sensitive state-of-the-art testing to test
5 for asbestos in talc, and to make those results
6 public.

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

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

21 In conclusion, I'll just say that

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

6 Thank you.

7 MS. KARI BARRETT: Thank you for
8 your remarks.

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

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

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

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

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

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

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

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

15 During the TEM analysis, we only
16 analyze a subset of those samples. During PLM, we
17 will look at the entire contents of one or more
18 cover slips. And onto the left, you can see sort
19 of a basic representation of the area analyzed with
20 XRD being the pink square, PLM being in orange. The
21 blue representing the TEM grid, and

1 the black dot in the center being the area that
2 we've only looked at by TEM.

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

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

19 I also agree with the preliminary
20 recommendations that the ISO 10312 counting rules
21 be implemented, as they are the most robust

1 counting rules we currently use. But I encourage
2 the working group to specify a minimum level of
3 identification. Without that, different labs will
4 use different levels, and will produce different
5 results.

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

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

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

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

1 chemistry diffraction can be very close.

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

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

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

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

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

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

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

1 protocol.

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

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

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

1 as new evidence becomes available. Thank you.

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

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

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

20 So I have that perspective both in
21 terms of policy, and in terms of my scientific

1 background. And for 20 years, I've been president
2 of the National Center for Health Research. So
3 our perspective really is on the public health, and
4 that's what I'm going to be focusing on today.

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

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

20 We know that animal studies have
21 found lesions caused by talc exposure, and we know

1 that talc fibers have been found in lung tissue in
2 people with cancer. So when we're thinking about
3 a relationship between talc and asbestos, we have
4 to remember, of course, that they both come from
5 mines. Talc comes from mines that also contain
6 asbestos, and, perhaps, almost always or always
7 contain asbestos.

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

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

21 The Working Group, as you know

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

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

20 And what are the mechanisms that
21 explain why asbestos causes cancer? Direct

1 interaction with cellular macromolecules,
2 production of reactive oxygen species, and
3 cell-mediated mechanisms, such as inflammation.

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

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

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

20 IARC has mentioned that fibrous talc
21 is carcinogenic and that the term, asbestiform

1 fiber means, "Any mineral, including talc, when
2 it's grown in an asbestiform habit."

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

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

1 are being exposed to.

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

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

18 Thanks very much.

19 MS. KARI BARRETT: Thank you for
20 your comments. At this time, I'd like to invite
21 my colleague up, Janesia Robbs up, she will help

1 facilitate the next portion of public commenters.

2 Janesia?

3 MS. JANESIA ROBBS: Thanks, Kari.

4 All right. Next we'll have Steven Compton from MVA
5 Scientific Consultants.

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

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

19 Generally, the non-litigation work
20 that we've done is considered confidential, so any
21

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

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

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

21 The PLM on the other hand does provide
some visual

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

13 TEM on the other hand looks at
14 fundamental properties of individual particles,
15 crystal structure, elemental composition. These
16 are the properties being used by geologists to
17 define the minerals in the first place. So the
18 drawback with this method is simply sample size.
19 For a positive result, that may not be an issue,
20 but for a negative result how representative is a
21

1 single analysis, and does that sample accurately
2 represent an entire lot or an entire mine?

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

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

16 Now, in 2015, Dr. Millette published
17 a procedure for the Analysis of Talc for Asbestos,
18 and it ultimately came to the recommendation that,
19 like I said earlier, XRD can be a useful screening
20 tool, but really a combination of PLM and TEM is

21

1 the most appropriate for an investigation of
2 asbestos in talc.

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

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

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

21 Some industry experts would argue

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

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

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

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1 This is some testing of 2017,

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

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

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

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

20 Now ashing, and acid digestion,
21 these are both commonly used for non-friable

1 organically bound building products, they're
2 standardized approaches, but they do nothing to
3 eliminate platy talc from the sample.

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

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

16 In 2010, I did aqueous elutriation
17 of an industrial talc. The image on the left is
18 before, the image on the right is after. So some
19 of the long, thin fibers that should have a small
20 aerodynamic equivalent diameter were lost. So it
21 needs to be carefully validated. Of all the

1 concentration methods that are available, density
2 separation shows a lot of promise, I'm not going
3 to get into that since it's been talked about at
4 length. It's a standardized approach, the ISO
5 method has some issues with it that we can talk
6 about later.

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

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

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

1 Scientific Analytical Institute.

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

5 Thank you for the opportunity. I'm
6 Sean Fitzgerald, I'm a professional geologist, I'm
7 a mineralogist and I've been working in asbestos
8 testing laboratories all over the country for over
9 30 years. And I'd like to thank the Working Group
10 for acknowledging the big elephant in the room, and
11 that's definitions: What is it we're talking about
12 when we say the word "asbestos."

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

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

1 habit.

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

10 When we originally sat down and
11 said, what are we going to do with asbestos in
12 building materials, we said this 1 percent rule
13 because manufacturers never actually intentionally
14 put less than 1 percent asbestos, raw asbestos, as a
15 material. And we also said, in the Federal Register,
16 that we'd better be careful about regulating anything
17 below 1 percent, because we know some mineral
18 resources, like vermiculite from Montana, can contain
19 less than 1 percent. And that's exactly -- so this is
20 not a new issue, this is a revisitation of an issue
21 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

1 my lunch and some hairs out of my head and I put
2 it on a penny. And I took the smallest amount of
3 asbestos and put it underneath Lincoln's nose, to
4 show that hundreds of thousands of individual
5 fibers can be so small that you wouldn't even see
6 it without a little circle around them.

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

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

19 Van Gosen talked about this a little
20 bit, about the different ways that talc can form
21 in the earth. And if we look at the ways that

1 they form, three of those four different ways
2 actually involve the asbestiform minerals.

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

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

20 So when we have asbestos, if we look
21 at the actual supplemental information when we

1 have our asbestos standards, we have a substantial
2 amount of talc because these things grow together.
3 We know this. If we look at high resolution TEM
4 of asbestos fibers, we see that the inter-fibril
5 areas includes the sheet silicates, T for talc or
6 S for serpentine. When serpentine is a scroll,
7 it's chrysotile. When it waves back and forth,
8 it's antigorite.

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

15 My laboratory, Scientific
16 Analytical, we've tested over 600 cosmetic talcs in
17 the last five years. And I was surprised when I was
18 putting this deck together, that over 100 of them had
19 countable asbestos structures. And these were not
20 uncommon brands, and they weren't all historical
21 problems. These were some things that

1 were fresh off of the shelf. I thought this was
2 important, especially when I found asbestos in
3 cosmetics, so I started writing a method, just
4 using a standard filtration, it was Groundhog Day
5 a couple years ago when I decided to put together
6 several samples of cosmetics where I found
7 asbestos and send them to my friends in different
8 laboratories. And I asked them, how many structures
9 do you see that would be countable if it was on an air
10 test. And what we see is that the seven labs that
11 responded were fairly, repeatedly able to detect
12 asbestos in these samples.

13 So what are these samples, sure
14 enough, Justice Just Shine Shimmer Powder was one
15 of the first that was made public, and created
16 interest from the FDA. And what came after that,
17 well, we found asbestos in Claire's, and sure
18 enough the asbestos was clearly countable in the
19 TEM analysis test materials. Here we might look at
20 the aspect ratio and wonder if it's countable,
21

1 but if we do a close up of the tip, we see that it
2 actually comprised of several fibers together. So
3 there is some subjectivity of whether or not
4 something counts from lab to lab.

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

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

19 So we need a method that works. And
20 I would also like to thank Dr. Longo and
21

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

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

17 I've got a couple of seconds, so I
18 think you should also consider antigorite. You
19 said that chrysotile was the only type of asbestos
20 that should be considered. We note that there is
21

1 negative health effects from asbestiform
2 antigorite and sepiolite. We need to be able to
3 differentiate, sepiolite that can be intergrown in
4 talc, and commonly occurs in talc, from chrysotile.
5 Thank you.

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

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

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

19 So I'm going to talk again about
20 ASTM, about the committee that is working on this,
21 our roster and where we are at, especially the

1 current status of these methods and the next steps
2 and expectations. I'm not going to cover ASTM
3 International in detail, it has been mentioned
4 previously throughout the day. I would submit to
5 you that the plane that you flew in on and the car
6 that you drove here, all were manufactured
7 according to ASTM and other organization standards.

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

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

18 I draw your attention to the
19 organization's mission statement talking about
20
21

1 possibly impacting public health and safety,
2 consumer confidence, and quality of life, and that
3 we have volunteer technical experts. There are 19
4 of us in the room today from ASTM International. It
5 would be 20 if Don Halterman was here, and 21 I
6 know is at least listening and sending me text
7 messages of the proceedings.

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

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

21 Part of that includes an

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

5 What makes a method valuable?

6 Everything listed here and more. I would draw
7 your attention to the interlaboratory study, and
8 the fact that with ASTM International, these
9 analytical methods are routinely reviewed and
10 there is a revision process that each of these
11 standards has to undergo.

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

17 D2207 has over 15 of our standards
18 dealing with TEM, PLM, and XRD, over 15 just with
19 TEM. The history of talc and asbestos with D2207
20 goes back to when USP, the Expert Talc Panel was
21 put together. We were also reproached. I will

1 tell you that just about everyone on that Talc
2 Expert Panel is also helping out with the ASTM side of
3 things in method development.

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

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

18 Right now, we can divide those work
19 items into the following categories, TEM, XRD,
20 PLM, and what I like to call the product method,
21 that is for things like cosmetic talc where we are

1 using a combination of PLM and TEM.

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

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

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

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

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

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

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

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

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

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

21 I wanted to also mention that there

1 are plenty of analytical methods that do count
2 less than five microns, including ASTM D6281.

3 FBAS, a fluidized bed. We actually have a work
4 item. So we do have a draft method that is being
5 put together for that-- Ed Cahill, shout out. I
6 think that's about it.

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

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

11 Next we have Eric Chatfield from
12 Chatfield Technical Consulting Limited.

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

17 My name is Eric Chatfield, and I'm
18 president of Chatfield Technical Consulting,
19 Limited, in Mississauga, Ontario. I'm convener of
20 the working group in ISO that produced these ISO
21 standards on asbestos. I first started doing that

1 in 1978, believe it or not, and it has been going
2 on like that ever since.

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

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

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

17 Now, when I got the Executive
18 Summary, I noted a number of items in it that
19 caught my attention. The first statement was that
20 the published analytical methods for asbestos
21

1 analysis were only intended to go down to 1
2 percent. Now that is actually incorrect because
3 ISO 22262-2 and 22262-1 were designed to go down
4 to even the British standard, which is kind of
5 vague, it just says "any asbestos".

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

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

18 Now, the Suzuki papers, moving on to
19 item B, those fibers were measured on photographic
20 prints, which kind of limits what you can say
21 about the identification of those fibers. They

1 also included many fibers which were less than 0.5.

2 Now, 0.5 was defined a long time ago.

3 It actually occurred in the drinking water method
4 of 1983. So it wasn't that 0.5 was not known
5 about, the dates of those papers, and we still
6 regard 0.5 as the minimum length for reliable
7 identification and detection.

8 That supported by work from NIST or
9 NBS, as it was originally. And also a round-robin
10 study we did in ISO in the 1980s. The ANSEs document
11 in 2015 is quoted as supporting the concept of not
12 count -- of counting between 0.5 and 5 micrometers.
13 An actual fact, it says precisely the opposite. With
14 only EMPs having lengths greater than 5, diameter less
15 than 3 be considered in natural materials. That's
16 from the main document, which is only available in
17 French. And the shorter fibers, air and material
18 analysis reports mentioned the presence of. It
19 doesn't say considered them in any kind of
20 regulation or regulatory manner, it says mentioned
21

1 the presence of.

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

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

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

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

21 Now, if you start out doing a TEM

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

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

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

17 Now, with respect to mass
18 measurement, it is possible but it requires the
19 specific counting protocol, a different counting
20 protocol. But bear in mind that mass is the only
21 invariant measurement, anything else like fibers

1 per gram is changed by any treatment we give the
2 sample. If you crush it, disperse it, you may break
3 it up into smaller fibers.

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

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

18 The next slide shows four population
19 distributions. Two studies, Davis and Aierken, et
20 al in 2014. No tumors through the JAWE 431. 5.6
21 tumors which it has tremolite. Lots of tumors

1 for the other two --

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

4 DR. ERIC CHATFIELD: The final slide
5 --

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

9 DR. ERIC CHATFIELD: Okay.

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

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

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

16 We were asked to list all of the
17 various things we do, so the pointer was -- first and
18 foremost, I'm an Emeritus Professor, that's worse than
19 the biggest bomb. I am also past president of the
20 Mineralogical Society of America, I was the 100th
21 President, which was last year, so

1 our society has been around for 100 years.
2 We know mineralogy, we're a deep field. It's very
3 well understood. I'm not sure anyone can be trained
4 to do many of these things, but I'm sure you can be
5 educated. I'm also a member of the Idaho State Board
6 of Geologists, and they're put in red because I also
7 do consulting, and I'm a defense expert witness.

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

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

17 This happens to be a -- look, I
18 brought this up for a reason. The reason being
19 that this is our textbook, and if you make it up
20
21

1 page 515, there's a lot here, that's the chapter on
2 identifying minerals, which I think are going to be
3 pretty important here. If you'd read -- whoops, go
4 back, I don't want to show that yet.

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

12 I don't think this person should go
13 unmentioned. I would like to dedicate whatever
14 part of my talk to Mac Ross. Mac was the person
15 who got me interested in this whole field a long
16 time ago. This is a picture of Mac and also an
17 article published in the American Mineralogist
18 1990 where he received our public service award
19 for the work that he had done, and was basically
20 helping, and people realizing there was more than
21 one kind of asbestos.

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

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

13 This is an SEM photograph, we've
14 seen these before. This is an EDS pattern, that's
15 a chrysotile fiber that happens to be out of a gravel
16 parking lot in Vermont. No one would argue that's
17 chrysotile. This is out of the same parking lot.
18 This is probably the mineral antigorite. This is
19 out of the same parking lot again, probably
20 antigorite. And if we consider these things EMPs,
21 we're counting all of these, and just so you know,

1 about 2 percent of the earth's surface is covered with
2 this rock-type serpentinite. In fact, we saw some
3 nice pieces of serpentinite out in the parking lot
4 this morning.

5 If you continue to look at how you
6 identify minerals this, again, is an EDS pattern.
7 And I see elongate material here, silica and
8 oxygen, probably a lot of you in the room would
9 go, well, that's quartz. It might be, you're not
10 exactly sure. You have to use some diffraction
11 techniques, one is powder X-Ray Diffraction, this
12 is out of our book, the bottom one would be quartz,
13 the top one would be a silica glass or amorphus. You
14 could use single crystal diffraction, or this could be
15 either with x-rays or with electrons, and this one is
16 the mineral quartz, which is common, the other
17 cristobalite. These are electron diffraction patterns.
18 All of those little numbers mean something, and I
19 think electron diffraction patterns without those
20 numbers on them don't mean much.
21

1 You could also use one of my
2 favorite things, is Polarized Light Microscopy.

3 You could put minerals into these liquids at
4 different refractive indices. And what actually
5 happens here, you can see the minerals here, you
6 barely can here. So you match the speed of light
7 through the mineral, that's a physical property. A

8 very quick, easy way to identify these things,
9 assuming you know how to do it.

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

16 In the bottom one, you can see it
17 clearly because I've rotated it back. So this is
18 talc, but it's the elongate piece of talc, it has
19 different optical properties in different
20 directions. If someone asks me my major research
21 interest anymore, I'd say it's the orientational

1 dependence of the physical properties and
2 minerals. It's a mouthful, but you have to
3 understand these things to correctly identify
4 them.

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

16 So again, I'm kind of in this
17 mineral identification thing is my main aspect
18 here. Talc, if you look at its crystal structure,
19 you have the drawing, you can then rotate it in
20
21

1 different directions, and this is the way we tend
2 to see it as a nice, flat thing, we can turn it
3 sideways, it looks like this. Its electron
4 diffraction pattern is different, just like the
5 optical property is different. So you get
6 different patterns as a function of the
7 orientation.

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

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

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

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

15 So this is the one to memorize or
16 possibly go blind. This is overlain two
17 diffraction patterns, one of anthophyllite and one
18 of talc. And one of the ways some of these
19 identifications are made is by measuring this
20 particular spacing in here. And you can see the
21 spacing for talc and anthophyllite would be the

1 same. And I'm really big into this mineral
2 identification, that's kind of one of my main
3 points in all of this.

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

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

20
21 So again, we have ways to check

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

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

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

16 DR. MICKEY GUNTER: Gone over?

17 MS. JANESIA ROBBS: Yes, you were
18 over.

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

21 MS. JANESIA ROBBS: Thank you.

1 DR. MICKEY GUNTER: You're welcome.

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

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

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

18 RJ Lee Group has been recognized by
19 EPA for the quality of its data, and for the
20 contributions to the development standard methods.
21 RJ Lee Group scientists have published extensively

1 in the peer-reviewed literature on a wide range of
2 topics, including those related to asbestos
3 analysis, methods, mineralogy, and geology.

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

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

20 OSHA and MSHA positions on this have
21 evolved over time to recognize this fact. In the

1 ensuing four decades since the 1970s, other
2 locations where elongate mineral particles are
3 present have been evaluated. Locations include
4 El Dorado Hills, California, Homestake, South
5 Dakota and Enoree, South Carolina.

6 Investigations performed of these
7 locations and several others have demonstrated
8 that not all elongate mineral particles pose the
9 same risk to human health. Furthermore, studies
10 to assess the potency of particles from these
11 locations have consistently demonstrated that
12 there is a significant difference between potency
13 of elongate mineral particles that are not
14 asbestos, from elongate particles that are
15 asbestos.

16 The resulting body of evidence has
17 led to clear direction from OSHA and MSHA that
18 only elongate mineral particles from an
19 asbestiform material are to be considered
20 asbestos.

21 The NIOSH roadmap document cited by

1 this Working Group in its recommendation also does
2 not indicate a clear correlation between exposure
3 to elongate mineral particles that are not asbestos
4 and increased rates of disease, but that additional
5 studies should be performed.

6 To be fair, there is ongoing
7 controversy surrounding what constitutes
8 properties of asbestiform fibers that should be
9 used in the enumeration of elongated mineral
10 particles, and more fundamentally, which
11 properties control potency.

12 Including all elongate mineral
13 particles in the analysis of cosmetic talc
14 products distracts from the actual risks that
15 could be posed if asbestos were, in fact, present
16 in these materials. If all elongate mineral
17 particles are to be counted, recognition is needed
18 that these particles represent a continuum of
19 morphologies, very few which may represent
20 significant risk.

21 By enumerating all elongate

1 particles longer than 5 micrometers with an aspect
2 ratio greater than 3 to 1 with no regard to the actual
3 morphology of these particles, significance of the
4 presence of asbestiform particles is reduced. It is
5 well known that grouping separate potential hazards
6 into one measurement dilutes the ability to understand
7 the potency and effect of exposure to them
8 individually.

9 Microanalysis of individual street
10 particles contained within various materials is
11 relatively straight forward when evaluating
12 components present in a concentration greater than
13 approximately 1 percent by weight. However, the
14 level of complexity steadily increases as the
15 concentration of the particle type of interest
16 decreases to less than 0.1 percent by weight.

17 Not only does the complexity
18 increase, but the impact of even a single particle
19 from the environment in which the samples are
20 handled is significant. It's impossible to design
21

1 a test method with an analytical sensitivity of
2 zero. There must always be a detection limit
3 below which it is not possible to differentiate
4 the mean value from zero.

5 Laboratory practices associated with
6 the preparation of bulk talc samples is at least
7 as important as the recommendations for analysis.

8 Handling bulk powders in a manner that prevents
9 cross-contamination between samples or introduction of
10 particulate from a laboratory environment is not
11 trivial.

12 Another serious drawback of TEM
13 analysis alone is lack of representativeness of
14 sample size analysis. In a typical TEM analysis of
15 bulk material, hundreds of particles may be
16 included in the analysis. Thus the finding of one
17 particle in any single analysis is in no way
18 significant or representative of the material being
19 analyzed.

20 Additional analysis using complementary techniques is
21 critical to

1 understanding the composition of the material.

2 Plate microscopy includes, perhaps, hundreds of
3 thousands of particles in a single analysis. An
4 X-ray diffraction includes, perhaps, billions of
5 particles in a single analysis.

6 Additional context is crucial for a
7 thorough understanding of the findings, and no one
8 analytical technique is a silver bullet.

9 If all elongate mineral particles
10 are to be counted, and all covered particles are to
11 be discriminated, current asbestos laboratory
12 capabilities and competencies in the United States
13 are inadequate for the task.

14 Current systems based on NVLAP
15 accreditation are insufficient to determine
16 whether laboratories can confidently identify even
17 the six regulated asbestos fiber types as these
18 diffractions demonstrate.

19 In this instance one laboratory
20 found two structures and identified them both as
21 chrysotile. However, based on the data presented,

1 only one of them is, in fact, chrysotile. And
2 even the data used by the FDA in its analysis of
3 various talc-based cosmetic products to
4 demonstrate that they contain asbestos is
5 seriously flawed, and does not support the
6 conclusions reached.

7 If, as a community of analytical
8 laboratories, we are to have any hope of providing
9 accurate and reproducible results that provide the
10 public with data in which there is confidence, we
11 will need to revisit all of the established
12 frameworks, which data -- with data in which there
13 is confidence. We will need to -- which we
14 currently operate.

15 Methods currently used to measure
16 airborne asbestos concentrations will not provide
17 meaningful answers if the supposition is that any
18 and all elongate mineral particles are of concern.
19 We will need to invest significant time and effort
20 in retraining analytical staff and re-establishing
21 protocols that are demonstrably improved over

1 those currently in use.

2 The costs to the analytical
3 community will be significant and require a
4 complete paradigm shift of those who operate
5 laboratories, as well as those involved with
6 laboratory accreditation processes.

7 Our daily group is willing to invest
8 the time, effort, and capital associated with
9 improving our analytical systems, provided that
10 they are representative -- responsive to
11 scientifically established measurements that
12 relate to established risk assessment procedures
13 that follow the public -- that allow the public to
14 make informed decisions.

15 Thank you for your attention and for
16 your efforts to improve our understanding of the
17 issues surrounding accurate characterizations of
18 talc in cosmetic products. Scientifically
19 accurate characterization of particles in the talc
20 and cosmetic products is our shared goal. Thank
21 you.

1 MS. JANESIA ROBBS: Thank you for
2 your comments. Next we have David Egliman from
3 Never Again Consulting.

4 DR. DAVID EGLIMAN: Okay. Back we
5 go. Okay.

6 So I agree with your report, let me
7 try to help you out with some comments on some of
8 the comments.

9 First of all, we can never get to
10 zero for something that causes cancer in a product
11 that has no health benefit. A warning is
12 insufficient it should, as Johnson & Johnson said,
13 if there's any question of safety of talc,
14 question of safety of talc, we had a lot of
15 questions here. We've had them for 50 years,
16 they're not going to be resolved today, as you've
17 just heard, it's complicated. This is what
18 Johnson & Johnson told the FDA in '74: "any
19 question of the safety of talc, Johnson & Johnson
20 will not hesitate to take it off the market". I
21 should sit down now.

1 Okay. Biopersistence. The articles
2 that you cite, in addition to the [inaudible] and
3 Sebastien show that where the cancer occurs, the
4 short fibers are biopersistent. What you heard
5 here from Roggli, which I rebutted, please feel
6 free, I'll send you the paper, okay, is
7 epidemiologic studies which don't look at things
8 less than 5 microns in length because they were never
9 counted in occupational studies, they can't show that
10 those short fibers don't cause effects. So
11 epidemiology does not trump pathology when you find
12 the fibers near the cancer.

13 In terms of the talc in miners, yes,
14 it looks like that wasn't asbestos. It looks like
15 they got a lot of mesotheliomas there. Same thing
16 with Vanderbilt, some of the folks who have come
17 and spoken today said that Vanderbilt material in
18 talc was not -- was asbestos-free. If so, it's 10
19 mesotheliomas in those workers. There is
20 mesotheliomas in the Italian, 1 Italian worker at
21 Val Chisone, and probably 2 Vermont talc

1 miners.

2 Those studies are small, there were
3 only 38 mesotheliomas in all of the Québec mining
4 studies of 38,000 workers studied for 100 years.
5 Studies have to be large to have any importance.

6 Okay. We pour this stuff on
7 ourselves. It is designed to be used as a powder
8 and to be inhaled. It is inhaled. When inhaled,
9 the asbestos in the lung goes into the lymphatic
10 system, as you heard, and gets carried everywhere.

11 The best test method has only been
12 discussed once, let me reiterate it. It is the
13 surface area of the lung, and I'm going to show
14 you the lung being the best area to find asbestos
15 from talc.

16 My estimate was, you heard a half a
17 football field, I was only a tennis court. Again,
18 I gave this in Italy, so that was in Italian. Okay.
19 Who should decide -- you got two issues here, right?
20 How to count, what to count. What to count is a
21 health question as Meeker from USGS

1 said, not a geologic question, okay?

2 From a health perspective, this is a
3 USG study 1980 is pretty much ignored. The
4 amphibole cleavage fragments have the same size,
5 shape, length, morphology, chemistry and same
6 surface charge, so do winchite, richterite and
7 erionite. And if you don't want to count all of
8 the EMPs, we know there's three EMPs that don't
9 get counted as asbestos. I just named them,
10 there's no question they cause cancer.

11 I reviewed this for a book chapter
12 in the ASTM publication, you can go to that link
13 at the top, I have the book chapter in question.

14 From a health perspective, I'm not
15 going to go through these things, but cleavage

16 fibers cause mesothelioma. Vermont talc miners,

17 Vanderbilt, that's the two examples. Some of
18 these things were discussed in '92, of course
19 this discussion started a long time ago. Okay.
20 In '92 NIOSH concluded that cleavage fragments
21 should be counted, because you couldn't in the

1 epidemiologic studies distinguish cleavage
2 fragments from fibers, never happened.

3 The ATS said the same thing. More
4 importantly, Dr. Chatfield showed you the data
5 from Davis' four animal studies, that was analyzed
6 by NIOSH and they testified in and incorporated in the
7 Federal Register comments that there were NOT zero
8 mesotheliomas in the animal studies, okay.

9 What happened in -- when OSHA
10 changed -- this is an Imerys document from the head of
11 Health and Safety at the time---OSHA threw in the
12 towel rather than fight with OSHA.

13 This is a paper from 2019. This is
14 geology. They looked at amosite. Amosite, no
15 question asbestos. They said looking at amosite from
16 the bad, it does not meet the definition of asbestos,
17 it is cleavage fragment. Amosite causes mesothelioma.

18 This is the -- what do you get from
19 a lung, this is a case series of ovarian cancer
20 cases that I just published. On the right is, see
21

1 the asbestos in the ovarian cancer tissue. It the
2 middle from the cans of the J&J baby powder, on
3 the left from the NIST standard. Okay. It gets in
4 and it moves, milling breaks talc bundles up. You
5 cannot use a test method that ignores non-asbestiform
6 habit asbestos when you mill the stuff.

7 This is reason 2,000. Again, this
8 is Dr. Gunter's testimony where he said that the
9 material found in Vanderbilt was cleavage
10 fragments. There is no known safe level, and there is
11 no medical benefit. The stuff, as Johnson & Johnson
12 said, should be taken off the market. Okay. I went
13 fast so -- by the way, in Europe, the CTPA, which is
14 the analogous organization to the U.S. industry
15 organization, said if the XRD was positive they didn't
16 even look at the thing for fibers, they just wouldn't
17 sell it, use it, all right.

18 J&J said that -- the same thing
19 early on. Imerys told the FDA the same thing, if
20
21

1 XRD is positive, we just get rid of it, we don't
2 care about fibers, we don't want to take the risk.
3 I agree. Product no health benefit, don't take the
4 risk.

5 Dr. Berdick said it was not feasible
6 to develop a sampling plan for talc. I think that
7 may be true, if so we're taking a big risk,
8 because there is no way to get to zero.

9 In terms of -- this is my example of
10 non-homogeneity. On the left, you see we have some
11 chocolate chips, you sample that, you may miss the
12 chips. On the right, that's not talc. Talc is
13 more like what's on the left. In terms of the
14 distribution that you heard from the geologist of
15 asbestos in broad formations, remember this stuff
16 is exploded. The rock formations are exploded and
17 the talc is carried off. It's complete mixing of
18 everything in that area from the rock that's in the
19 sidewall from the head -- from the footwall,
20 everything, okay?

21 There's been a 50-year campaign to

1 deregulate cleavage fragments. It should end.
2 That's the history of that. Thanks. It went
3 pretty fast.

4 MS. JANESIA ROBBS: We appreciate
5 you being here today and offering public comment.

6 All right. So at this time, we will
7 break for 15 minutes -- for about 20 minutes, I'm
8 sorry. It is 3:06, we will come back at 3:25.
9 Thank you.

10 (Recess taken.)

11 MS. JANESIA ROBBS: All right. We
12 will go ahead and get started. And as a reminder
13 for the remaining public commenters, just to state
14 your name and affiliation and speak clearly into
15 the microphone.

16 First, we have Mark Ellis from
17 Industrial Minerals Association.

18 MR. MARK ELLIS: Thank you. My name
19 is Mark Ellis. I'm President of the Industrial
20 Minerals Association of North America.

21 My presentation today will try to

1 avoid addressing asbestos, talc, geology or
2 mineralogy, but I may not succeed. It will instead
3 focus on customers and consumers.

4 I want to offer a new conceptual framework for
5 viewing the physical world around you: if it can't be
6 grown, it has to be mined. I ask you to think about
7 that. In the charades analogy the question one
8 typically asks is, is it animal, vegetable, or
9 mineral. And if you think about that, that universe
10 is pretty all-inclusive. Consider food and natural
11 fibers. Examples include, fruits, nuts, vegetables,
12 grains, fish, meat, poultry, cotton, leather, and
13 wool.

14 If you consider minerals, you're
15 looking at metals, liquid and gaseous petroleum
16 products, examples would include clay, marble,
17 sand, copper, gold, iron, crude oil, and natural
18 gas.

19 I'd like to ask you to consciously
20 reflect on where the things that you rely on every
21 day come from, including consumer products. Look

1 around the room, where do these things come from.

2 I did that and with the exception of maybe the
3 fabric on the table that's in front of you, the
4 leather on the back of the chairs or the wood
5 that's in front of me, most of this stuff comes
6 out of the ground.

7 Okay. This may be hard to see, so
8 I'll try to cover it for you. The minerals
9 industry is the beginning of the manufacturing
10 supply chain. Manufacturers are our customers.
11 Consumers are the customers of the manufacturers.
12 Each year, every person in the US consumes roughly
13 40,000 pounds of new minerals to make the things
14 that we use every day.

15 Stone, sand, and gravel and cement,
16 about 16 -- or 18,000 pounds or roughly nine tons
17 goes into roads, buildings, sidewalks, landscaping
18 concrete, asphalt, blocks, and bricks. The
19 metals, iron, aluminum, copper, zinc, manganese,
20 and others, roughly 300 pounds a year. It's used
21 in steels, and to make planes, trains, and

1 automobiles. Beverage containers, wire, plumbing,
2 batteries, phones, television, and recreational
3 products.

4 Minerals including salt, limestone,
5 phosphates, clays, soda ash, and other
6 non-metallic minerals, roughly 1400 pounds a year.
7 It's used to produce chemicals, highway deicing,
8 food, agriculture, animal feed, floor and wall
9 tile, dinnerware, sinks and toilets, paper,
10 plastics, rubber, glass, fiberglass paints, kitty
11 liter, laundry detergent, computers, medicines and
12 water treatments.

13 Get down to the end we talk about
14 the energy fuel, thousand gallons of petroleum,
15 about 100,000 cubic feet of natural gas. 400
16 ponds of coal, and roughly two ounces of uranium
17 per year. And that's used to generate power, make
18 electricity, produce heat and lighting. So slide
19 number three address one of the recommendations of
20 the Working Group on elongate mineral particles,
21 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

1 Working Group's stated intention clear, they
2 support equating the non-asbestiform amphibole
3 analogs with the asbestiform minerals, one and the
4 same. If you identify a covered mineral, and it
5 meets the new size criteria, count it as an EMP.
6 Asbestos and cleavage fragments are one and the
7 same.

8 My organization does not support this
9 recommendation. The non-asbestiform analogs may
10 have the same chemical formula as their asbestiform
11 cousins, but they are not asbestiform in their crystal
12 growth habit. Moreover, we do not believe they
13 present the same health affects as asbestos.

14 The Working Group recommendation is open to
15 including other amphiboles in the covered minerals
16 criterion, even if they do not have an asbestiform
17 growth habit. Some of these are listed in the
18 second paragraph displayed on this slide.

19 In the next -- is the next step
20 counting any mineral as an EMP if when crushed, it
21

1 can occur in a 3 to 1 aspect ratio.

2 So slide 4 primarily addresses
3 geography and a little geology. It identifies the
4 geographic distribution of rocks or ore bodies
5 with the potential to include amphiboles, those
6 are indicated in the gray area. The red and blue
7 dots identify known amphibole asbestos locations.

8 As you can see, vast areas of the
9 west, east, south, and midwest, not to forget
10 Alaska and Hawaii had the potential to include
11 amphibole-containing rocks.

12 No mines are indicated on the map.
13 I assure you that there are mines in the U.S. in
14 the areas indicated, producing metals, minerals,
15 and petroleum products. These mine products are
16 being supplied to customers. These customers in
17 turn are manufacturing products for consumers. Is
18 there asbestos in these products, I really don't
19 know.

20 Are these covered or non-covered
21 EMPs and are there covered or non-covered EMPs and

1 are there covered or non-covered EMPs in these
2 products, again, I don't know.

3 Does the Working Group know or do
4 agencies represented by the Working Group know? If
5 not, I submit that the recommendations of the
6 Working Group are premature because they have not
7 considered the potential impact of their
8 recommendations.

9 Finally, slide five. As an
10 extension of the concern expressed in my previous
11 slide, this slide addresses the potential of soils
12 potentially containing amphiboles. As I hope you
13 will recall from your earth science class in
14 grammar school, sand and soil once were rocks and
15 were converted to sand and soil particles by
16 processes of erosion and glaciation.

17 So to get to the ore that we mine to
18 produced the metals, minerals, and petroleum that
19 are manufactured into products that we use every
20 day, we first must dig through the soil which we
21 call overburden.

1 What do we do with the soil that we
2 excavate, is it just dirt or EMP-containing
3 material, that's a legitimate question to ask.

4 Anecdotally, I lived in California,
5 serpentine is the official California state rock.
6 As covered earlier, serpentine can exist as
7 asbestiform chrysotile or as non-asbestiform
8 antigorite. At the time I lived in California,
9 utility companies were asking what they needed to
10 do with the soil they excavated to install a
11 telephone pole, treat it as dirt or as a hazardous
12 waste. I think that question is still relevant
13 today.

14 In conclusion, the purpose of my
15 presentation was to get the Working Group and the
16 agencies the Working Group members represent to
17 consider the potential unintended consequences of
18 developing convenient counting criteria for EMPs,
19 and the potential unintended consequences of
20 imposing them on the mining industry, or
21 manufacturing customers and ultimately on

1 consumers.

2 With that, I'll close and thank you
3 for your attention.

4 MS. ROBB: Thank you for your
5 comment.

6 Next we'll have Leigh O'Dell,
7 Deborah Giannecchini, Marvin Salter from Beasley
8 Allen Law Firm.

9 MS. LEIGH O'DELL: Hello, my name is
10 Leigh O'Dell, I represent claimants who have been
11 injured by mesothelioma and ovarian cancer. I
12 serve as co-lead counsel of the ovarian cancer
13 MDL, and I'll be joined in just a moment by two of
14 my clients who have been terribly injured as a
15 result of ovarian cancer.

16 The emphasis thus far today has been
17 on asbestos in lung disease and mesothelioma, but
18 I want to talk about another elongated mineral
19 particle that's important for these proceedings,
20 and that is fibrous talc. The testing methodology
21 for identifying EMPs should include not only

1 asbestos, but fibrous talc. Fibrous talc should
2 be identified and reported in all reporting
3 requirements. Fibrous talc is another component
4 of talcum powder products besides asbestos that
5 has the potential of causing ovarian cancer,
6 particularly when women apply talcum powder to
7 their genital area for feminine hygiene. This
8 means that talc is applied to the genital area, it
9 enters the vagina, it sends to the ovaries, it's
10 deposited there, sequestered, and that is a
11 biopersistent particle that remains in the ovary.
12 Unlike the lung, it does not have a clearance
13 mechanism, causing carcinogenesis.

14 Fibrous talc is used in the
15 literature and used synonymously with talc fibers
16 in asbestiform talc. And for purposes of health
17 effects, these terms should be considered the
18 same, should be considered synonymously.

19 Fibrous talc is a cancer-causing EMP
20 that should be included in all protocols. Fibrous
21 talc, as you've heard previously today, has been

1 determined by IARC to be a group one human
2 carcinogen.

3 For purposes of illustration today,
4 I took some photographs from the FDA's testing from
5 AMA Analytical. This is a very simple comparison
6 between platy talc on the left, and fibrous talc on
7 the right.

8 From the FDA's testing also, see the
9 comparison between fibrous talc on the left, and
10 chrysotile on the right.

11 Just as the FDA required testing for
12 talc fibers and recording talc fibers, all
13 manufacturers should be required to do the same
14 thing.

15 In addition, as an illustration from
16 Dr. Longo's report on the testing of historical
17 Johnson & Johnson samples, on the left you'll see
18 a talc fiber, on the right you'll see
19 anthophyllite asbestos.

20 In the FDA's testing, as well as
21 Dr. Longo and Rigler's testing, both the talc and

1 asbestos structures are needle-like. They have
2 substantially parallel sides. They have an aspect
3 ratio of greater than 3 to 1, and they have a
4 particle length of greater than 0.5 microns. This
5 is important and these fibers should be reported.

6 Also this was talked about earlier
7 today by Dr. Van Gosen. And in regard to
8 transition fibers, the NIOSH Bulletin 62
9 photograph on the cover shows a transition fiber
10 from anthophyllite asbestos to fibrous talc,
11 making clear the relationship between the two
12 minerals-- a relationship that has been known for
13 decades.

14 In the testing methodologies, it had
15 been recommended by the working group to use TEM
16 for morphology, EDXA for chrysotile -- I mean, for
17 chemistry, and SAED for crystalline structure.
18 That's the methodology Dr. Longo and Rigler used
19 to test historical samples of Johnson's Baby
20 Powder from the 1960s through the early 2000s for
21 purposes of identifying fibrous talc.

1 When the structure met each of those
2 criteria, it was counted as a talc fiber. In
3 98 percent of the samples tested, there was
4 fibrous talc present, that's very important. And
5 when you think of that finding, it's very
6 consistent with the literature. Crowley 1968
7 reports in the 22 samples of cosmetic talc that he
8 tested, 100 percent of those samples had fibers,
9 including fibrous talc. Why is this important?
10 Because the burden of EMPs contributed through --
11 fibrous talc is very significant.

12 Looking at Dr. Longo and Rigler's
13 results for the samples from 1960s to the early
14 2000s, what you see is a range of a low of 82
15 million fibers for a ten-ounce bottle to as high as
16 289 million fibers for a ten-ounce bottle. What
17 does that mean for a woman who is using this for
18 genital hygiene? Many of these women use the
19 product on a daily basis for decades using tens, if
20 not hundreds of bottles. This results in an
21 extraordinary deposit of EMPs in the ovary.

1 And these calculations were based on
2 an aspect ratio of greater than 5 to 1. If the
3 committee's recommendation of greater than 3 to 1
4 was used, it would be even greater.

5 What's the impact? The impact of
6 these fibers are that they have the potential to
7 be directly genotoxic. We've heard today about
8 frustrated phagocytosis, and the potential of a
9 fiber to result in direct genotoxicity in
10 carcinogenesis.

11 Dr. Weis described also the presence
12 of fibers causing chronic inflammation that
13 results in oxidated stress, resistance to
14 apoptosis, stimulation of self-proliferation, and
15 other cellular changes which can lead to
16 genotoxicity and carcinogenesis. Not only
17 mesothelioma and lung cancer, as dreadful as those
18 diseases are, but also ovarian cancer. And when
19 we're thinking about cosmetics, and the primary
20 users being women, and particularly for talcum
21 powder, the primary users being for women in their

1 genital area, this is critically important.

2 IARC has long recognized that talc
3 can form into fiber. In 2010, IARC stated that an
4 asbestiform fiber should be understood to mean any
5 mineral particle, including talc. They reiterated
6 this in 2012 and concluded that the monograph for
7 2012 should apply to talc containing asbestiform
8 fibers to include fibrous talc.

9 Now, just very briefly I'd like to
10 discuss asbestos. We've heard a lot about the
11 definition, and I would just say this very simply,
12 that companies should no longer be able to say
13 that a fiber is not asbestos because it cannot be
14 proven how it grew into that shape in the ground, as
15 opposed to being milled into that shape and becoming
16 an EMP. The health effects are clear, regardless of
17 how it was formed.

18 So in sum, all asbestos and fibrous
19 talc fibers that meet the appropriate chemistry,
20 morphology, and crystalline structure should be
21 included in the definition of EMPs, and reported

1 as such by manufacturers.

2 Thank you. Let me introduce my
3 clients, Mr. Marvin Salter and Deborah
4 Giannecchini who have brief remarks.

5 MR. MARVIN SALTER: Thank you,
6 Leigh.

7 Hello, my name is Martin Salter and
8 I am the son of the late Jackie Fox. In 2013, my
9 mother was diagnosed with ovarian cancer and went
10 through chemotherapy along with multiple surgeries
11 before I watched her die of that disease in 2015.

12 After learning of the relationship
13 between talc and ovarian cancer, she filed a
14 lawsuit. In 2016, the jury returned a verdict
15 against Johnson & Johnson for failing to warn of
16 the dangers of baby powder and Shower to Shower.
17 My mother did not live to attend the trial, but
18 the jury heard evidence that she had absolutely no
19 family history of ovarian cancer, a negative
20 genetic test, 50 years of daily talc use, and
21 substantial burden of talc found in her ovaries.

1 Consumers like my mother were
2 unaware that fibrous talc and asbestos had been
3 found in Johnson's Baby Powder. Had proper
4 testing methods been used, my mother and thousands
5 of others could have avoided cancer.

6 Thank you for considering this
7 matter, and I urge you to require adequate
8 testing, although it won't bring my mother back,
9 it will save thousands of others. Thank you.

10 MS. DEBORAH GIANNECCHINI: Hello, my
11 name is Deborah Giannecchini. In 2012, I was
12 diagnosed with metastatic ovarian cancer after
13 having used baby powder for 46-plus years.

14 I can't tell you how it's altered
15 the course of my life, and I would urge you
16 strongly to require adequate testing to provide --
17 prevent this from happening to any other woman.
18 Thank you.

19 MS. JANESIA ROBBS: Thank you so
20 much for taking time to give your personal
21 testimony and public comment.

1 At this time, I would like to turn
2 it over to Kari Barrett.

3 MS. KARI BARRETT: Thank you, again.
4 We will continue with our listing, and our next
5 commenter is Laura Plunkett, Integrative
6 Biostrategies, LLC.

7 MS. LAURA PLUNKETT: Yes, hello.
8 Thank you for allowing me to speak today. My name
9 is Laura Plunkett, I own my own consulting company
10 known as Integrative Biostrategies.

11 Just very briefly, I provided a
12 slide to let you know who I am. I'm a little
13 different than some of the other people that have
14 spoken today, I am a toxicologist like Dr. Weis,
15 but I'm also someone who deals with clients that
16 have to operate within the regulatory world,
17 finding ways to comply with regulations,
18 understanding the differences between how different
19 products are regulated by the FDA, and that's an
20 important distinction here that I want to talk
21 about at the very end. These are not drugs.

1 These are not something that have a benefit.

2 These are something where risks should be what is
3 considered when you're talking about what to tell
4 a consumer about the product. They need to
5 understand what the risks are when this product is
6 not something that's going to save their life,
7 provide them with a benefit like a drug, for
8 example, that might be formulated with talc as an

9 excipient. I have worked in the plaintiff's
10 litigation, you'll see down here under my current
11 company, I'm working on behalf of women who have
12 been -- either died of an injury due to ovarian
13 cancer and their long-term talc exposure.

14 I would also point out however when
15 I worked in 1989 to 1997 at Environ Corporation,
16 it's interesting one of the products that I worked
17 on had to do with whether or not talc could be
18 safely used as a dusty powder on medical condoms -- on
19 medical devices known as condoms.

20 It's interesting that those medical
21 devices no longer allow the use or are not being

1 used, that company actually voluntarily took that
2 out of what they were dusting their condoms with
3 in the early '90s. So I think that's something to
4 understand. This is not a new issue, it's been
5 something that on the issue of talc safety, has
6 gone back to the '70s, came out in the '90s, it's
7 still around today.

8 So we've heard a lot today about --
9 I'm not going to repeat some of these things that
10 I actually have bulleted on my slide, but I wanted
11 you to understand that I agree it's not just
12 asbestos. As Ms. O'Dell just said, fibrous talc
13 is indeed a hazard, talc powders, generally, when
14 they've been administered to animals, when they've
15 been found in tissues of humans, those particles
16 injure tissue.

17 So when you talk about talc fibers,
18 you're not just talking about whether it is
19 asbestos itself, but whether or not, indeed it's a
20 fiber or the type of particle that has a toxic
21 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.

16 Very quickly, I think you've already
17 seen what the powder bottles look like. I put
18 this slide for two reasons. First, I wanted you
19 to understand, which I think has already been
20 said, that the talc body powder is a mixture, it's
21 not just platy talc. It has other things in it.

1 I have a yellow-red listing on my slide here to
2 show you that in this bottle, there are
3 constituents that have been identified by IARC as
4 either possible or known human carcinogens.

5 Again coming back to the fact that
6 it's a cosmetic. If you're delivering something
7 with possible known human carcinogens, don't you
8 think consumers should know that? I don't believe
9 consumers understand that that is what is
10 necessarily in the talc, especially when you come
11 up here and look at the bottle and it says talc
12 and fragrance. And then you see this little leaf
13 about the fact that what we have here are
14 naturally-derived ingredients.

15 I believe if you read the published
16 literature on risk communication, you'll find that
17 many people believe "natural" means safer, and
18 that's not the -- that's not the issue here. I
19 don't think that we should be letting people think
20 that because it's natural, it's something that they
21 should assume is safe.

1 This has also been covered a bit
2 today, but I actually have providing -- I have a
3 published -- I have a list of all of the
4 publications I cite on my slides that I've listed.
5 It's a two-page, one-page handout. I encourage
6 anybody to take it home with you, you can get the
7 full citations.

8 I just wanted to show here that,
9 again, since the 1970s, there have been published
10 studies, publicly available information to show
11 that not only is asbestos being repeatedly found
12 in talc body powders, but also fibrous talc.

13 I wanted to touch on a point that I
14 think has been talked about a bit today, but I
15 believe there has been some people who have raised
16 the issue of whether or not the animal studies
17 actually showed cancer with exposure to talc, or
18 whether or not there is some concern over whether
19 or not it's the whole, just the asbestos issue, or
20 is fibrous talc, or is it the whole talc powder
21 that's the issue.

1 I would encourage you to look at the
2 literature, and I'm going to talk about a little
3 bit more in a minute, but to understand that fiber
4 toxicity, I think a lot of speakers have said
5 that, is indeed a function of the chemical nature
6 of the fiber, as well as its physical form.

7 So I don't believe that there is a
8 lot of controversy in the scientific literature
9 over the fact that these elongated mineral
10 particles, the form of it is extremely important
11 to the toxic insult that you get when you leave in
12 the tissue for a long period of time. Both
13 fibrous talc and fibers of asbestos have been
14 shown to trigger the responses that are consistent
15 with a carcinogenic process and tissues. And
16 again, I'll have a slide on that in a minute, and I
17 have a -- in my bibliography listed for you papers
18 that show the kind of molecular mechanism, the studies
19 that support that you're getting these
20 preneoplastic changes in tissues, or you're getting
21 changes in the cellular mechanism that are

1 related to oxidative stress, inflammation. And
2 those are all the types of processes that have
3 been linked with the risk of cancer or the
4 carcinogenic process, not only in animals, but
5 also in humans.

6 As Ms. O'Dell pointed out, indeed
7 IARC has classified fibrous talc, as well, as a
8 known human carcinogen. I'm going to skip over
9 this, because I believe the previous speaker just
10 covered this, but again, I think it's really
11 important to go back and look at those IARC
12 documents and understand that they're talking
13 about fibrous talc, not always about asbestos.

14 This slide is also one I think is
15 also similar, I noticed. Although, it's one that
16 I've used before when I've discussed this -- I'm
17 sorry.

18 This is the important end points I
19 wanted to point out as a toxicologist, we know
20 that fibers, particles in fibers of the powder
21 itself can lead to a chronic inflammatory response

1 in tissues, there is studies that show this in
2 isolated cells, as well as in animals, and also in
3 human cells, as well as in humans.

4 The genotoxic events can occur due
5 to direct interactions with the fibers, these
6 direct effects of the -- of the exposure, but also
7 this inflammatory process develops and produces
8 these indirect changes in the cells that can also
9 produce genotoxic events.

10 Genotoxicity is damage to the DNA in
11 the cell. These things lead to these
12 preneoplastic cells. Again, there are studies in
13 the literature that show this in animals, that if
14 you just go from the inflammatory response, you can
15 actually see these preneoplastic lesions, and I
16 think the toxicological sciences have shown that
17 when you start along this process, the tumors can
18 form.

19 So what do we also know about talc
20 is that there are numerous studies out there that
21 can document this, that's why I'm providing the

1 bibliography for you. That the focus should be on
2 more than asbestos, but also on this issue of
3 fibrous talc. And just really briefly on this
4 issue of regulatory issues, I'd like to point out
5 that a warning is something a consumer can see.
6 So by even if there is controversy over what we're
7 going to test for and what we see, what is the
8 reason for not providing the consumer with the
9 information to say that there is a potential,
10 because that's what the cosmetic standard is.
11 It's a potential for whether or not there can be a
12 risk to your health. Thank you.

13 MS. KARI BARRETT: Thank you for
14 your comments. Our next commenter is John
15 Godleski. John Godleski, MD, PLLC.

16 DR. JOHN GODLESKI: Thank you very
17 much.

18 I'm going to talk about the
19 identification of the talc and fibers in the
20 female genital tract. I'm Professor of Pathology
21 Emeritus at Harvard Medical School, and CEO of my

1 company, John Godleski, M.D.

2 My disclosures include that I've
3 been an expert witness for both plaintiffs and
4 defendants in environmental disclosure and product
5 liability litigation. I've been an expert witness
6 for plaintiffs in talc litigations.

7 Why identify foreign material in
8 human tissue? The specific identification of
9 foreign particulate material in human tissue
10 confirms exposure to materials associated with the
11 development of malignant tumors and other
12 diseases.

13 So finding it in the tissue is
14 important. Okay. Let me talk about the
15 preparation techniques that we use to find
16 particulate material in the tissue. It was
17 mentioned in one of the other talks that you can
18 use tissue digestion with strong acid, Clorox, or
19 incineration. Isolate the inorganic particulate
20 and chemical characterization by TEM, SEM, EDX in
21 electron diffraction.

1 What I'm going to talk about today
2 is the in situ identification of particles with
3 SEM and characterized by EDS. This shows you that
4 the particles are truly in the tissues.

5 Now, the advantages of having it in
6 the tissues is that the tissue context remains,
7 and there is much less preparation when you use
8 variable pressure Scanning Electron Microscopy and
9 EDS, because you can actually look at the face of
10 the paraffin block tissue.

11 Disadvantages is that you are
12 looking at a very small volume of this tissue.
13 Now, here is our approach. We first do Polarized
14 Light on the tissue sections that are taking that
15 pathology when the -- there is surgery on the
16 patient.

17 We look at that, and what we're able
18 to see is that by Polarized Light, and many of the
19 tissues we can see large numbers of both particles
20 as well as fibers. This is a very important step
21 because there is a distribution among the tissues

1 that you'll see, and so we have to follow that
2 identification.

3 So we get the block of tissue, and
4 the first thing we do is take some sections off of
5 it. This is important because pathology
6 departments where people wear gloves that have
7 talc on the surface of the gloves. So you have to
8 assume that these have been touched by all sorts
9 of things with all sorts of contamination.

10 So you take the surface off by
11 cutting a few sections. You can also cut
12 additional sections for other kinds of microscopy
13 and then you can also do Scanning Electron
14 Microscopy directly on the block.

15 So we do this, and what we are able
16 to find is that we can then see the particles
17 within the tissue. And here you can see some of
18 these particles, you can see that they're clearly
19 inside cells, we can do -- and do electron Energy
20 Dispersive analysis, and we can see these in this
21 picture. This is the same picture a lower

1 magnification than this one, and when we do the
2 EDX spectrum, we can see it has the chemical
3 nature of talc.

4 So how much tissue do we really
5 examine with this? It's actually a very small
6 amount. The area of tissue and paraffin blocks
7 from resection is at the most 20 by 20 by two
8 millimeters deep.

9 The length and width can depend on
10 the tissue, but the depth is almost always two
11 millimeters. SEM, EDX in this setting assesses a
12 depth of about two microns. So one millimeter
13 equals 100 microns we're actually looking at 1,000
14 of the paper -- the surface.

15 So that if we look at the analogy,
16 if we have 1,000 sheets, two reams of paper, and
17 we take out one sheet, we're essentially looking
18 at what would be comparable to one sheet or one
19 one thousandth of a tissue.

20 Now, we studied this back in 2007
21 where we looked at talc in the pelvic lymph nodes

1 of a woman with ovarian cancer and long-term
2 genital exposure to cosmetic talc.

3 What we're able to see, this was a
4 woman who was 68-years-old. She had stage 3
5 ovarian papillitic carcinoma. She had used talc
6 daily for 30 years. Examination of her lymph
7 nodes under Polarized Light Microscopy showed
8 diffuse areas of birefringence compatible with talc,
9 and confirmed by Scanning Electron Microscopy and X-
10 ray spectroscopy.

11 In 2018, we reported on a case of
12 accumulation of talc in the ovary. We're looking
13 to identify foreign particles in human tissue
14 using both Scanning Electron Microscopy and Raman
15 spectroscopy as a way of doing this.

16 You can see how much birefringence
17 is in this ovarian tissue in this particular
18 patient. This is all intracellular, and you can
19 see here that it's also intercellular, here it is
20 by Scanning EM. And you can also appreciate that
21 these are all small particles less than 5

1 microns, and by Scanning EM, we're able to show that
2 this is talc.

3 We more recently, in this past year,
4 have described migration of talc from the
5 peritoneum to multiple pelvic organ sites. And
6 this is taken from the paper, and it's actually
7 Table 3 in this paper, and it's a bridge to show
8 all of the total numbers.

9 The number in parentheses is the
10 number of blocks that we studied. The number ND
11 is "not done", NS is "not sampled". Note how much we
12 can find by this method in the ovaries, we can
13 also find it in the cervix, uterus, fallopian
14 tubes and lymph nodes.

15 Here is pictures of this where you
16 can see what it looks like. Here is another one
17 where looking at the microscopy, you can see
18 macrophages by Polarized Light are filled with
19 particles and by SEM, we can identify these as
20 talc. We can also find fibers, and here you can
21 see some of those fibers.

1 Now, here's our total experience.

2 We start out with 196 cases. Of those, 180 were

3 positive by polarized light, 16 were negative. On

4 those that we've done SEM, EDX. We have 82

5 positive, nine negatives. So we don't always

6 confirm that these are talc.

7 When we look at the average number,

8 we have 40, average number of talc particles per

9 patient. Number of patients with greater than 50,

10 out of this group, 24.

11 But here is the important piece, the

12 number of patients with fibers by this in situ

13 analysis, we have 21 talc, nine asbestos, two

14 patients had both talc and asbestos. Here is our

15 examples of tremolite asbestos --

16 MS. KARI BARRETT: We do need to

17 wrap up.

18 DR. JOHN GODLESKI: -- and these are

19 my summary. Thank you very much.

20 MS. KARI BARRETT: Thank you. Thank

21 you for your comments today. We'll go to our last

1 public commenter, Jeniffer Carson, CMBG3, Law,
2 LLC.

3 MR. JENIFFER CARSON: Thank you. I
4 am Jeniffer Carson, the managing partner of CMBG3
5 Law in Boston and California. We represent
6 individuals and corporations in litigation,
7 compliance, and government's affairs.

8 I'm here to talk today, I'm a
9 non-scientist, about the impact of these decisions
10 that you're about to -- that you're going to be
11 making and how they impact the litigation.

12 I want to set the stage, because I
13 don't think everybody always understands what the
14 litigation actually looks like for both sides of
15 the equation. There are judicial resources
16 dedicated exclusively to asbestos litigation and
17 now talc in many states.

18 It consumes lots of man-hours, takes
19 away jury pools and other things from other cases
20 that also need to be attended to. There are
21 hundreds of individuals who have been diagnosed

1 with diseases that cause them concern, and then
2 there is also an extensive amount of social medial
3 presence and media attention on this issue that's
4 causing fear in individuals who are not harmed, but
5 who have concerns that they may have harmed their
6 children or others by using talc products.

7 It's an important piece to not
8 forget, that the information that's circulating
9 out there can cause undue harm when it's not
10 matched with education and proper science. There
11 are also hundreds of companies impacted by both
12 asbestos and talc litigation. These are not all
13 large corporations. I personally have represented
14 in the last 20 years everything from small Mom and
15 Pop companies to Fortune 500 and 100 companies.

16 The bulk of the clients that I
17 represent usually are the smaller entities that
18 did their best to be in compliance, to following
19 the rules, to do what they were told. And those
20 companies are impacted just the same as everybody
21 else. And there are no real metrics for people to

1 look at how that's actually impacting the industry
2 and the court system. There are multiple jury
3 verdicts as everyone has read about, and there is
4 mixed results in those jury verdicts.

5 It's important to think about all
6 aspects of this. We've heard today from a number
7 of different, I want to say factions. We should
8 all be here to try and reach good decisions
9 together, collectively and let true science come
10 through, but there are different entities involved
11 and it's important to recognize that there are both
12 interests in play, and money to be made on all aspects
13 of this, both from the lawyers, from the judiciary,
14 from the individuals who are being injured, and from
15 the corporations. It's not a one-sided story.

16 There are a number of things that we
17 could talk about, and I'm not going to speak to the
18 science, because I'm not a scientist. But I can tell
19 you that I lived for the last 20 years trying to
20 manage the impact of the decisions that
21

1 are made by governing bodies in the court systems.

2 Regulations and testing, I will talk
3 very briefly about my attitude towards it.

4 Regulations and testing requirements should focus
5 on fibers that are respirable and actually
6 transmigratable through the body. That's an
7 important piece. We talk about counting
8 everything, you're not focusing on the real harm,
9 and that's what everybody wants us to do, is focus
10 on the real harm, the things that actually cause
11 problems.

12 If you count everything, you are not
13 recognizing that some things are not respirable in
14 human beings. Some particles are not able to be
15 transmigrated through the body, and that's
16 important to speak to scientists, biologists,
17 people who focus in exclusively toxicology and
18 actually understand the impact of the particles on
19 the body, and not just talk about counting
20 particles in the abstract.

21 You want to count the particles, all

1 of us want you to count the particles, regardless
2 of what side of the coin everyone is on, we want
3 to focus on things that impact cellular
4 development negatively, not things that have no
5 impact. Creating a system that counts everything
6 causes more confusion. It does not fix the
7 problem. Testing methods should be clear and
8 follow objective science as appropriate for the
9 circumstance.

10 Science created in litigation or for
11 litigation purposes is not true science. It's not
12 objective. It's subjective. It's desires to feed
13 and approp a win, that's not what we should be
14 trying to do in our government. Regulatory
15 requirements should be documented using clear and
16 plain language. How does that play out in the
17 courtroom? We used a lot of terminology here
18 today, and there are some very bright minds in
19 this room. The people in this room understand the
20 science better than your average citizen. Try
21 explaining that to an average person who has never

1 gone, looked at any of the scientific issues, who
2 doesn't understand what an EMP is, or asbestos, or
3 asbestiform. Most of the juries I've ever
4 interviewed think asbestos is a chemical. They
5 think it's made. They don't understand it is a
6 rock mined from the earth.

7 So when you get into these types of
8 issues, and you're making decisions about the
9 language, and the process, and the methods used,
10 remember that average people need to interpret
11 this information, and these decision every day
12 that impact both individuals who are harmed who
13 want to be heard, have a right to have their cases
14 heard, but also the companies have a right to be
15 heard and judged fairly by a process that exists
16 in today, and applying knowledge that we know
17 today to cases that occurred 20 years ago.

18 Most of our cases and our clients
19 involve incidences of use of a product that
20 occurred upwards of 60 years ago. Based on
21 science and technology, today's companies are

1 judged by that information, and what we know now,
2 as opposed to what was known then.

3 When the regulations, whatever,
4 ultimately is decided here, you have to remember
5 that there is an impact, and that the knowledge we
6 have now is seen through a lens of today.
7 Hindsight is always 20/20. And when you're making
8 regulations, that's not your focus what happened
9 60 years ago, you're trying to make good decisions
10 about what we know now. But the cases in the
11 courthouses are not being judged fairly.

12 Consider creating a mechanism to
13 educate the judiciary who also wrestles with very
14 complicated complex issues in this litigation.
15 And very few of the judges have any science
16 background, no anatomy background, no biology
17 background, no toxicology background, and yet they
18 are being held to hold their one responsibility
19 which is to create an unbiased forum, a fair
20 forum for decision making. Under very high stress
21 moments, with no time, no unbiased educator at

1 their disposal and those decisions have real
2 implications.

3 A procedural mechanism should be
4 created to allow for companies whose products have
5 cleared the governing bodies, the Consumer Product
6 Safety Commission, for example. Those products have
7 been cleared by them, they shouldn't have to go all
8 the way through litigation for years, paying for
9 something that they know and have been told was
10 fine. It's an important thing and there are more
11 than one aspect of this, and I really implore the
12 governing body, the Work Group to think about all
13 aspects of it, not just what we do from here going
14 forward, but also the implications in the
15 courthouses. Thank you.

16 MS. KARI BARRETT: Thank you. Thank
17 you for your comments. At this time, I just really
18 want to thank collectively everyone who offered public
19 comment today, I recognize, as you all do, that there
20 are a number of different
21

1 perspectives in the room and really do want to
2 thank all of you for taking the time to give a
3 comment, and to remind you to consider any
4 additional materials that you would like to submit
5 to the docket, further thinking that you have on
6 these important topics.

7 So with that, I am now going to turn
8 the podium over to Dr. Linda Katz, who will give
9 some closing remarks and wrap us up for the day.

10 DR. LINDA KATZ: Good afternoon,
11 again. I'm Dr. Linda Katz. I'm the Director for
12 the Office of Cosmetics and Colors. I appreciate
13 everybody staying here, being as engaged as they
14 have for the entire day. So my remarks actually
15 will not be all that long. So that we'll try to
16 get through this relatively quickly. But what I'd
17 like to do is just to identify some of the
18 discussion points that we've heard today. Talking
19 about mineral fibers of potential concern in talc.
20 Mineral fibers that we heard about and what they
21 can do to the lungs regarding exposure and

1 toxicity. Talk about some, again, the preliminary
2 recommendations from the Interagency Work Group,
3 identifying the mineral fiber terminology and
4 definitions, analytic approach, the content and
5 format of the report, again, which you've heard
6 earlier. And once again thank the public for their
7 comments. And I will put a plug in at the end with
8 our Federal Register notice for the docket number to
9 have all of those comments get taken, and if you have
10 additional comments that you would like to make to
11 submit them to us.

12 So let me begin and just briefly
13 summarize. With regard to mineral fibers of
14 potential concern in talc, we heard a lot about
15 the geology. We heard about how talc is formed,
16 how it's mined, where the different mines are,
17 some of the problems that can be seen, but
18 basically because of some specific geologic
19 conditions that do form talc, it can result in some
20 internal variation, even within the prospect of a mine
21 itself. So even within a mine, there is

1 some variability.

2 Talc ore is used for cosmetic raw
3 material talc would benefit from a comprehensive
4 mineralogic assessment, and we heard about that
5 earlier today.

6 With regard to mineral fibers in the
7 lung, we've heard about exposures and toxicities.
8 We heard about asbestos and EMPs that can cause
9 both cancers and non-cancer health effects. The
10 proposed mechanism of action appears to be an
11 inflammatory response, and we heard a lot about
12 the details, again, specifically with reference to
13 the lung.

14 The EMP characteristics that
15 potentially influence this process appear to be
16 probably length and width, the mineral type, the
17 persistence in biologic tissue, the surface area,
18 surface reactivity, and the surface charge.

19 With regard to our preliminary
20 recommendations, I'm not going to belabor the next
21 two slides, but I'd like to go through them one

1 more time again, because not only have you heard
2 them from the Work Group, but you've heard them
3 from others referencing the Work Group's
4 preliminary recommendations.

5 The first was to adopt the term EMP
6 as in a mineral particle with a minimum aspect
7 ratio of 3 to 1. As we listen to the comments,
8 the public comments, we realize that there may be
9 more things that we need to consider there as
10 well. That the testing laboratories should report
11 all EMPs having length greater or equal to
12 0.5 microns.

13 The test method should specify
14 reportable EMPs identified as amphibole or
15 chrysotile particles as covered minerals. And
16 test methods should include directions in enabling
17 reporting and counting of primary and secondary
18 structures. That is examples with bundles
19 clusters and fibers of covered EMPs as a function
20 of sample mass.

21 We heard that Polarized Light

1 Microscopy may be required analysis of each sample
2 using established guideline methods. X-Ray
3 Diffraction is also a useful method for detecting
4 asbestos. However, it may be limited due to some
5 sensitivity issues. The use of TEM with EDS and
6 SAED to address deficiencies and sensitivity that
7 cause false negatives by PLM also need to be looked
8 at.

9 We heard that Scanning Electron
10 Microscopy might be useful as a complementary
11 method, but currently has significant shortcomings
12 for identifying chrysotile.

13 And finally, we heard that the mass
14 percent, a unit is frequently -- that a unit is
15 frequently used to express the content of asbestos
16 in commercial bulk material is not appropriate for
17 measurement of EMPs in talc, and products
18 containing talc.

19 The reasons for this, again, we
20 heard earlier is that mass percent does not
21 correlate with the number of fibers, and that a

1 single atypical EMP could dominate and skew the
2 conclusions of the mass percent, making it appear
3 larger than what it is.

4 Also, with today, identified were
5 additional needs, and additional research needs
6 that need to happen as we try to go through and
7 address most of these issues.

8 That research is needed to minimize
9 false negative or positive rates, improve
10 sensitivity and accuracy of counting, to determine
11 the sources of variation in the sampling, to
12 improve sample preparation methods, such as with
13 concentration methods, and reference standards
14 specific to talc and talc-containing products.

15 We also need more research regarding
16 the validation of analytical methods, such as
17 X-Ray Diffraction, Polarized Light Microscopy, and
18 Transmission Electron Microscopy. Specific to talc
19 and cosmetic containing talc products, we need to go
20 back to look at ways to try to increase laboratory and
21 analyst proficiencies, and we need

1 to increase interlaboratory concurrence of results
2 that are seen when products are analyzed.

3 So what are our next steps? The
4 Interagency Work Group will continue its work on
5 these and other topics, specifically related to
6 health and health concerns. That it will review
7 the information that was presented at this meeting, as
8 well as the information that's submitted to the
9 docket.

10 I've included the docket here so
11 that for reference in case people can't find it
12 readily, and to let you know that the docket
13 closes on March 4th. So that if you have comments
14 that you'd like to consider, they need to be in by
15 then.

16 What our ultimate goal would be is to
17 complete and post a white paper that addresses
18 these issues presented in our Executive Summary,
19 the issues that were described today, and issues
20 that come into the document and that we -- so that
21 we can move forward.

1 The final slide that I have is
2 really with a special thanks. This was a
3 tremendous undertaking by the Agency, as we heard
4 earlier from -- with a relatively short period of
5 time to try to get this public meeting together.

6 I'd like to thank the following
7 individuals from CFSAN specifically, Debbie
8 Smegal, Steve Wolfgang, Susan Spence, Denise
9 Hodge, Caroline Linder, Janesia Robbs, Kari
10 Barrett, Juanita Yates, Lindsey Haake, Jessica
11 Larkin, Phil Chao, Doug Ticker. And I'd also like
12 to thank, the Work Group members who you see up
13 here, Paul Howard, Brad Van Gosen, Chris Weis and
14 others such as Dayle Cristinzio, Beth Fritsch, Steve
15 Morin, Monique Richards, Alyssa Polovoy, and all of
16 our federal partners and other Work Group members, who
17 without their help and assistance, could not have made
18 this day a success.

19 So with that, I would like to thank
20 everyone again for all of their attention, and for
21 coming, and we will adjourn the meeting. Thank

1 you.

2 (At 4:21 p.m., the meeting concluded.)

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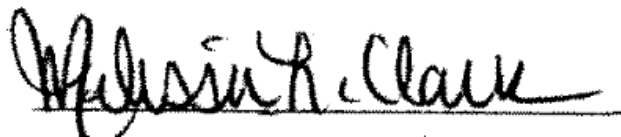
CERTIFICATION

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.

A handwritten signature in black ink, appearing to read "Melissa L. Clark", written over a horizontal line.

Court Reporter

Melissa L. Clark

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