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JIFSAN SYMPOSIUM
ASBESTOS IN TALC
MAIN SESSION
Conducted by Catherine Sheehan
Wednesday, November 28, 2018
8:04 a.m.

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C O N T E N T S

| | |
|-----------------------|-----|
| Catherine Sheehan | 3 |
| Bradley Van Gosen | 10 |
| Gregory Meeker | 29 |
| Martin Rutstein | 44 |
| Martin Harper | 77 |
| Brooke Taylor Mossman | 115 |
| Ann Wylie | 137 |

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

2 CATHERINE SHEEHAN: Good morning everybody.

3 Since we are -- I have 15 minutes to introduce --
4 welcome everybody. Please bear in mind that we have a
5 webinar aspect of this meeting as well. So in the
6 interest of time, I would like everybody in the meeting
7 room to take their seats, please, so we can commence
8 with the meeting.

9 So welcome, everybody. My name is Catherine
10 Sheehan, and I've been given the honor of doing the
11 opening and closing remarks. So can I have quiet,
12 please? Thank you.

13 We do have a webinar component, so we need to
14 keep that in mind as well.

15 So as part of the introduction, the symposium,
16 as you all may know -- okay. All right. The symposium
17 is organized by the JIFSAN Symposium Committee. Who
18 are the stakeholders supporting this meeting? For
19 those of you that want to know, funding is through a
20 cooperative agreement between JIFSAN and FDA.

21 The purpose of this symposium is to develop a
22 standard and methodology for analysis and testing of

1 asbestos, and hopefully we'll be able to achieve that
2 goal here today or at least tackle it in some form or
3 fashion in that we are providing a forum for experts.
4 We have an audience from regulators, industry, and
5 academia, so I think we are well-equipped here to
6 hopefully move this discussion along.

7 I see some folks in the audience as well that
8 I know of to work with the United States Pharmacopeia.
9 So we also -- if you don't know, the United States
10 Pharmacopeia also have a standard for talc; and we,
11 also, are very interested in the work that is going on
12 today. Of course, we will share knowledge and come to
13 a consensus on future testing approaches and adequately
14 analyzing talc containing products for the presence of
15 asbestos fibers; and this symposium will include
16 presentations and, most importantly, the concurrent
17 breakout sessions on test methods, characterization,
18 and interpretation of data.

19 So that's kind of a lineup in terms of what
20 our purpose and goals are. Let me see if I can get
21 this thing moving.

22 Tim, help. It's not moving. Technical

1 difficulties here. It doesn't seem to want to move.

2 All right.

3 So morning session -- briefly, we have divided
4 the morning session into three key areas: definitions
5 and mineral fibers, test methods, and a break, and then
6 followed by two sessions of presentations on the
7 interpretation of data obtained from microscopy
8 measurements.

9 The afternoon session, the breakout sessions,
10 you can see here we have -- Sessions A, B, and C will
11 be repeated to allow each attendee to have a chance to
12 participate in two of the three planned sessions.

13 Session A, test methods for analysis of talc
14 and mineral fibers in cosmetics; and Session B,
15 measurement criteria for identification and fiber
16 counting; and then Session 3 will be the interpretation
17 of the testing data.

18 So after that -- some important information
19 here in terms of housekeeping and how we're going to
20 handle the breakout. Co-moderators will pose questions
21 and record input from the audience using flip charts,
22 computers, and other audio/visual aids. In addition to

1 that, notetakers are available among participants, and
2 they may use recording devices. Also, transcriptionist
3 will be on site. And then immediately after the
4 breakout session, there will be a break during which
5 the co-moderators will review the input from the
6 audience and draft their summary to report out to the
7 larger group.

8 So after the break -- after the breakout
9 sessions, all attendees will reconvene for the record
10 out session; and then each pair of the session co-
11 moderators will give time to deliver an oral summary of
12 the input to attendees.

13 During the symposium, most importantly, there
14 will be time for Q&As and if all questions are not
15 answered, they will be posted on the JIFSAN website,
16 and a summary of the meeting will be available shortly
17 after the meeting. And so the date that I have here is
18 that the moderator/speaker will present the summary of
19 the presentation or results by January 5th. So you
20 won't get anything before that date.

21 So any questions on that? One more thing, the
22 restrooms are directly behind the registration desk.

1 That's it. So --

2 AUDIENCE MEMBER 1: Where will the breakout
3 sessions go? Where are the breakout sessions?

4 CATHERINE SHEEHAN: Good question, Marty

5 . Very good question.

6 Help, JIFSAN.

7 TIM: They are two corridors down behind us.

8 So if you got out of the elevators, you just go

9 straight.

10 CATHERINE SHEEHAN: Okay. I'm sure we will

11 get more information. I'll go and find out and get

12 everybody familiar with the three certain breakouts.

13 Okay.

14 AUDIENCE MEMBER 2: Catherine?

15 CATHERINE SHEEHAN: Yes.

16 AUDIENCE MEMBER 2: Could you explain a little

17 bit about the webinar and what it is and where it's

18 going and --

19 CATHERINE SHEEHAN: Good question as well.

20 The webinar has just been communicated to me by Tim.

21 So my understanding is that we have this webinar going

22 on, and we are recording this as well.

1 Tim can -- I think that's all we know about
2 now in terms of they're listening to our presentations.

3 AUDIENCE MEMBER 2: Who is they?

4 CATHERINE SHEEHAN: Anybody that was invited
5 to this JIFSAN meeting that cannot attend in person --

6 AUDIENCE MEMBER 2: Okay.

7 CATHERINE SHEEHAN: -- has the ability to
8 join by webinar, so --

9 TIM: I do believe there's only like five or
10 six people.

11 CATHERINE SHEEHAN: Okay. Thank you, Tim.

12 All right. So with that, we'll move on.

13 AUDIENCE MEMBER 2: Is there Wi-Fi access in
14 this room?

15 TIM: Yes. I can come around and talk to you.

16 CATHERINE SHEEHAN: Okay.

17 AUDIENCE MEMBER 3: Just for technical
18 difficulties, I had -- I'm getting a message from
19 somebody that's on the webinar, but they can't hear
20 anything. They can see the screen, but they're unable
21 to do that. I don't know. Is there a way for them to
22 contact help for that?

1 CATHERINE SHEEHAN: I see.

2 TIM: I am -- I'm actually listening to the
3 webinar, and it's being broadcast just fine.

4 AUDIENCE MEMBER 3: Okay.

5 TIM: So --

6 AUDIENCE MEMBER 3: Do you have, like, an e-
7 mail or something that I can have him reach out to you
8 to --

9 TIM: Yes.

10 AUDIENCE MEMBER 3: -- get help?

11 CATHERINE SHEEHAN: Yeah, that would be good.
12 Yeah.

13 TIM: Just Tshaffer@dodwu.

14 Who needed the Wi-Fi?

15 CATHERINE SHEEHAN: Right. Yeah. If they had
16 an e-mail just in case they have any questions. Okay.

17 So in the interest of time, let's move on, and
18 then I'll navigate through this.

19 TIM: Okay.

20 CATHERINE SHEEHAN: Okay. So our first
21 speaker this morning -- very briefly introduce Brad Van
22 Gosen. He's a research geologist at the U.S.

1 Geological Survey, and he began his work with asbestos
2 in 2000, so if Brad could come up to the podium.

3 BRADLEY VAN GOSEN: First of all, I want to
4 thank the JIFSAN committee for the opportunity and the
5 invitation to speak here today. It's very much
6 appreciated.

7 I'm hoping that my product will just provide a
8 context for the rest of the day, and that is to just
9 describe to you the elongate mineral fibers, particles
10 that we're even going to need to think about in terms
11 of commercial talc deposits. And I'm going to do this
12 and -- these minerals will be some of the amphibole
13 mineral group as well as the one type of deposit that's
14 relatively spatially associated with Chrysotile, the
15 serpentine mineral group.

16 The amphiboles and serpentine that are
17 associated with talc deposits of mineable commercial
18 size are dependent entirely on the geologic
19 environment, the geologic conditions that form that
20 type of deposit. I'll describe four basic types of
21 geologic settings and conditions that form talc
22 deposits -- not all are created the same -- and give

1 you a little geology.

2 I thought I'd provide just a quick background
3 on the current talc production. In the United States
4 there are three companies producing from three
5 different states, and these include the American Talc
6 Company, which operates several pits in the Allamore
7 District, which is in far western Texas. Most of their
8 product is being used in paints is my understanding.
9 Barretts Minerals operates two large open pit mines in
10 southwestern Montana, and then Imerys operates the
11 Yellowstone Mine also in southwest Montana and another
12 mine here in Ludlow, Vermont.

13 The photo there is a distant view of the Yellow
14 stone Mine, which is the largest talc producer in the
15 U.S. for several years now. By state, production is
16 largest from the Montana deposits followed by Texas and
17 then Vermont.

18 Just a little background on our most recent
19 domestic talc production and uses. This is information
20 from our USGS National Minerals Information Center. In
21 2017, the last data that's been published, U.S.
22 production was estimated about 540,000 metric tons,

1 valuated at about 108 million dollars. And at least
2 during 2017, the talc that we [the U.S.] produced and
3 sold was used mainly, as you can see, in ceramics,
4 paint, paper; followed by plastics, rubber,
5 refractories, roofing; and just about 3 percent was used
6 in cosmetics.

7 We [the U.S.] export about 210,000 metric tons
8 per year. We also import an estimated 380,000 metric
9 tons of talc, as compared to 540,000 metric tons that we
10 produce commercially. So talc is actually one of the
11 rare mineral commodities in the U.S. these days that we
12 produced more than we import, but it's still a
13 considerable amount of import. By decreasing the amount
14 by tonnage, about three-fourths of our imported talc was
15 used in cosmetics, paint and plastics. So if you
16 include imported talc and domestic production, the
17 primary uses are plastics, ceramics, paint, paper,
18 roofing, rubber; and cosmetics is a distant end of the
19 spectrum.

20 According to our Minerals Information Center,
21 the main import sources in recent years have been
22 Pakistan (35%), Canada (28%), and China (26%), and a
 small amount of processed talc coming from Japan (5%).

1 Just the very basics to get you started. Talc
2 is a magnesium silicate mineral. As you've heard, it's
3 probably -- it's number one on the Mohs hardness scale,
4 meaning, it's used as the example of the soft mineral.
5 It has perfect cleavage on the 001 plane, basically
6 meaning that it's very platy, usually; but as we will
7 see, and as you know, there are fibrous varieties of
8 talc.

9 There are very weak lines between the layers,
10 so they're easily sliding past each other. It gives
11 talc its greasy and slippery feel and its very low
12 hardness. Well-developed, sort of, gem-quality
13 crystals of talc are extremely rare; and common
14 impurities include nickel, iron, aluminum, calcium,
15 sodium, and some excess water, iron probably being the
16 most common impurity to ideal composition of talc.

17 This is the amphibole group of the regulated
18 amphibole minerals we all know and love, if they occur
19 and when they occur in the asbestiform habit, which
20 will be discussed much today. Of these, principally,
21 the minerals -- amphiboles that we're going to find in
22 the commercial scales talc deposits are anthophyllite,

1 actinolite, and tremolite. There is and, of course,
2 has to be always an exception in geology. There is
3 some manganese variety of cummingtonite in the New York
4 deposits that's also been reported and well documented,
5 but for the most part, we're gonna -- I'll show you
6 examples of different deposit types, and we're gonna
7 find that anthophyllite is very common. Tremolite's
8 very common, and occasionally, as part of the
9 actinolite/tremolite series, we'll find some
10 actinolites in deposits.

11 We also -- as I said, spatially, in one
12 deposit type I'll show you. Chrysotile is associated
13 in the -- abounding in wall rock, country rock; and
14 chrysotile, being of the amphibole -- or I mean -- I'm
15 sorry -- of the serpentine mineral group. But if
16 you'll notice the formula for anthophyllite, chrysotile
17 and, if I back up to the other amphiboles, magnesium,
18 silica, and water hydroxyls are the critical elements
19 to form all of these -- the regulated asbestos
20 minerals. And also, if you notice, talc is, again, a
21 magnesium silica hydroxyl formula. So the same
22 chemistry involved in the formation of the amphiboles

1 is also the same chemistry in the -- or critical
2 elements that form talc, so it's not unusual to find
3 the amphiboles in a talc deposit, at least based on the
4 chemical components of the systems.

5 Talc is a replacement mineral. For example,
6 it doesn't form, you know, straight from a magma like
7 mag minerals. It's replacing a preexisting magnesium-
8 rich mineral with preexisting magnesium-rich host rock,
9 and these would include either a dolostone -- you've
10 heard of dolomite, a magnesium calcium carbonate rock -
11 - or replacing an ultramafic rock, which is a magnesium
12 iron-rich metamorphic rock. So you have the magnesium
13 in the host rock already available, and then, if
14 heated, core fluids, usually waters, carrying silica in
15 solution, react with the host rock to provide the
16 elements to form talc. And these processes can be
17 driven by regional metamorphism, tectonic scale, and a
18 regional scale, heat and pressure, whereby, contact
19 metamorphism where igneous intrusion of magma intruded
20 directly into the host rock or the -- by the
21 circulation of magnetic hydrothermal fluids. Those are
22 heated fluids, heated by magma that's at depth that

1 didn't come in direct contact with the host rock, but
2 I'll show you examples in the United States of each of
3 these.

4 Probably our best example of regional
5 metamorphism in this case is -- cold stone magnesium
6 calcium carbonate is a good -- our best example of a
7 regional metamorphic talc deposit. These were mined on
8 really for the first time on a larger scale mainly
9 underground mining, but a lot made smaller open pits
10 starting in 1948, shown by the red squares; and then
11 the open pit -- larger open pit operations were from
12 1974 till about 2008 when the mines closed, shown by
13 the hot pink ovals.

14 The conditions that form these deposits over a
15 billion years ago, again, were from regional
16 metamorphism shortening the depression of the crust in
17 that region over a large area; and this drove the
18 fluids, under high heat and pressure, from the silica
19 being gathered from silica-rich rocks beneath and then
20 probably accessing fault and fracture systems, moving
21 the silica in fluids up into the dolomite, massively
22 replacing portions of the dolomite by talc and

1 amphiboles.

2 This is -- take you back to chemistry a little
3 bit, but these were -- progressive reactions from top
4 to bottom go from highest heat and pressure down to the
5 lower portions of heat and pressure in the system as
6 the system start to relax and heat also decreased.

7 First we take dolomite in the presence of the
8 invasion of that silica in fluids to form tremolite and
9 calcite. Carbon dioxide can easily leave the system.
10 Now we have tremolite in the presence of the remaining
11 dolomite, again, with waters involved can form
12 anthophyllite and calcite; and as the heat and pressure
13 decreased even further, that new anthophyllite in the
14 presence of siliceous waters, again, forms talc. This
15 is a progressive stepwise occurrence that are in this
16 metamorphic system, starting with a dolomite -- a
17 magnesium calcium source rock.

18 Most of the tremolite in these deposits is
19 described as, I would say, prismatic in shape. They're
20 elongate but certainly not clearly fibers. But then
21 you have this fibrous talc, which is the replacement of
22 the anthophyllite, formed during phase 2, if you will;

1 and the talc has, occasionally, partially to completely
2 replaced the fibrous anthophyllite; and this gives the
3 -- the terms fibrous talc or tremolitic talc have been
4 used to describe the Gouverneur talcs, and this shows
5 you a map of why.

6 And then we also have quite a few of these
7 transitional fibers, which are the partial and
8 sometimes complete replacement of the preexisting
9 anthophyllite by talc, so it can get very complex.

10 Our next deposit type to consider are these
11 amphibole. They're tremolite. They're in talc
12 deposits in the southern Death Valley region. I
13 started studying these about 15 to 16 years ago, just
14 curious to see what the morphology of the tremolite
15 within these deposits looked like under high
16 magnification. They're -- well, I should go back a
17 little.

18 There are 43 talc deposits that were either
19 mined or prospected in the Death Valley region,
20 including a couple dozen within Death Valley National
21 Park itself. These became part of Death Valley
22 National Park. They are now property of the national

1 park when the national monument was converted to
2 national park status in 1988. There's still a couple
3 dozen other talc deposits outside of the realm of the
4 national park boundaries which lie on a mixture of
5 mined claims and federal lands. These talcs were used
6 primarily in ceramics, especially ceramic tiles, as an
7 -- and as an extender within paints. This is an
8 example of some of the mines outside of the national
9 park. As I said, there's quite a few. They're easy to
10 spot from long distance. White piles against the gray
11 dark background of the region. I'm getting hot looking
12 at this again. (Audience laughs.) It was 110 that day.
13 There are a combination of open pits and underground
14 mines that are actually not deep underground mines.
15 They're just added straight into the talc tremolite ore
16 bodies.

17 This is a schematic diagram from Warren
18 Wright's very fine descriptive report on the Death
19 Valley deposits. He has a description of each one of
20 those 43 deposits in the region. It's more of a
21 general geology discussion. He did not have the use of
22 microbeam technology to look at very fine fibers at

1 that time, but it's a very good guide to where these
2 occur in their basic geology.

3 And, essentially, what you have is that gabbro
4 soil is the magma that intruded into the tridy (ph)
5 dolomite, which is a term being silica; and it's a
6 silica magnesium carbonate-rich host rock providing the
7 magnesium for this reaction; and this reaction formed a
8 talc-tremolite orebodies which can be generally around
9 50 feet in thickness. So the heat drove this reaction.
10 Warren has suggested, and it seems reasonable, these
11 sediments may have actually been -- or this dolomite
12 might have actually been a sediment -- part of a
13 sediment sitting on the shallow ocean floor when it was
14 intruded by the magna; and this could accomplish some
15 of the sodium we find in a little bit of the mineralogy
16 in here. So in the end, this reaction formed talc -- a
17 mixture of talc, tremolite, calcite, dolomite, and
18 quartz. So these were not considered, therefore, a
19 high-purity talc; but they are very suitable for use in
20 ceramics and paint.

21 This is just a good view of the system I just
22 showed schematically. The gabbro soil magma that

1 intruded into the tridy dolomite -- the silk magnesium-
2 rich host rock -- and the reactions on the talc
3 tremolite rock would be the ore itself; and it has very
4 sharp contact between the intrusion and the talc
5 tremolite rock, the replacement of the dolomite. You
6 put your finger on that. And forgive me, I'm a
7 geologist, I got to show some of these details; but
8 they're very layered sometimes, and it's very crumbly.
9 The advantage of mining talc is that it generally
10 doesn't require blasting. Heavy equipment can easily -
11 - you're talking about the softest rock, and if you
12 find a talc rock that's even the least bit hard, that
13 means it has a fair amount of quartz or calcite in it.
14 There's a little rock number for -- scale number on the
15 side there.

16 So what we see, via scanning electron
17 microscope, is a wide variety of shapes and
18 morphologies within the tremolite in the Death Valley
19 talc. For the most part, what I describe as
20 "prismatic" is the most common form; but we do find
21 these circular needle-like particles of tremolite and
22 some that are very characteristic of the stuff it

1 formed. For example, we find fiber bundles of
2 tremolite mixed with the clay you tab (ph), or if the
3 analysis was by electron dispersive spectrometer that
4 is, of course, part of our SEM, so -- and we do find
5 these -- most of these are dust, dabbed from the inside
6 of the plastic sample bag; so these would represent
7 dust that easily release here in the sample, but we did
8 find plenty of individual fibers in the dust and little
9 -- again, fiber bundles. The Smith liner is east of
10 the park, and I've been told that there is a company
11 that in recent years has been looking -- or has been
12 excavating former stockpiles of talc, and I'm not sure
13 it's being shipped to a paid factory or not, but this
14 is something I think should be kept in mind.

15 We also found scattered particles with a sodic
16 composition. Again, this is from electron dispersive
17 spectroscopy, which would not be considered a precise
18 method; but they're clearly a sodic-calcium amphibole,
19 and the best fit would -- from our work is the
20 amphibole winchite. And, again, we find some fibers
21 and fibrous bundles that fit another sodic-calcic
22 amphibole being richterite.

1 So my point here is these Death Valley talc
2 deposits formed by contact metamorphism where the magma
3 protruded directly into the host rock I think need to
4 be considered if you -- oh, we hear of activity of re-
5 mining these deposits and the dust that can be created.

6 Our third category of talc-forming
7 environments include the replacement of ultramafic
8 rocks. These are magnesium iron-rich rocks formed by
9 either metamorphism and alteration of an olivine-rich
10 rock, a pyroxene-rich rock or an amphibole-rich rock;
11 and these alter to form a rock called serpentinite,
12 which is a serpentine-rich mineral -- or serpentine-
13 rich rock; and these can, of course, as we know on many
14 instances, contain chrysotile and occasionally and
15 sometimes anthophyllite and tremolite.

16 This is a very cartoonish diagram of work by
17 Rick Sanford in 1982, his long article in the
18 American Journal of Science, which is basically a
19 summary of his Harvard PhD study. And first of all, he
20 determined, at the bottom there, these reactions
21 occurred at very high temperatures, very high
22 pressures; and this would be -- it's hard to generalize

1 a complex system, but this would be the general
2 zonation of what would be visible at the Vermont talc
3 deposits, for instance. And on the left, they're
4 replacing an ultramafic rock, that magnesium-rich,
5 serpentine-rich; and those can, certainly locally,
6 contain chrysotile, tremolite, actinolite, and
7 anthophyllite.

8 You move inward towards the talc ore, you have
9 a talc carbonate rock, a talc with magnesite --
10 magnesium carbonate unit, which contain lesser amounts
11 of dolomite and calcite, and evidence of talc replacing
12 apophyllite. And we move into the talc zone, which it
13 is often described as a high-purity talc, meaning it
14 really has a little courser clay or calcite. It's not
15 gritty. It's a very soft, relatively pure talc.

16 The occurrence of anthophyllite mentioned or
17 actinolite or tremolite fibers within this talc were
18 still a matter of some debate. I, personally,
19 unfortunately, have not been able to look at any of the
20 raw ore, but I welcome samples or an opportunity to
21 sample.

22 This is bounded by an actinolite fluoride-rich

1 rock. There's evidence of talc replacing actinolite to
2 minor amounts. Perhaps much of this is actually
3 tremolite. Rick did not have the benefit of microbeam
4 analysis at the time.

5 Then we move outward to the altered country
6 rock, which is the country rock being a metamorphic
7 silica-rich rock or gneiss; and some of the metamorphic
8 texture remains, and you have some prismatic classic
9 amphiboles and then outward to the unaltered gneiss on
10 the opposite side of the system. So you're getting
11 this silica sourced by the country rock and the
12 magnesium clearly sourced by the ultramafic rock, and
13 it's a complex system that occurred under very high
14 heat and pressure.

15 But the good news, not all talc is created
16 equal. There are another type of talc deposit. These
17 are formed like the upward circulation of hot silica-
18 rich fluids that are heated by igneous intrusion that
19 lies at depth. It's not coming in direct contact with
20 the host rock, and these can form very large talc
21 deposits by the massive replacement of that dolostone
22 and magnesium-rich marble; and in this system no

1 amphiboles or serpentine are created. And they're
2 relatively simple reaction on a stone, like, again,
3 heated silica -- or heated fluids would carry silica,
4 forming talc calcite and carbon dioxide.

5 This is a very cartoonish depiction of that,
6 but you have the magma rising through the crust heating
7 any fluids, core fluids or even if groundwaters exist
8 in the system. The black lines representing fault and
9 fracture systems which surely help to plum the heated
10 waters upward through silica-rich metamorphic sedentary
11 rocks that can provide the silica and then massively
12 replacing parts of the magnesium-rich marble above.
13 The edges of the deposit can have considerable quarts,
14 calcite, and dolomite, and pockets within the talc
15 body; but for much of the talc body, more than 90
16 percent of it is platy talc. There's a -- of --
17 deposits of this type in a quarter -- we're in
18 southwestern Montana -- are very large deposits, and
19 these may be -- this may -- probably represents the
20 largest talc district mill in the United States; and
21 they all form from the replacement of those dolomitic
22 marbles, intrusions at depth; and this includes the

1 Treasure Mines and the Regal Mines of Barrett Minerals
2 and the Yellowstone Mine of Imerys.

3 This slide and the next I credit to Childs
4 Geoscience, consulted out of Bozeman, who published one
5 of his PowerPoint presentations. This is a generalized
6 geologic map of the Yellowstone Mine area, the
7 Yellowstone deposit. The blue being the marbles that
8 have been replaced. The red is the talc -- the talc or
9 body which is about a half a mile in length north and
10 south, and all the black lines being fault systems
11 which surely helped plumb the -- in the plumbing system
12 for the heated silica-rich fluids that moved up and
13 invaded and replaced the dolomite.

14 That Burlington northern pit up at the north
15 was another large talc deposit mined many years ago,
16 and that pit has been reclaimed.

17 The Yellowstone talc mine itself, it's very
18 large. It's the largest known talc deposit in the
19 United States. I'm not here -- I want to make it
20 clear, I'm not here to endorse the deposits of
21 southwest Montana. I'm just making the point that not
22 all talc deposits are created equal. Some can lack

1 amphiboles we plan to discuss, but it -- my work has
2 led me to show that the geologic conditions that came
3 to form the talc deposit directly impact whether
4 amphiboles or serpentine, in one case, exist at all to
5 discuss.

6 And as a lead into Greg's talk, again, I want
7 to emphasize that even within one talc district, or even
8 within one talc deposit, you can get a wide range of
9 mineral morphologies; and these may not be obvious or
10 visible without microbeam analysis. So I think we need
11 to -- well, this will be discussed all day long
12 hereafter; but there will -- to get down to the scales
13 that clearly show this variation, it may require things
14 beyond standard microscope work.

15 And with that, thank you for your time; and
16 hope we can -- well, you'll hear a lot more in
17 discussion today about -- that led to the
18 identification of this type of variation. Thank you.

19 (Applause)

20 CATHERINE SHEEHAN: Thank you, Brad.

21 I think we can move along and get Greg up, and
22 then we have time for Q&A.

1 So introducing Greg, he's a research scientist
2 specializing in the characterization of fibers and
3 asbestiform minerals. Greg worked as a mineralogist
4 and geologist in the U.S. Geological Survey for 23
5 years before his retirement from federal service; and
6 in 2009, Greg served as a member of the National
7 Academy of Science Institute of Medicine Committee to
8 review the NIOSH program for asbestos research.

9 Greg, thank you.

10 GREGORY MEEKER: Good morning. Catherine,
11 thank you for the introduction.

12 I'd like to thank JIFSAN for inviting me here
13 today to give this talk. It's good to be back in the
14 mix. I've been retired now for six years and enjoying
15 it, but it's good to see a lot of my old friends here.

16 I want to put up this -- oh, and Nora --I want
17 to thank Nora so much for all the hard work she's done.
18 She's really put this together, and thank you very much.
19 I never see her in the room.

20 I guess I need to put up this disclosure here.
21 I have done a little bit of consulting since I retired
22 from USGS, but mostly I've been enjoying summers in

1 Colorado and winters in Florida.

2 So the question today is: Has anything really
3 changed in the last 15 years? And I chose 15 years
4 because I'm going to use a presentation that was put
5 out 15 years ago, and I think we're still having some
6 of the same arguments today that we were then.

7 This is going back a little farther to 1981.
8 Well-known and important mineralogists from University
9 of Minnesota, and he wrote a paper, and he wanted to --
10 said, "Asbestos is one of the most durable [sic]
11 industrial minerals because it possesses an unusual
12 combination of exploitable properties, such as long
13 fibrous shape, high tensile strength, and flexibility,
14 both thermo and electric conductivity, high absorbency,
15 high chemical and mechanical durability and
16 incombustibility." And then he says, "Ironically,
17 industrial desirable properties of asbestos also appear
18 to be responsible for carcinogenicity."

19 I'm gonna come back to this at the end of the
20 talk, but I just wanted to put that out at the
21 beginning because it -- I think it kind of frames the
22 whole discussion.

1 So I think the questions for us here today --
2 it was hard for me to know quite what to talk about,
3 but I -- is it possible to protect human health without
4 regulating everything? Is regulated asbestos the only
5 health hazard? Is commercial-grade asbestos the only
6 health hazard? Not necessarily the same thing. And
7 what have we learned over the last 15 years about
8 asbestiform and related minerals? Most important
9 question is: What does the human lung or the human
10 body know about all of this?

11 Now, traditional analytical methods may not be
12 adequate for characterizing natural-occurring asbestos
13 or contaminated materials. Most of the methods we use
14 today were developed for the analysis of commercial
15 asbestos. It's when you've got asbestos in ceiling
16 tiles and floor tiles or asbestos in the siding and you
17 want to go in and find out if that material is still
18 there after a clearance or if workers are being exposed
19 in production. So you're dealing with a known --
20 you're dealing with a commercial-grade material, and
21 the methods -- most of them -- were developed to look
22 at that -- the EPA 600, an analysis of asbestos in

1 building materials.

2 There are very -- there's so much nomenclature
3 and definition -- issues with definitions to talk about
4 that we could have a meeting like this for two weeks
5 and just begin to get into the issues, so it's -- one
6 of the issues is the name of an amphibole and how well
7 can we identify an amphibole. Some are listed in the
8 ranks, others are not. Actinolite and tremolite are
9 listed in the government regulations;
10 magnesiohornblende is not; richterite is not; winchite
11 is not; and the analytical methods we have to identify
12 these different amphiboles, because they're based on
13 chemistry, is -- it's not easy to do.

14 And this is an electron probe microanalysis of
15 a -- probably an actinolite particle, and it was done
16 in an electron microprobe on a bulk sample -- polished
17 bulk sample. It's probably the most accurate chemical
18 analysis you can get on a micron or two micron spot,
19 and according to Leake, if you look at this --

20 MAN: I can't see it.

21 GREGORY MEEKER: -- the pointer -- if you look
22 at the diamond right here, if you use the method in

1 Leake 97 to identify what this mineral is, you get that
2 point right on the line between actinolite and
3 magnesium -- magnesiohornblende. If you change the way
4 you calculate the analysis, if, for instance, you use
5 all ferric iron, or all ferrous iron, to make the
6 calculation, because an instrument cannot tell the
7 difference, you could end up with a point up here or a
8 point down here and other ways of calculating the
9 analysis will fall in between these two lines.

10 So the point is that even the best analysis
11 you can get on a very tiny spot does not -- you've got
12 air barns (ph) here. You don't really know if you're
13 looking at actinolite or magnesium --
14 magnesiohornblende.

15 I'm not gonna talk anymore about chemistry
16 because I think the issue here today is morphology, and
17 that's because the amphiboles that you find in talc are
18 fairly easy to identify chemically on a TEM with
19 crystal structure. So the chemistry is not as big an
20 issue with the -- usually with the minerals you find in
21 talc, except for the -- the few that Brad talked about
22 -- the richterites and winchites.

1 So let's talk about morphology. Traditional
2 thinking, I think, uses an in-member (ph) approach.
3 In-member is a term that enterologists are familiar
4 with. It's an in-member approach with no solid
5 solution, which means you either have one solution at
6 one end and the other and nothing in between. I think
7 this is a way to look at it is stove piping. So you
8 either have commercial-grade asbestos over here or you
9 have everything else, which really, over the last about
10 30 years, have incorrectly been termed "cleavage
11 fragments." Some of them are; some of them are not;
12 but it's just all been kind of dumped into this one bin
13 that everyone seems to call cleavage fragments. So
14 it's either the bad stuff -- whoops. Sorry. It's
15 either the bad stuff over here on the right or the
16 stuff that doesn't hurt you on the left.

17 Well, there are a lot of definitions for
18 cleavage fragments; and I mean, I can't read all of
19 this, but they're really all saying the same thing.
20 And the summary, I think, is that cleavage fragment is
21 not any particle that does not meet some specific
22 definition of asbestos, and there are a lot of

1 definitions of asbestos also. Cleavage particles must
2 be particles broken from larger crystal, along specific
3 crystallographic point. So it's not only a broken
4 particle, it's broken in a certain way related to the
5 crystal structure in the mineral.

6 EMP. Why people don't like the term "EMP."
7 EMP is a general term for any elongate mineral
8 particle. It could be a cleavage particle. It could
9 be an acicular crystal. It could be an asbestiform
10 particle. The term was meant to be used for research,
11 not for regulation.

12 Cleavage fragments, over the years, in my
13 opinion, have become the proverbial get-out-of-jail-
14 free card; and that's due to misuse and
15 misunderstanding of the terms: asbestos, asbestiform,
16 cleavage fragment, and a whole bunch of others. The
17 term "EMP" is not meant to be used in place of specific
18 mineralogical nomenclature when the correct terms are
19 known and when they are properly used. A lot of these
20 terms are misused, and that's a problem.

21 I want to go into this presentation. I think
22 at least one of the primary authors is here, Ann Wylie.

1 I don't know if Kelly Bailey is here, but I want to use
2 this. There's a lot of good information in here. I
3 want to say that at the beginning, and there's a lot of
4 good health information that I'm not going to get into;
5 and we need another meeting like this to deal with
6 that, but I want to use this to illustrate some of the
7 points that I feel important.

8 The introduction says, "Despite this
9 attention, a clear understanding of what asbestos
10 actually is remains a source of confusion to many," and
11 that's very true; but that's also talking about
12 commercial-grade asbestos. "No federal regulatory
13 agency treats elongated nonasbestiform particles as
14 asbestos, yet some in the regulatory and health
15 community believe they should. These individuals
16 mistakenly believe that the essential differences
17 between nonasbestiform minerals and asbestos is not
18 significant," and that's getting back to the first
19 slide I showed from Zoltai from 1981. And I think a
20 lot of people here would agree with this, and I think
21 there are a lot of people who would not.

22 "Health researchers who fail to understand

1 these differences can assign and have attributed the
2 carcinogist -- carcinogenic" -- excuse me -- "effects
3 of asbestos exposure to nonasbestiform minerals."

4 And so here is an example from that
5 presentation showing what asbestos should look like,
6 and again, I think this is a good example of good
7 quality commercial-grade asbestos, particularly
8 serpentine; but it says the single most important
9 morphological characteristic of the asbestiform habit
10 is the fibrous polyfilamentous characteristic.

11 This is an example that I think shows what
12 that drawing -- previous drawing was trying to show.
13 You can see these features -- very thin fibers,
14 parallels, maybe some curvature there. This is
15 tremolite from Death Valley. I think Brad had this
16 image or took this image. It's from the USGS website -
17 - on the microprobe website.

18 This is the diagram showing the nonasbestiform
19 particles, and nonasbestiform crystal growth tend not
20 to grow -- excuse me -- not to grow with parallel
21 alignment. They form multidirectional growth patterns
22 instead. I guess they're saying that crystals are

1 strong, but crystals grow in a cluster like that. And
2 then it says that when pressure is applied, they easily
3 break apart and form the particles that you see over on
4 the right with stair-steps on the surface and -- so if
5 we tried to find one that looked like this, maybe this
6 one would be a good example. This is an amphibole
7 particle. The -- let me get this pointer. You can see
8 these stair-step patterns on the edge. Maybe if we
9 look a little closer, I think this looks very much like
10 this guy over on the right here; but you've got these
11 steps on the side, kind of a flat top. Things look
12 like they might be breaking off or partially broken off
13 on the side.

14 So what is this that we're looking at? This
15 is UICC crocidolite, and you know what? Ore mag looks
16 like this. There are a lot of particles that look like
17 this, and maybe some people would call those cleavage
18 fragments, and then here's the particle we looked at
19 earlier.

20 Another publication that came out in '77 from
21 the Bureau of Mines. This one's showing massive
22 anthophyllite here and massive actinolite over here and

1 then saying that this is not asbestos. Anthophyllite
2 asbestos looks like this. Actinolite asbestos looks
3 like this.

4 I'd like to show you some other images of a
5 similar theme. Here's a massive gem part richterite.
6 This sample is very hard. If you hit it with a hammer,
7 it will crack. You can't just peel it apart like we
8 used to do in mineralogy class decades ago. And then if
9 you look at -- down here there's some little particles,
10 and if you look at those particles, if you can just kind
11 of brush off the surface, that's what they'd look like.

12 Here's another one. El Dorado Hills tremolite.
13 Again, it's a massive-looking rock here. Hit it with a
14 hammer, it's hard, it will crack; but it sheds
15 particles, and this is what those particles look like
16 under the SEM.

17 Here's Libby. This is a very hard rock. I
18 spent a lot of time beating on these rocks. (Audience
19 laughs.) And believe me, they are hard, and -- but this
20 stuff just flakes off the surface. If you look at it
21 under the microscope, that's what you get. This is

22

1 from USGS publication on El Dorado Hills from 2006.
2 And this curve on the left is from camera 77 showing
3 the aspect ratio versus frequency for particles that
4 they classified as cleavage fragments, and you can see
5 they're all down here with a very low aspect ratio.

6 They also did asbestos particles. I can't
7 remember what they used, but this curve for asbestos is
8 hard to see; and I apologize, but if you follow the
9 pointer, it goes way out here, and the aspect ratios
10 can be very high.

11 Well, the material from El Dorado Hills,
12 California, falls in between. It's not here, and it's
13 not under this -- similar to this asbestos curve. It's
14 in between. These are not from a single deposit.
15 These are particles that were gathered over a wide area
16 that come from a range of sources, but still, they're
17 in the dust that people are breathing in the park in El
18 Dorado Hills.

19 This is Libby showing kind of the same thing.
20 There's asbestiform material. There's stuff pretty
21 much everybody would call cleavage fragments, a lot of
22 stuff in between. Here's the asbestiform cleavage

1 fragments, but I've looked at a lot of this material,
2 and most of it looks like this. What do you call that?

3 Again, here's another Libby particle. It's
4 got a little bit of everything. There's very long,
5 very thin things breaking off up here. There are
6 things breaking off that look like cleavage fragments.
7 Top of the slab, you've got structures like you see
8 here. What do you say about this? I say it's very
9 difficult to say what this is, but I think a lot of
10 people here would agree that there are hazardous
11 particles here.

12 AUDIENCE MEMBER 4: It's not respirable.

13 GREGORY MEEKER: Pardon me?

14 AUDIENCE MEMBER 4: The particle you showed is
15 not respirable.

16 GREGORY MEEKER: This big one isn't, but this
17 one over here, which looks like it's fallen over, it
18 is.

19 AUDIENCE MEMBER 4: I understand. Yes.

20 GREGORY MEEKER: So for years the toxicity of
21 asbestos has been attributed to the special properties
22 of commercial-grade asbestos -- tensile strength --

1 when aspect ratio, curvature, and chemistry of these
2 properties really only by an aspect ratio have been
3 clearly demonstrating to correlate with toxicity.

4 We're working on this instrument now, and I
5 hope to get it operational soon. (Audience laughs.)

6 So let's go back to that Zoltai paper, and
7 this has been referenced numerous times over the years
8 by many, many people; and we already looked at the
9 first page, and this is a very long paper. It's 39-
10 pages long. So when I first found this, I thought, oh,
11 great, this is really gonna explain the difference
12 between asbestiform and nonasbestiform particles.

13 Well, you read the paper, and 39 pages later, this is
14 all that is said -- (audience laughs) -- in that paper
15 about the difference between why you need those
16 properties for toxicity. That's the end of the paper.
17 It references this Stanton and Layard. It's the NBS
18 special publication 506. And you go to heating, there's
19 nothing here either. I mean, this is all you get. If
20 you heat it up high enough, it's not as toxic.

21 AUDIENCE MEMBER 5: It's not asbestos then.
22 It's another mineral.

1 GREGORY MEEKER: That's right. So here's the
2 slide I stole from Aubrey Miller. I think it kind of
3 sums up what we're talking about here. You've got the
4 total respirable material. You've got the regulated
5 asbestiform material here, and then you've got all this
6 other stuff that's not regulated. It's not commercial-
7 grade asbestos. What do you do with it?A lot of people
8 believe that -- this and that and so can any doctor or
9 toxicologist but believe that these things here are a
10 problem. What does the lung know?What does the body
11 know? I think that's the real question we're dealing
12 with here, and I think as we move forward in any kind of
13 effort to put together a statement or a summary for
14 this, we have to keep this in mind.

15

16 So that's all I have. Thank you very much.

17 (Applause)

18 CATHERINE SHEEHAN: So next up I would like to
19 introduce professor Martin Rutstein. He's a retired
20 professor of mineralogy, teaching and research
21 interests in: mineralogy, metamorphic petrology,
22 optical mineralogy and environmental geology,

1 especially particulates and toxic chemicals; and
2 presently co-chairs the U.S. Pharmacopeia Expert Panel
3 on talc and asbestos in pharmaceuticals and is an
4 expert witness in state and federal courts on asbestos
5 and lead-based paints, so --

6 MARTIN RUTSTEIN: I guess I don't get to go
7 for a bathroom break. (Audience laughs.) That's a lot
8 to ask for. Let me just set the timer. Are we ready?

9 It's -- no, like this. We're just saying. I
10 know where the mic is.

11 CATHERINE SHEEHAN: Okay.

12 MARTIN RUTSTEIN: There's going to be a -- she
13 got me all set. We'll go back to that. Okay.

14 When I got the call, "Would you talk? Would
15 you like to talk?" oh, yeah. Sure, I would love to
16 talk. (Audience laughs.) They said, "This is what
17 you're going to talk about," four things, which
18 injected a tremendous --

19 You gonna fix this thing?

20 -- which injected --

21 TIM: Yes.

22 (Background noise)

1 TIM: Will you test it?

2 MARTIN RUTSTEIN: Okay.

3 MAN: Sure.

4 TIM: All right.

5 MARTIN RUTSTEIN: Here we are. Okay.

6 Which injected, immediately, controversy over
7 limitations, damages. Mickey was beside himself. If
8 you're there, Mickey, on the webinar, ha-ha-ha.
9 (Audience laughs.) I took -- I listened, to you
10 honest.

11 So I'll tell you how I picked the topics. I
12 didn't even know who I'd be talking to. It started
13 off, is it going to be done with regulators? Would it
14 be people who are wizards in this? Some division -- I
15 had no idea. It wasn't until just a few days ago that
16 I finally got a handle on who would be in the audience.
17 I've been working on this for some time. I think I've
18 tailored it in a way that you'll all get something out
19 of it.

20 My life has largely been teaching students and
21 also out in the real world where somebody does
22 something about asbestos, in terms of containment. I

1 dare say to Brad, I probably spent more time in
2 containment than him and anybody in this room. It's a
3 different world out there from the laboratory. I also
4 headed up a NVLAP/ELAP lab, so I know my way around a
5 laboratory.

6 So how do we measure and characterize the
7 elongated stump? Before Brad jumps up and down on this
8 one, we never use "elongated." Beat that into him. It's
9 elongate particles. So we're really looking at these
10 things that are longer, and let's talk -- I'll talk
11 about those. I've got a lot of stuff to do, a short
12 time to do it, so let's get on it.

13 First, there's some really smart people that
14 I've had the honor to work with -- the USP panel. The
15 first one, I put it on the reference list, the first
16 stimuli article. It's really worth looking at. Five
17 years of heavy intense work from really bright people.

18 The second panel, many of you are here. I
19 thank you. It's because of you if I seem further, it's
20 because I've stood on their shoulders; and some of them
21 people are so darn smart when it comes to analytical
22 work that I find it scary, and they were fortunate.

1 They have some of the best instrumentation going. I'm
2 talking as an individual, not on behalf of USP. They
3 drill into us every meeting we have that the meetings
4 are confidential, they're works in progress, it's where
5 we're going; and I think probably three years into this
6 -- or two and a half years -- and were able to get a
7 stimuli article on methodology published. At the
8 beginning I said we had a certain amount of time to do
9 it in.

10 Okay. Their idea, the first one.
11 Mineralogists, it's like the cowboys and the cow have
12 been in this sprint for decades on whose language,
13 whose words we use. There are thousands of minerals,
14 and mineralogists have their own cult, in terms of
15 understanding the words we use and then often not the
16 same that the regulatory community uses or that
17 biologists use.

18 We go at minerals to identify them, and we
19 characterize them. We do it on the basis of structure
20 and composition. And probably, if you're interested in
21 this two-page summary from Micky's and Gabby Diers's
22 (ph) book, 2008, it's posted as a reference;

1 and it's really worth reading if you want to understand
2 the side of the geological and mineralogical community.
3 Not all of them. We all differ. We disagree. We
4 argue. It's a pretty good summary on how we identify
5 minerals.

6 However, asbestos is also defined as the
7 regulatory six. We all know those. We dream about
8 them. We eat, sleep and -- we know them so well. I
9 like the sum that Brad just did on -- or Greg did on
10 the chemistry. In one version of this presentation, I
11 got over 50 tremolite mineralogical cousins based upon
12 the Leake classification -- name after name after name
13 after name, and it really is messy.

14 We have the regulated six, and I'm working off
15 those. That's what's in the regulations that we have
16 to live with -- chemistry and usage, also shape and
17 size. The standard five microns long, bla, bla, for
18 the long asbestos fibers. You don't regulate the short
19 asbestos fibers, but they're out there. They're at one
20 end, and then we've got the cleavage fragments at the
21 other end and this EMP thing that we'll talk -- I'll
22 talk about in a little bit too.

1 We also define asbestos medically and
2 bioreactivity. I've come a long way over the decades.
3 I've looked at this. I did my first asbestos
4 inspection in 1972, before many of your parents were
5 even born. I looked at this stuff in the field, I've
6 look at it in the lab, and more and more I'm evolving
7 toward: What's respirable? What gets into the body?
8 What can cause harm? But we have to live within the
9 rules of what's regulated.

10 We also have this characteristic of a motion.
11 I can empty a building by saying, "Asbestos is falling
12 down from the ceiling." People have been convinced --
13 it's almost a religious thing, good versus evil --
14 asbestos is bad. There's very little debate out in the
15 public area, and I think that one of reasons the jury,
16 say, in St. Louis are coming down so hard against
17 Johnson & Johnson is because they hear the word
18 "asbestos" and right away the bell goes off -- bad,
19 death, evil, punish somebody.

20 I put together these several pictures of
21 different materials: talc ore; talc powder, the
22 products; and then, from Brad, some of the stuff from

1 Death Valley; and the calcium amphiboles. In 2007,
2 Dodson came up with 30 different analytical methods for
3 asbestos. The number's even larger now. If you do a
4 search and you spend the time -- is Ella (ph) here?
5 Ella, is she at break?

6 AUDIENCE MEMBER 6: Yes.

7 MARTIN RUTSTEIN: Thank her. You know, you
8 put together that list on the definition of "pride."
9 It was you, wasn't it? Or was it Lee (ph). It was
10 Lee. Sorry, Lee.

11 AUDIENCE MEMBER 6: Go get after him.

12 MARTIN RUTSTEIN: Get after him for all of us.
13 (Audience laughs.)

14 But the list goes on. Hey, I got -- Friday
15 one person says, "Well, I've got asbestos." Another
16 person says, "I don't have asbestos." They used two
17 different methods, and they're not communicating; and I
18 hope to convince you that that's one of the really
19 important goals that we have to come up with is a
20 definition that we agree on.

21 The big issues, as I see it, are these
22 elongate particles, the so-called EMPs: talc,

1 tremolite, anthophyllite. Chrysotile, I worry less
2 about because I think it's so easily identifiable. I
3 can just put it on the side.

4 I don't even put actinolite up because I think
5 that's just a slightly ironness tremolite. There's
6 also a lot of other minerals, especially sepiolite; and
7 one of Mickey's grad students, Marian Buzon, finds
8 really neat fibrous sepiolite in some of the Montana
9 mines which could mimic talc, which would mimic, maybe,
10 anthophyllite.

11 The three categories of materials: the
12 cleavage fragments, from a mineralogist, they're broken
13 crystals. They start as big things and you break them,
14 it's a cleavage fragment. How do we break them? A
15 plate or weakness. That's all another source. It's
16 just a broken fragment. The shape, acircular and
17 prismatic. They're just shapes. We used to talk about
18 them as just a morphology. That was a generalization:
19 tall, short, fat -- I guess it's fat shape -- thin,
20 whatever. Thin shape is so much later, but they're
21 just general terms, and they've taken on to some as
22 very important regulatory criteria. Talc (inaudible).

1 Then there's asbestiform minerals, fibers
2 formed by crystal growth. I won't even touch getting
3 into the finding of fiber. There are dozens of
4 different definitions of that all depending upon the
5 method that is being used.

6 So we've got to worry about cleavage, shape,
7 and asbestiform materials. I've stopped talking about
8 asbestiform talc, fibrous talc, because the word
9 "asbestiform" immediately connotes something really
10 bad and regulatable.

11 A couple of time symbols. What you see
12 depends upon what you're looking from. There's a human
13 bias on this. It's real. This is very important. I
14 call it environmental outcome. If you change the way
15 you look at things, the things you look at change.
16 It's one thing to have it in hand sample where we can
17 identify it; it's another thing to go through the
18 microscope, another thing to go in an electron
19 microscopy. Pretty soon you've got really good
20 measurements at both ends of the spectrum but you're
21 coming up with very different answers. What we find in
22 most rocks is something elongated. It just happens,

1 the way it breaks. So it's a level of how much of
2 something is something of concern.

3 Take a look at doctor's papers and Mary's (ph)
4 papers, especially sepiolite on that one. He
5 summarizes in a pre-notation to SME 2016 all the
6 different deposits, and one of the things you should
7 recognize is that the three categories: the regional
8 metamorphic, the ultrabasic, and the -- the basic, the
9 metamorphic and the --

10 AUDIENCE MEMBER 6: (Inaudible).

11 MARTIN RUTSTEIN: -- gabbro, the Death Valley
12 types. Death Valley type, a single heating event. The
13 regional metamorphic, multiple heating events changing
14 of the character of the rock and real effects are water
15 and carbon dioxide during their formation. So it's
16 like boxing around when one mineral forms, and you
17 really have to take that into account, along with the
18 ultramafic rocks. In Vermont, they produce raisins --
19 I mean prunes -- prunes are even a better for you now
20 that you're a senior citizen -- mixed into a dough and
21 then the dough is kneaded, and these individual masses
22 -- the prunes and the raisins -- get cooked differently

1 and they represent a different composition. So you go
2 to one deposit and you find one thing. You go to
3 another deposit, you find something else, and the
4 producer is mixing stuff from each deposit.

5 I thought it was critical. I loved Gouverneur
6 Talc at one level. They were very kind to me over the
7 years, letting me into their mines with my students;
8 but the stuff over at talc mill was very different from
9 the stuff at the iron pit; and for many years, without
10 knowing this, I think was the case, they were mixing
11 stuff in the talc fill. I went there one year, and I
12 think -- actually, they were draining the pit; and I
13 could see fibers blowing in the breeze. I went down
14 and said, "You really don't want to start mining that
15 stuff. Just cover it up." Some of the work that's
16 been done on South Hill has been through surface
17 samples. The stuff at depth in the literature is very,
18 very different. They were bodies that were largely
19 fibers of anthophyllite, contrary to what's on -- they
20 use mining at the surface.

21 Building materials, I think, are really
22 relatively simple. We put the stuff in. We have a

1 criteria of 1 percent, which was only adopted because
2 most of the stuff is 10, 20, 30 percent asbestos. You
3 can see it in the sample.

4 When I mentioned irrespirable, I thought of a
5 funny sketch that I was doing in school where the
6 student was sitting inside a pipe that had a magnesium
7 block filler with cristobalite; and the student was
8 spending the class time, not listening to the teacher,
9 pulling out the blue fibers and going -- (blowing) --
10 in the air. (Blowing) I had closed the room. It was
11 very inadequate.

12 So building materials -- I would say that
13 mineralogists, who's into asbestos, can identify a hand
14 sample easily 80 to 90 percent of the asbestos that he
15 sees just by a hand sample. Pharmaceuticals, much more
16 complicated -- much more. If there's anything there,
17 it wasn't put there deliberately or it was put there
18 inadvertently, and it's much smaller, and you can't
19 really see it most of the time in a hand sample.

20 So the definition of conundrums, as I
21 characterize stana (ph), are mineralogical, industrial,
22 regulatory, and legal. We have to agree upon some

1 method that gives us an answer that discriminates
2 asbestos from nonasbestos particles, and you heard Brad
3 and Greg pretty much address this issue. We got these
4 things. What are they as we start to look at them with
5 finer and finer analytical techniques?

6 Take a look, if you haven't seen it already,
7 the papers by Gordon et al. against versus R.J. Lee and
8 Drew Van Orden. I slugged through these papers, and at
9 first, this guy is right. This guy said, "No. He's
10 wrong." And this guy seems right. This guy says, "No.
11 You're lying. You're wrong," and it goes back and
12 forth. Have a bottle of Advil right beside you as you
13 go through it. (Audience laughs.) That illustrates to
14 me some of the profound questions are trying to come up
15 with the answer for the property owner, a building
16 manager, a miner, and a government regulator.

17 So which method is best? Go to all types or
18 tab asbestos four. The alphabet soup, for anyone who's
19 into this -- and I'll explain one of them -- each has
20 individual and corrective advantages. Each one is
21 unique in its own way. Here's a -- fundamentally, in
22 geology and mineralogy we teach students to identify

1 hand samples. Mickey, in that chapter 19 introduction,
2 says that's really -- if I understood it right, not
3 completely adequate. You need more sophisticated data,
4 chemistry, and structure. I think that a large part of
5 traditional mineralogy and probably part of the core
6 arm of this disagreement with some of the regulators
7 and biologists has been that geologists will take
8 something that they know is fibers -- you can see it.
9 You can roll it between your fingers. You can take a
10 torch or a barbecue lighter, try to burn it. A really
11 convenient field method -- we do it all the time in the
12 field -- is to take building material, hit it with a
13 flame; and if there's something left over that we can
14 rub and ball up, it's almost certainly going to be
15 asbestos.

16 I'm looking over here at some fibrous talc.
17 It's that picture that is -- whether it's
18 anthophyllite, asbestiform going to talc, as some
19 believe, or nonasbestiform anthophyllite going to
20 asbestiform or fibrous talc, as others believe, is
21 really the heart and soul in this. I look at this under
22 the microscope. I look at the images that

1 others have taken with TEM, and boy, some of them really
2 walk and talk like anthophyllite being asbestiform.

3 Then there's this stereo zoom microscope.
4 Remember in '79 arguing with the people who were writing
5 the original RE's book on methods for hand sample
6 analysis building materials. Saying, "Look at it with a
7 stereo zoom scope. You can see so much. Even for some
8 of the talc products you can see them prismatic. You
9 can see light coming up at you from a prismatic
10 fragment," and I am going to move more and more toward:
11 If you have anything, you're probably going to have
12 aggravation. So maybe that's the goal is to find
13 products that don't have any amphiboles.

14 Optical microscopy. Two major methods: the PCM
15 and the PLM. PCM industrial site. Their samples gave
16 us lethargy and as Dan Prey (ph) always says to me and
17 to colleagues when we're talking: This is what's
18 regulated by Government -- the federal five, the 3 to 1.
19 PLM, this is a really useful technique from building
20 materials -- polarized light microscopy. This one you
21 actually get some clue from structure

22

1 decomposition. This one clearly is interference by
2 defect -- right interference defect where you just see
3 shapes. So the way I might go with this with you is
4 that I'll march through the different methods -- PLM,
5 polarized light microscopy -- and let's talk about
6 advantages and then quote something more than
7 disadvantage. The big thing about light microscopy,
8 PLM, it's coded. We have rules, and it's wide spread.
9 Any lab who's doing asbestos has the PLM, and sometimes
10 they have people who have been trained with courses in
11 polarized light microscopy. Other times we're taking a
12 shake and bake. Unfortunately, in the geologist
13 community more and more universities are getting rid of
14 light microscopy as a course saying instead let's go to
15 the TEM, the SEM. Let's go to more sophisticated
16 techniques because this is an old fashioned technique,
17 but boy, it really works. It's especially good for
18 building materials. So I give it, on the scale, a
19 really high grade. It's up in the green. It's a
20 pretty good technique.

21 Then instead of just disadvantages or limitations, I
22 describe it as issues along with disadvantages. One of

1 the big criticisms on PLM has been its magnification
2 limit -- 400. If the wind is blowing right, maybe you
3 can get up to 450 and hope you see something; but
4 there's really anything to me beyond 3'-350 you go
5 easily in the wind. However, that quantification is
6 improvable by techniques such as sieving quality
7 nitration and you can probably -- as someone told me,
8 they can get down to a detection with 100 parts per
9 billion on polarized light microscopy which is really
10 pretty good because 100 ppm or something probably
11 doesn't have a whole big effect on human health. At
12 least I would gladly be exposed to 100 ppm if I had to.
13 It just doesn't concern me when I look at the
14 regulatory limits of what we can have in an industrial
15 workplace.

16 So I'm not going to talk about all these
17 things. Look at them. I showed them to you. There on
18 the notes that I posted, and if you're into PLM, we can
19 talk about these at great length; but the big thing to
20 me are the disadvantages -- its supposed limitation. So
21 I give it not so good a score. This is Dancing with
22 the Stars kind of thing. You moving over but you can

1 correctly bring it back if you do this.

2 Then we get to high-tech instrumentation or
3 the stuff that's out there now and clearly unamazing.
4 We have x-ray diffraction from structural fingerprint,
5 and we have electron microscopy that will give us
6 structure and chemical analysis all of which has to be
7 done right. The advantages are extra. It's fast. I'm
8 getting -- I'm trying to convince Carlisa (ph). The
9 minute you get a sample in, the first things you do is
10 look at a PLM and while you're looking up there trying
11 to make up your mind, do a scan, do an XRD scan of a
12 certain portion of the spectrum -- of the angular
13 region of interest and look at both of these states
14 together.

15 So it's fast. It gives you gross ID. You get
16 much of the minerals that are present, and you can
17 improve it again by concentrating the sample and
18 adjusting the scan speed. So we'll give it a good
19 grade from XRD.

20 The disadvantages, there's a lot of
21 aggravation if you have an X-ray machine: radiation
22 protocols, you need to the calibrate the machine to the

1 standards, etc., and it gives you very poor shape
2 information. Back when the pre hero rules were being
3 written, X-ray was really omitted. Why? Because it
4 didn't tell you anything about shape, so people just
5 pushed it aside, and it lost a lot of its relevance. I
6 think it's coming back now because it gives you a quick
7 answer in the case of talcs over whether there are
8 other minerals concerning them.

9 The two issues that I'll talk about are
10 overactive beats and detection levels, and they are
11 really both the same which will allow us to raise the
12 negative score to something that's better.

13 So here is a measuring fractured scale taken
14 at (inaudible), and the critical point is right about
15 here. There's an amphibole at 2 degrees -- two
16 category, 2 degrees to fail, and it's very hard to see
17 because the talc peak is masking it. So the way you
18 can get around that is just to do a slow scan -- the
19 talc peak stands out and the amphibole peak right here
20 on the shoulder is identifiable at 10.2. So you can
21 see if you've got amphibole in your system, but right
22 away we've got two techniques that work very, very

1 quickly and independently of one another: the PLM to
2 see whether you have any fibers. You push it in and
3 out when you measure and the inside (inaudible), and if
4 you've got amphiboles, they know you have aggravations.
5 Then you can immediately decide: How far do I push the
6 envelope on this before rejecting the material as a
7 product?

8 SEM. SEM is another one that is our very
9 history. When we first started in the '70s looking at
10 this, people loved SEM. It was a great machine. You
11 could see the shape beautifully. You could get
12 analytical information, and I gave it a high score.
13 However, SEM, because it had no structural capability,
14 when AHERA came out, it was pushed to the side because
15 AHERA and TEM. TEM was perceived gold standard. That's
16 the one we should use. So I don't argue that SEM has a
17 very important place just seeing what's actually in
18 there. It's just increasing the magnification from
19 PLM, and you get a quick answer if you have any fibers
20 or elongate mineral particles. So the negative score
21 is because the perceived conflict with TEM under a
22 hill.

1 TEM. We can get great prevention from
2 morphology, chemistry, and structure. We distinguish
3 the amphiboles species if done right, and it's perceived
4 as the AHERA gold standard. Remember that TEM, under a
5 hill, was designed for asbestos abatement or remediation
6 projects. It was designed to look at the particles that
7 would be left over, if at all, in the air from the
8 removal of asbestos. It didn't open up the water to
9 look at any EMP. The rules were codified to look for
10 residual asbestos to signify that the cleanup was not
11 going accurately. So it has a really good story.
12 However, there were disadvantages too. And the
13 disadvantages are endurance of the interpretation of the
14 shapes. You saw that a few moments ago with the tossup
15 thing. What is this elongate thing? The population, is
16 it detected? Is it confirmed? What does milling do to
17 it? How do you change it from the product as it was put
18 out for sale versus what we do in the laboratory? And
19 very importantly, this talc versus anthophyllite -- that
20 kinky talc. I wanted to get up here with red kinky
21 boots to put up there, but I thought that would be
22

1 pushing the issue too much.

2 Kinky talc is twisted talc. And there's a
3 reference that I will call to your attention. I don't
4 have it here. There's a reference that I will call to
5 your attention in a few moments by Jim Millette where in
6 his last -- the last page of it, he defaults on twisted
7 talc 25. I think this is a real concern, and it's
8 generated a lot of controversy between people who agree
9 with him, people who don't agree with him. So let's look
10 at that one.

11 If you have a single fiber or just two fibers,
12 how many fibers are too many? How many fibers are
13 acceptable? How do we deal with just a few fibers
14 compared to looking at something you can hold in your
15 hand and you know it is definitely asbestos because you
16 can look at all the classical products. It's likely to
17 be asbestos on the basis of these factors. The aspect
18 ratio, whether it's 3 to 1 -- which I don't like, but I
19 understand it. Going out as the others shown, you
20 really need 20 to 1 or greater. You need a large
21 population. You can't just look at one.

22 Now, in a PLM, you've got a whole bunch of

1 fibers, a whole field of viewers. We're on step. It's
2 just not a problem. If you're looking at otomicroscopy
3 then we have a few fibers down here, then it becomes an
4 issue. The geometry, the power of size, determination,
5 the end; and some of these come down to just judgment,
6 as you saw -- as I mentioned a few moments ago. Truly
7 a judgment on whether it's a cleavage fragment, whether
8 it's asbestiform.

9 And then there's nomenclature. Nobody saw
10 leaky at all with the multiple divisions are amphibole
11 nomenclature. We have so many things out there in
12 nature and rocks that would fit as being cousins to
13 tremolite or even some of the amosite minerals, but
14 I'll stay with tremolite because -- and anthophyllite
15 because we're into calcium-rich systems.

16 Litigation is driving a large part of this.
17 The realities to me seems to be that if you got law
18 cases being won with huge sums of money being awarded,
19 people will start to say, you know, I'm gonna get in on
20 the business -- like bad people. John? (Audience
21 laughs.) But you know, they're going down the road
22 saying, "This is what I asked to show," and sometimes

1 the evidence gets interpreted based upon pride and
2 reception. We scientists like to think we're pure and
3 good, but sometimes bias does creep into it.

4 The chemistry issues and -- the reason for the
5 crazy fuzziness there is that they switched them back
6 from PC. If you look at anthophyllite talc and
7 tremolite, tremolite is really easily distinguishable
8 because it has calcium. Calcium is a talc and
9 anthophyllite is infinitive. You've got all this
10 calcium. So if you're seeing calcium on the spectrum,
11 you can be pretty sure that it's going to be tremolite
12 if it fits the other criteria. Anthophyllite and talc,
13 however, are a little bit of a problem. The ratio
14 between calcium and magnesium for both of these is
15 very, very similar. So there are some talcs which
16 could appear both logically like anthophyllite and the
17 chemistry seems to be the same, and this was the
18 problem that I saw with Merlet. So it takes real work
19 to distinguish anthophyllite from talc.

20 Take a look, if you're at all plugged into
21 this. It's only to read a paragraph on -- let's --
22 page 17, fibers with kinks. That if it has this

1 twisted characteristic -- and Garret's arm is showing
2 you a lot of pictures of twisted fiber. We're calling
3 it -- he's calling them "rivets," and they twist; and
4 if you look at them, they can turn out to have a
5 different interpretation unless you connect the dots
6 right. So the issue is this 5.27, 5.27, 5.28
7 dimension.

8 In a deposition once I got hammered by a
9 lawyer saying, "What about the 5.28?" 5.3 I think is
10 what he was saying. It's required to be able to
11 identify the asbestos, and that's down 5.3. I know. I
12 said so. "I really don't know what you're talking
13 about." (Audience laughs.) And he went back and
14 looked it up and scope with a gun to about this long in
15 back. "What type of now?" It was like a golden eagle
16 on this --

17 AUDIENCE MEMBER 7: It's as easy as ABC,
18 right? (Audience laughs.)

19 MARTIN RUTSTEIN: Yeah, ABC. Easiest -- and
20 the ABC, by the way, of the dimensions. We don't talk
21 about knock down sideways. We talk about ABC unless we
22 go into reciprocal space, and then it's XYZ, but you

1 guys -- you don't have no problem here.

2 So it's how you connect the dots in this
3 twists talc, and it's not always correct to use just
4 the 5.27. On this part too, here's a crystal
5 structure. You'll get a tab, and here's one of
6 anthophyllite and tremolite.

7 (Phone ringing.)

8 MAN: You're 30 minutes.

9 MARTIN RUSTEIN: Shut up. Go away. Stop.

10 On talc, same dimension. Same dimension. So
11 you need two dimensions and one angle for the correct
12 identification. And Matt and RJ Lee have published on
13 this one, and this will clarify if done right on largely
14 ambiguity.

15 So summary. There are limitations and
16 advantages of a single map. There's no one size-fits-
17 all. What we're trying to do is prove the absence of
18 relevant amphiboles and chrysotile. That should be the
19 overarching goal for us. We need a full spectrum of
20 analytical tools to put together in this crossword
21 puzzle. We need to be able to look at them with a
22 common analyte definition. If we don't agree, on what

1 we're looking for, then the measurements become highly
2 mental. One side is saying, "You're doing the wrong
3 thing. Blah, blah, blah."

4 PLM will remain the primary technique, given
5 its simplicity, and part of what we're doing is to find
6 something for industry that they can really go with
7 instead of having a whole separate analytical vat.

8 I think SEM will start to come back. SIB,
9 especially useful. It's fast, down and dirty. You go
10 through there with only about 5 degrees of stamp, and
11 you're getting answer about amphiboles. TEM, likely to
12 be the ultimate tool, but only, only if we can agree on
13 the definition of making irrelevant shapes.

14 Prior to the meeting, the speaker sent in
15 questions. I asked one question. Can we agree on some
16 kind of definition? And the sponsors, the conveners of
17 this, their answer was pretty much, "We don't think so,
18 not in this short time." And if we want out of here and
19 we don't agree, then we're going to continue the debate.
20 Remember that under TEM (inaudible), you can use
21 ambiguous in a determinant. This cartoon, three nights
22 worth, I don't know. Throw the problem up to

1 management. Throw the problem to those who are
2 deciding whether to use the product or not. It may be
3 that our analytical techniques aren't good enough yet
4 to decide what these things are. It takes it out of a
5 whole realm of aggravation.

6 So going down with guard free and our patriots
7 to the Wizard of Oz, the Emerald City as we seek the
8 perfect method and we chase after analytical zeros
9 because I can always measure it better. I can look at
10 it smaller. I can do better, da-da, da-da. Make sure
11 you remember as we go to utopia, we're looking at
12 commercial progress. We're looking at minerals and
13 they both vary in physical and chemical properties,
14 what we're trying to measure. Watching what we did and
15 watching what we're going. We're inheriting the wind,
16 so to speak, because I'll get you because you didn't
17 define asbestos clearly enough. This is a joke.

18 (Audience laughs.) We all remember the wicked witch
19 and she's out to get us, and we didn't define it right
20 because we were looking at stuff. We were looking at
21 schools where stuff was falling down from the ceiling.
22 We were looking at building environments where workers

1 were exposed. You can see the clouds of asbestos in a
2 workplace, and I've been there and done that. I
3 understand that, but I'm not so sure about these trace
4 amounts, whether they really held any flag in trying to
5 protect human health.

6 So looking back, which you get to do after you
7 get older and you go on Social Security, you get to
8 think a little bit about this life. You can't tell how
9 deep a puddle is until you step into it. If asbestos
10 is really as dangerous as many perceive, if it's
11 ultimately the killer rock that they are asbestos, is
12 it logical or bias that leads us to be concerned about
13 EMPs? This is philosophical, but it's profound. Why
14 are we looking at EMPs? Do we have the health data?
15 Do we have evidence that this is something that should
16 be of concern?

17 When I started with this decades ago, I should
18 have paid attention to this part. I didn't, and I got
19 trapped in asbestos muck in a mine, and I had to beg
20 for people to pull me out. Now I look at the younger
21 people now and I say, "You got to solve this problem
22 because you've been handed really not a good plate of

1 material." And somebody somewhere has to be able to
2 say, "Let's back up. Let's define what it is we're
3 looking at and what we're measuring."

4 I'm urging some colleagues I'm working with
5 now to say, "This is what we're going to take, yeah."
6 Other people may disagree with that, but this is the
7 rule. This is the regulation that we're looking at.

8 So any questions? (Applause) Thank you.

9 AUDIENCE MEMBER 8: I'm new to this and
10 learned a lot. The question I have is which of these
11 methods is quantitative?

12 MARTIN RUTSTEIN: Quantitative?

13 AUDIENCE MEMBER 8: Yeah, because that's --
14 you know, TMS, CM --

15 MARTIN RUTSTEIN: They're all quantitative. You
16 can make them all quantitative. You can make PLM easily
17 quantitative by doing point counting, looking at the
18 number particles in the field of view, whether you were
19 looking at four slides or two 400 points or 200 points
20 or 100 points. You can quantitate very easily with
21 optical microscopy.

22 SEM, I don't think so. TEM, it depends on the

1 number of points you count. Do you count or do you see
2 something? The XRD is easily quantified. You can set
3 up standards and go with that and Gary may want to talk
4 with you. He might be out. Gary? Gary has done some
5 really fine work on quantitation with metrics.

6 Anything else? Yes, sir.

7 AUDIENCE MEMBER 9: When you say that that's -
8 - I'm sorry. Thank you very much for the talk and the
9 document about Canada.

10 MARTIN RUTSTEIN: Thank you. Hey.

11 AUDIENCE MEMBER 9: I'm sorry?

12 MARTIN RUTSTEIN: I was talking to me.

13 (Audience laughs.)

14 AUDIENCE MEMBER 9: Oh, okay. When you say
15 that TEM is essentially the world standard, PLM it will
16 probably be the primary technique, I guess the part
17 that we struggle with is that the two are not
18 necessarily looking at the same thing with both, so --

19 MARTIN RUTSTEIN: It was PLM and what?

20 AUDIENCE MEMBER 9: Well, using PLM while I
21 was sad for TEM. You're not necessarily getting the
22 same results with both, so --

1 MARTIN RUTSTEIN: Right. Because you can't --
2 it's environmental alchemy. It's when you change the
3 magnification, you're seeing something that it wasn't
4 before. When you look at a hand sample, when you look
5 at the chrysotile under a back light on fedra (ph), you
6 don't see fibers. It can be 7-meters long and you can
7 just ball it up. If you get out of your car, you can
8 make a snow ball out of it and throw it, but when you
9 look at electron microscopy, you're only seeing
10 individual fragments, small; and I think we fail to see
11 the disconnect between the two, so we have to be very
12 careful, in my view, of how we interpret the TEM. The
13 PLM is relatively easy.

14 AUDIENCE MEMBER 9: Well, because what we
15 found is -- one of the huge challenges that we've found
16 is something -- a sample that looks like it's really
17 out, there's no asbestos whatsoever. You use PLM, all
18 of a sudden you see and now there's lots of it.

19 MARTIN RUTSTEIN: And the crazy days around I
20 hear are starting. The city of my kids, I walked in
21 New York City. Shut down their water supply. They
22 were taking it from the Hudson River and they said,

1 "There's asbestos in the intake in the water." And it
2 turned out that what they were calling asbestos in the
3 water was actually pond mar, which is no longer a
4 mineral, but it's a common term. It's the black
5 amphibole; and it was coming out of the iron ducts and
6 it wasn't a health hazard but they were measuring it
7 with TEM, and that's just part of the issue. What are
8 we looking at, and is it something that we have to be
9 here starting with exposure to human health? I think
10 that's the bottom line. That's where I'm coming
11 around, personally, on these EMPs in terms of --
12 where's Ray? No, I was -- when he said, "What does the
13 lung see?" I thought that was very profound. What is
14 the body seeing on this one that makes it a problem?

15 So I -- just let me -- just get out there.

16 Mark? Is this Mark? Hi, Mark. Okay. Thank you.

17 (Applause)

18 CATHERINE SHEEHAN: Okay, Markey. We're doing
19 pretty good on time, so --

20 So next up is Dr. Martin Harper, and he has a
21 BS and MS in geological sciences and a PhD in
22 occupational health in the London School of Hygiene &

1 Topical Medicine. He's a fellow of the Royal Society
2 of Chemistry and the American Industrial Hygiene
3 Association. He recently retired from the NIOSH after
4 completing many projects and publications related to
5 asbestos and other mineral particles, including being a
6 co-author of the NIOSH roadmap.

7 So let's get you started here.

8 MARTIN HARPER: You know, I'm following on
9 from I would estimate to be about 100 years of
10 accumulated wisdom in the first three speakers. So if
11 I sort of stall or stutter a little bit, it's because
12 I'm already getting the I'm-not-worthy feeling. But,
13 yeah, again, I'd like to thank, particularly, Nora for
14 all her hard work; the JIFSAN organization for inviting
15 me; and I hope I have something worthwhile to
16 contribute.

17 As I said, most -- as I was introduced, most
18 of the work that I've done regarding asbestos --
19 practically all of it was done while I was at NIOSH,
20 but I have now retired from NIOSH, and so -- why isn't
21 this working? All right. So I got to put up this
22 disclaimer. It says I am no longer speaking on behalf

1 of NIOSH or any other part of the Federal Government;
2 and also, in full disclosure, I have never participated
3 in any legal action with respect to asbestos or mineral
4 products.

5 Now, the general characterization issues, as
6 we've already heard, are the nature of some. I mean,
7 we have so many different samples that we have to
8 analyze for asbestos or other elongate mineral
9 particles; and we're looking at those media with
10 different purposes and different requirements, and so
11 we often have to use different techniques that are
12 appropriate to coming up with the answer that they're
13 looking for; and so we need to ask questions like: How
14 much of the sample is representative of the whole
15 sample? So, for example, how many samples do you need
16 to take in a talc mine to establish the absence of
17 asbestos throughout the mine? You have, you know,
18 veins of minerals that go through different properties.

19 I remember at one point I was going to look at
20 a taconite mine, and I was told, "Oh, there's a vein of
21 amosite going right through it." "Oh, yeah, but we
22 avoid that." Really? Wow. Okay.

1 And there's a lot of different laboratories
2 out there, and they don't all come up with the same
3 answer all the time. How can we resolve that
4 variation? When we're looking at particles, what's the
5 minimum number we need for accurate characterization?
6 And there are all kinds of issues of analytical
7 calibration, proficiency testing, and reference
8 materials; and this is all a bit of interest to me out
9 of my analytical chemistry background. We can, again,
10 as been noted, examine materials of different levels of
11 magnification; and all of these have their own issues,
12 different purposes and, therefore, also different kinds
13 of quality assurance.

14 Looking at I4 and handlets, it's difficult
15 sometimes to characterize things in the field. This is
16 a serpentine outcrop in California, and as you start to
17 look at it in a little more detail, you start to see
18 things that are prismatic and even fibrous up here; and
19 it's pretty clear that there's a range of morphologies
20 spanning different fibrosities.

21 So what is the appropriate sample to determine
22 asbestos component? Because even commercially

1 exploited asbestos partially include some material that
2 might not be considered asbestiform. So we need to
3 come up with some kind of sampling protocol. At least
4 in the prior example you can see that some of the
5 material is composed of elongate mineral particles and
6 some receive an asbestiform, but as we've -- it's shown
7 there are rock types that you can hit with a hammer and
8 you don't necessarily know that they're composed of
9 fibers.

10 How many particles do we need to examine?
11 Well, it was reported at a Johnson conference a few
12 years ago that even though UICCB, Chrysler power
13 reference material was examined to the extent of 20,000
14 fibers, that trace tremolite and amosite could be found
15 -- tremolite at .045 percent and amosite at .003
16 percent. Because it's a Johnson conference, I can't
17 give you a reference. I can't tell you who said it,
18 but it was there.

19 And how many particles do we need to measure a
20 reproducible distribution? Well, I would say the bare
21 minimum is 300, but really you need to measure about a
22 thousand particles. It's kind of tough to do that on

1 TEM, especially when a lot of particles actually are
2 longer than the field of view and they get outside the
3 field of view. And for accurate chemistry? You know,
4 I see people reporting at formulae two-three
5 significant figures based on one EDS analysis. Are you
6 kidding me? And with no attribute of uncertainty to
7 that formula. Wow. You'd be dropped out of the
8 analytical chemistry class for this, but I see it all
9 the time.

10 So we also have this notion of fibrosity, and
11 this has been popularized by Eric Chatfield (ph) and
12 others to compare fiber dimensions of materials; but
13 the -- you know, the preparation procedure is
14 absolutely critical to the result that you get. What
15 did you do to it? Jaw crush it? Did you grind it in a
16 mortar and pestle? Did you put it in a jet mill? Did
17 you sonicate it? All of these things will end up
18 giving you a different distribution from the same
19 starting material, and none of us really studied this
20 to any great extent. But we have this comment, which I
21 think was very appropriate, from -- from Sterling (ph)
22 in 2010.

1 So if we're going to report fibrosity
2 measurements, we really need to have a standard
3 procedure to prepare the material prior to making those
4 measurements. So this absolutely calls out for an ASTM
5 Standard. Please, Frank, put it on the agenda. We've
6 got to have this.

7 Now, there are existing reference materials;
8 and this is the bulk of my talk now is the talk about
9 reference materials and quality assurance, and there
10 are some problems even with the existing materials.
11 Take a careful look at the Wittenoom actinolite here,
12 which is very nice and clean, and this UICC chrysolite
13 here, which I refer to as a lollipop stick of gems.
14 Little particles stuck to it, and all of this material
15 that I've looked at from the UICC -- the amosite, the
16 crocidolite, the anthophyllite -- kind of looks like
17 this; and I thought, well, how come no one's noticed
18 this before? So I went back to the original papers
19 describing UICC material, and it dawned on me, they
20 didn't have SEM. All those pictures are just under
21 optical microscopy. You can't see this effect, but
22 what's happened is because they jet milled it, some of

1 these longer fibers fragmented into tiny little pieces
2 that then adhered, probably by electrostatic
3 attraction, to longer fibers.

4 And you know, when you look at the Addison-
5 Davis tremolite that was used in those experiments,
6 they're all clean, just like this Wittenoom fiber here,
7 because they didn't jet mill; and we know this because
8 we also had a tremolite reference material, and we
9 tried jet milling it, and guess what? It ended up
10 looking just like this.

11 So NIOSH has a roadmap goal, a reference
12 material repository for minerals; and I was working on
13 that for a while, and ISO defines a reference material
14 as "a material sufficiently homogeneous and stable with
15 respect to one or more specified properties which has
16 been established to be fit for its intended use in a
17 measurment process." That's not -- sounds like
18 gibberish.

19 And NIOSH has some reference materials of its
20 own that were prepared many years ago by Fitree (ph).
21 Not very many -- not very much of it left, and it's
22 over in the Minerals and Materials Branch at the

1 Pittsburgh Mining Research Division now. And then
2 there are some UICC reference materials still out
3 there, but most of the remaining material got
4 landfilled a few years ago. It all got transferred to
5 the South Africa NIOH, and when they stopped receiving
6 requests for it, they didn't want to keep it anymore,
7 and so it's now down at the bottom of the landfill.
8 They have a little bit left; however, you're the ones
9 that are gonna have to figure out how to get it out of
10 South Africa. They're still willing to give it away.

11 And then, of course, you know, there's been a
12 lot of complaints that nice, common and uncommon
13 materials, are no longer available; and indeed they
14 weren't all -- all of them weren't all that good
15 either. I mean, this is a photomicrograph of the nice
16 tremolite asbestos, which has been criticized heavily
17 for not being very asbestiform; and I'm comparing this
18 with the tremolite asbestos that is the reference
19 material of the Health and Safety Laboratory in the UK,
20 and this is about the same magnification. So you can
21 see there is a tremendous difference here.

22 The UK reference materials -- the Health and

1 Safety Executive, HSE, is the parent body of the HSA --
2 of the Power for Safety Laboratory -- are described in
3 a publication, and we wanted to see if we could get a
4 hold of some of that. So we wanted to know where the
5 tremolite asbestos came from, but the company person
6 who donated the material to the HSE died, and the
7 company had changed hands, and they had no record of it
8 as well. All we knew was from this description that it
9 came from the Salt Woods mine in southern California,
10 and we couldn't find that in the gazetteer. We
11 eventually found it. Brad Van Gosen was a great help
12 in this because we identified it as coming from this
13 Macaroy (ph) property, and here's the mine. I know
14 several of you have visited it. I don't think there's
15 very much left of this thing. Most of it's been taken
16 out, and it was in the past sold to the Powhatton
17 (ph) Company in Maryland for lab-grade asbestos, all of
18 that stuff that you used to buy in the big jars from
19 Baker and Mallinckrodt and so forth. And it's a very
20 nice tremolite asbestos, and it's available from NIOSH.
21 If you ask them nicely, they'll direct you to RTI who
22 holds it, and RTI will give it to you. You have to pay

1 shipping I think, and that's a lot, like 50 grams. If
2 I had known that somebody was selling the UICC stuff
3 for \$1,000 a gram, I would have kept hold of it. It
4 could have been my retirement. (Audience laughs.)

5 And like I said, this is what it looks like;
6 but if you're jetting it, this is what it looks like.
7 So be careful what you do with this stuff.

8 Another material that's going to come out of
9 NIOSH shortly, I hope, is this one, an anthophyllite
10 from the Percival Dunn mines in California that I
11 collected, again, with Brad; and it's also a rather
12 nice anthophyllite; but frankly, I'd rather get after
13 this one, which is my favorite. This is the beekeepers
14 anthophyllite fragments is what I'm talking about. One
15 there. One there.

16 So then the other issue that we have to deal
17 with is cleavage fragments and fine prismatic crystals,
18 and the work that I've done on this has actually been
19 through PCM of hair samples. And I know that's not of
20 great concern to the audience here except that I think
21 what -- my findings are relatable to PLM analysis,
22 definitely; and the cautionary tale that I'm going to

1 give you is also relevant, I think, to SEM analysis.

2 And the reason that we were interested in
3 cleavage fragments is because OSHA practices
4 discriminatory counting, even though NIOSH and EPA do
5 not, and there was an ASTM Standard under development
6 D7200 with an attempt to codify discrimination; but the
7 fact is, the procedure for discrimination really needed
8 to be confirmed by an internal laboratory study, so I
9 decided to do an internal laboratory studies. So for
10 that I needed nonasbestiform amphiboles, and that
11 wasn't actually as simple as it sounded. You got onto
12 the mineral dealers, and you say, "Oh, give me, you
13 know, a ton of riebeckite." They say, "What do you
14 want that for? Nobody buys that." And I said, "Yeah."
15 And then we found that things were not always what they
16 claimed to be. So you know, we bought anthophyllite
17 that turned out to be enstatite. We got tremolite that
18 turned out to be inesite. And we ended up with five
19 good minerals: Actinolite, tremolite, grunerite,
20 brookite, and anthophyllite; but all the samples of
21 anthophyllite that we examined contained that fibrous
22 talc, and that's just in the nonasbestiform in Buffalo.

1 So in the work that we did, we used actinolite
2 from Rockwood, California; NIEHS tremolite, which I
3 believe came from New York; grunerite from Portugal;
4 and riebeckite from Colorado. And these are pictures
5 of them, and while some of them do appear fibrous, the
6 fibers are really nonasbestiform.

7 And then we have to make cleavage fragments of
8 a respirable size -- a respirable particle size. Well,
9 that's not easy, actually. There's a sense that I get
10 from people that as soon as you hit a massive amphibole
11 with a hammer, you're gonna generate tons and tons of
12 respirable sized cleavage fragments, and that's not
13 actually the case. Most of the particles that are
14 produced by Krishi, Megapee -- actually, eCORP -- and
15 the fiber-like ones are pretty rare, I mean, about 1
16 percent or so. And if I grind up the material where
17 only 1 percent is my material of interest, I can't use
18 that for tests. It's ridiculous.

19 So with RTI, we worked out a procedure to
20 concentrate the fiber-like fracture; and RTI was able
21 to make the 100- to 150-milligram quantities of these
22 materials containing about 50 percent federal fibers. I

1 hate that word, that expression, but it saves me having
2 to describe it further.

3 And so we used the tremolite, actinolite,
4 grunerite, and riebeckite for the PCM round robin that
5 we did; but tremolite and riebeckite cleavage fragments
6 are also being used in toxicity tests at NIOSH right
7 now; and I really hope that the results from those
8 tests will settle some of the discussions that we've
9 been having.

10 So this is an artificial creation of mind.
11 The slides that we sent around to the different labs
12 were dosed with different levels of asbestos fibers and
13 the equivalent of cleavage fragments. So this is a
14 photograph of the crocidolite and the riebeckite, and
15 you can see sometimes it's pretty clear that that's an
16 asbestos fiber. It's pretty clear that that's a
17 cleavage fragment, but you know, what's this? I don't
18 know. Is it a cleavage fragment or is it a show of
19 part of them? No idea. Can't tell through PCM.

20 Now, the procedure for discrimination involved
21 a subjective evaluation of morphology, and that was one
22 of the things that we wanted to test. So we sent these

1 examples out to 11 laboratories, all of which, except
2 mine, were accredited by the American Industrial
3 Hygiene Association for asbestos analysis; and we asked
4 them -- gave the set of slides to indicate all those
5 particles which they thought met the morphological
6 criteria for asbestos and which not. And this is the
7 100 percent asbestos fiber slide, and this is the zero
8 percent asbestos slide. These were all cleavage
9 fragments, and you can see that the -- yeah, the
10 results are all over the place. Here, we've got one
11 lab that correctly identified 96 percent of the
12 asbestos fibers as asbestos but; look here, two
13 percent; and same with cleavage fragments. You know,
14 we have labs that correctly identified, you know, zero
15 or near zero asbestos particles in the cleavage
16 fragments; but here, look at this level. So you know,
17 it was very subjective. It could not be done, in my
18 opinion.

19 What we did find is if we looked at width
20 distributions, a rather good discrimination, at around
21 about 1 micron -- it was actually about .85 micron --
22 gave us the best discrimination between our fragments

1 and our fibers. Now, you know, these were artificial
2 creations, okay? So I don't know how this reflects the
3 real world except that I believe Ann's gonna show
4 similar data later on, and so I don't think it's far
5 off.

6 And we found the labs could actually do a very
7 good separation by width. In fact, it was about as
8 good at 1 micron as it was at .85 micron. You know, I
9 just like round numbers. And so this standard, which,
10 by the way, is applicable to my two quarries only, it
11 does currently include this width criteria of 1 micron,
12 which does a pretty reasonable job of ensuring that we
13 count asbestos. We can't completely clear the cleavage
14 fragments of -- you know, out of this; but you know, we
15 can err on the side of caution, which is always, you
16 know, good public health practice.

17 Okay. There's some other proficiency tests
18 out there. There's the NVLAP, the AIHA's bulk asbestos
19 testing, and there's also the Health and Safety
20 Laboratory Asbestos in Material Scheme, or AIMS, which
21 I'd like to bring to your attention. It's asbestos in
22 building materials, generally targeted to

1 identification and qualification greater than 1
2 percent; but occasionally you get samples of interest
3 to the folks here, I believe, such as round 62, which
4 included a sample with .1 percent chrysotile and .1
5 percent amosite; and these were not detected by several
6 laboratories in the scheme. And that round also had a
7 crushed marble containing wollastonite when many saw
8 asbestos. Twenty-three of the labs, by PLM only,
9 identified the wollastonite as asbestos, and even six
10 with electron microscopy identified the wollastonite as
11 asbestos.

12 There's another scheme that comes out of the
13 Health and Safety Laboratory called the Low Asbestos
14 Content Scheme, which I think would also be of interest
15 to people here. And round two was a sample of talc
16 containing wollastonite with no asbestos, and 18
17 percent of the labs incorrectly reported the presence
18 of asbestos.

19 Now, if you're a lab and you want to join
20 these schemes, there's a little benefit to that. You
21 can purchase the HSL reference asbestos samples,
22 otherwise, you can't. They don't have very much of it

1 left, and so they're reserving it only for people that
2 are in their schemes.

3 So there's some new asbestos standards that
4 are being worked on. I call them "new" because, for
5 example, this one was first initiated in 2010, which is
6 not that new anymore. And this is my understanding of
7 how these methods are, based on the minutes of the last
8 two ASTM Committee meetings. I'm gonna be pretty
9 interested in gathering a round robin here, and also,
10 I'm going to be pretty interested in insurance round
11 robin, which I understand he's going to be presenting
12 it today at conference; is that correct?

13 AUDIENCE MEMBER 9: I am not certain if I will
14 be or not.

15 MARTIN HARPER: Okay. These are quotes, by
16 the way, out of the committee minutes of the April
17 committee meeting.

18 AUDIENCE MEMBER 9: All right. This is ours.

19 MARTIN HARPER: Okay. So the future work,
20 obviously, is to extend the number of materials
21 available to include other minerals of interest, such
22 as zeolites and clay minerals, and to characterize

1 those that we already have, particularly in NIOSH; make
2 them available as analytical standards; use them in
3 identification round robins. But I want to see them
4 being used for hypothesis-driven toxicological studies
5 to determine if our theories of disease induction and
6 progression are correct, and then we can use the
7 results to derive mineral-specific risk assessments.
8 And as part of that initiative, I've been working, most
9 recently, on fibrous glaucophane from California. This
10 is the Calaveras stand, which some of you know and
11 several of you have visited; and this is the rock at
12 the Calaveras stand, but this rock is not pure
13 glaucophane. It's only about -- I think about 60
14 percent -- 70 percent glaucophane. There's other
15 minerals, like lawsonite; and it's not that fibrous
16 compared to this material, which I collected with Mark
17 Bailey (ph) from Marin County, California; and it's
18 really nicely fibrous, and it's about 85 percent
19 glaucophane, and it's really interesting to use as a
20 reference material and also to test our ability to --
21 toxicity of elongate mineral particles. And you know --
22 - oh, by the way, this is an undatee (ph); and this --

1 I think, clearly, some of it is definitely asbestiform.

2 And so this is what we've done to it -- a full
3 mineral characterization. We've hit it with just about
4 everything that we can think of, and I think this is
5 what we need to do. If we really want to know a
6 material well, then one technique; one single SEM
7 analysis; one single EDS result; one single, you know,
8 X-ray is not enough. And so we've done all this to it,
9 and we actually had several disagreements. And I could
10 discuss all this, but the paper has been submitted for
11 publication, including calculating the potential
12 toxicity based on a model from my colleague Alexandre
13 Walteare (ph). And what I need now is for some
14 toxicologists to step up to the plate and come and get
15 some of this stuff to confirm whether the model is
16 accurate or not. Please, please pick up stuff. Come
17 and get it.

18 And then, you know, just to, you know, clarify
19 that we can't use a single technique, this is a PCM
20 photograph of an air sample from a talc mill; and I
21 don't know what that is or that or that or that. You
22 know, but these were some samples that we were taking

1 while the talc mill was open; and I bought the first
2 set of samples back to the lab, and I prepped them, and
3 I looked at them myself, and I immediately got on the
4 phone to my guys working in the field, and I said,
5 "Don't take off your powered-air purifying respirators.
6 I don't care what they call these things. I just don't
7 want you guys breathing them, please."

8 And then because it takes a village, I have to
9 acknowledge -- and I -- even after I've written this, I
10 realized I left at least three other people off, you
11 know? And this list is -- and most of these people
12 have worked with me at no cost to me; you know, it just
13 blows my mind that so many people are so interested in
14 this field that they're willing to give up their time
15 and resources to help me in what I've done, so thanks
16 very much.

17 (Applause)

18 And I still remember one said, "This is proof
19 that asbestos is still used in construction."

20 (Audience laughs.)

21 CATHERINE SHEEHAN: We have plenty of time for
22 questions. So do we have any questions at this point,

1 Greg?

2 GREGORY MEEKER: Yeah. I'd just like to say
3 the process of making a standard, and you said it
4 either way, is -- it's so difficult. USGS did it, and
5 I never want to do that again. It was a terrible job,
6 and using every technique you can bring to the table to
7 understand what you have is so important. Thank you
8 for setting them.

9 AUDIENCE MEMBER 10: I really liked the
10 pictures of the fibers that have been jet milled that
11 had on it what you called "Jimmies."

12 How much of an effect do you think this has on
13 the results we're seeing from toxicology using milled
14 fibers versus --

15 MARTIN HARPER: Beats me. I'm not a
16 toxicologist. I wouldn't even begin to speculate.

17 AUDIENCE MEMBER 10: It just struck me though.
18 If we're looking at something that's not necessarily a
19 singular shape, we're making pronouncements about the
20 shape relative to that, we should consider --

21 MARTIN HARPER: Well, the fact is, we did, you
22 know, 30 years' worth of work on that stuff without

1 really understanding what it was; and that, you know,
2 goes back to exactly Rick's (ph) point, that, you know,
3 we got to know this stuff inside-out, backwards.

4 AUDIENCE MEMBER 11: Have you used any of the
5 data from the tissue burden studies to evaluate these
6 dariets (ph) you're looking at in terms of toxicity and
7 biological potential?

8 MARTIN HARPER: I'm not a toxicologist. It's
9 not my field. Other people can do that too. I don't.

10 AUDIENCE MEMBER 11: Did you know Molly
11 Newhouse (ph)?

12 MARTIN HARPER: Oh, yeah. She was in the
13 department while I was there.

14 AUDIENCE MEMBER 11: The golden age.

15 MARTIN HARPER: Yeah. Oh, it was great. It
16 was amazing. Charles Rossiter (ph) and Cole Coldest
17 (ph). It was great.

18 AUDIENCE MEMBER 11: You mentioned the UICC
19 samples. UICCs were blends. They were blends from
20 different mines, for example, Chrysler (ph) Town UICC
21 beats Canada.

22 MARTIN HARPER: Right. Right.

1 AUDIENCE MEMBER 11: And it's a blend from
2 nine different mines based on the production figures
3 the year that this formulation was --

4 MARTIN HARPER: Yeah. But I'm not so sure
5 about the others. You know, UICC a Chrysler Power came
6 from --

7 AUDIENCE MEMBER 11: Rhodesia.

8 MARTIN HARPER: Rhodesia.

9 AUDIENCE MEMBER 11: Michelle D. Anderson
10 (ph), yes.

11 MARTIN HARPER: And I don't know if that came
12 from multiple mines or not. So I -- yeah, definitely B
13 was a blend, but I don't know what the other two is.

14 AUDIENCE MEMBER 11: Yeah. Chris Bodanic (ph)
15 experimented with the nine separate blends, and he got
16 nine separate biological assets.

17 MARTIN HARPER: Right. But that -- like I
18 say, they were all jet milled to produce respirable
19 fracture.

20 AUDIENCE MEMBER 11: Yes. Yes. Jet milling
21 in the introduction of metal particles was also an
22 interesting hypothesis --

1 GREGORY MEEKER: Excellent.

2 AUDIENCE MEMBER 11: -- that was raised.

3 MARTIN HARPER: And also the amosite
4 contamination is in all of them, which means it's
5 probably a carryover from, you know, one batch to the
6 next, I'm sure. But then the Addison-Davis materials,
7 the tremolites, were not jet milled. Those pictures
8 all look nice and clean.

9 AUDIENCE MEMBER 11: Yes.

10 MARTIN HARPER: And so, you know, you've got
11 to understand the materials and how they got to be what
12 they are. It's how you use them.

13 AUDIENCE MEMBER 11: Is the NIOSH study an
14 inhalation study?

15 MARTIN HARPER: No. You know, 100-150
16 milligrams, it's not enough for a inhalation study.
17 It's a study of variscite, and there may be a road
18 terminal study. I can't remember now. The NIOSH guys
19 might be able to tell you.

20 AUDIENCE NUMBER 12: There's nothing specific
21 about jet milling, right? Like probably any milling is
22 coding the fibers with those --

1 MARTIN HARPER: Well, the way it was done by
2 Addison-Davis was to use a copy trail, you know, the --

3 AUDIENCE NUMBER 12: Yeah.

4 MARTIN HARPER: -- the rotary chocolate.
5 Okay.

6 AUDIENCE NUMBER 12: And any milling. The
7 pictures have me thinking, you know, the effect it's
8 probably having on --

9 MARTIN HARPER: Well --

10 AUDIENCE NUMBER 12: -- the energy dispersive
11 spectroscopy too, you know, so --

12 (Crosstalk)

13 MARTIN HARPER: The problem with the jet mill
14 is that the fibers end up hitting the walls and
15 breaking up. When we decided to try to reproduce the
16 UICC for the tremolite, we bought a jet mill; and we
17 started off with just glass fiber because we didn't
18 want to contaminate the whole lab, and we wore away the
19 jet mill just with glass fiber. We had to get a
20 specially made silica carbide insert in order to be
21 able to do any jet milling. And then this is what we
22 got out, you know, those lollipops and cheerleaders is

1 what we got out of this.

2 CATHERINE SHEEHAN: Brad?

3 BRADLEY VAN GOSEN: I may be getting ahead of
4 the schedule a little bit, but in the talc cosmetic
5 issue right now there's a lot of analysis being done of
6 the product, but how much of the raw ore is being
7 redone?

8 MARTIN HARPER: I don't --

9 GREGORY MEEKER: Can you repeat the question?

10 MARTIN HARPER: Yeah. The question was: How
11 much of the raw ore is being examined in the talc
12 industry? And I would suspect that, you know, people
13 associated with the talc industry would be way better
14 able to answer that than me. So is there anyone that
15 wants to -- I know you --

16 AUDIENCE MEMBER 13: No. But I'd like to
17 introduce a complicating fact. Most of the
18 pharmaceutical-grade materials are actually blends from
19 different mines, from both foreign and domestic.

20 MARTIN HARPER: Yeah, I'm not surprised.

21 AUDIENCE MEMBER 13: So the properties of
22 color, lift, or fragrance, other properties -- skin

1 modification and chemical -- they all play some
2 interest role.

3 MARTIN HARPER: And I mean, it's one thing if
4 you're in charge of your own mine in the USA, and it's
5 another thing when you're dependent on analyzing some
6 bulk carbo product from some other country and how that
7 varies from day to day, batch to batch, and then so on.
8 I think Matt was going to say something though.

9 MATT SANCHEZ: Yeah. I can't be too specific.
10 I guess it would depend on the talc mine company, what
11 their internal procedures are; however, it's open to
12 some companies. I know they're not even mining
13 companies. Those that would use talc, get their
14 plastics, ceramics, or cosmetics, it's not unroutine to
15 actually go to the mines independently and do full
16 assessments of the mining properties as well as ongoing
17 quality control of talcs before they're shipped, before
18 they're accepted by companies. But again, it's going
19 to be company-specific how detailed they are. Some are
20 probably not doing anything; others are doing a whole
21 lot. It would really just depend on who the actors
22 are.

1 BRADLEY VAN GOSEN: Yeah. That was probably
2 where I was going with this important talc. Just
3 curious how much quality control is on every talc.

4 MARTIN HARPER: Well, you know, the other
5 issue is that you can't prove an absence.

6 BRADLEY VAN GOSEN: Right.

7 MARTIN HARPER: Yeah. How many particles do
8 you want to look at? Like I said, with the UICCB, they
9 looked at 20,000 particles and found no amphiboles. By
10 virtue of a pre-concentration technique, this other
11 research finally found .045 percent tremolite. Well,
12 is that acceptable, you know?

13 If I was a talc producer and somebody came to
14 me and said, "Well, have you got any asbestos in your
15 talc?" and I said, "Well, I've got .045 percent," you
16 know, are they gonna buy it? I mean, what's --

17 AUDIENCE NUMBER 14: How can you have
18 something that you analyze 20,000 particles and find
19 zero and yet a half of percent of it is another phase?

20 MARTIN HARPER: Point .045.

21 AUDIENCE NUMBER 14: Let's say a half a
22 percent for analytics, .45 percent.

1 MARTIN HARPER: Point zero.

2 AUDIENCE NUMBER 14: Oh, you're say 0.45?

3 MARTIN HARPER: Yeah. Yeah.

4 AUDIENCE NUMBER 14: So they should have found
5 some of it in 20,000.

6 MARTIN HARPER: Maybe. Maybe --

7 AUDIENCE NUMBER 14: I mean, if they would
8 have sensed it in the system.

9 MARTIN HARPER: Maybe. Well, you know -- I
10 don't know because, you know, that study has not been
11 published. So --

12 CATHERINE SHEEHAN: Hey, Martin, it's yours.

13 MARTIN RUTSTEIN: When the public pressed on
14 the Johnson & Johnson business, I concluded that one of
15 the reasons the jury has ruled against Johnson &
16 Johnson was because they tried the strategy of diluted
17 the ore. They apparently saw that they had elongate
18 stuff in it, at whatever percent, so they mixed it with
19 a lower concentration, thinking dilution would be the
20 solution to pollution, but it came back to bite them.

21 I also suggested that maybe the way to look at
22 what's in the ore would be to look at the sediment --

1 at the runoff from the ore piles from rain and snow
2 melt because the smallest particles would be carried
3 away from the pile, and it would be like sluicing for
4 gold. You would be looking at those, and it would be a
5 down-and-dirty way to see whether it was any percent.
6 I think the answer is, if there's anything in there,
7 nobody wants to buy it.

8 MARTIN HARPER: What I didn't -- in my
9 original version of my presentation, I had slides, but
10 I took them out, that described the fluidized -- they
11 had a fluidized --

12 MARTIN RUTSTEIN: (Inaudible).

13 MARTIN HARPER: -- that's been segregated,
14 which maybe we'll talk about too; and that is a way of
15 releasing respirable fibers from a sample and
16 concentrating them in a way that way you can seriously
17 get down to .000 -- you know, four zero, 1 percent
18 (inaudible). And you know, it's a process that I use
19 to look at soils or ZMI periodine, and it was amazing
20 how low you can go in that world.

21 MARTIN HARPER: That was published. In fact,
22 there's -- what? -- three publications on the FDAS now.

1 Anybody that wants one of these, let you know or talk
2 to Ed (ph).

3 AUDIENCE MEMBER 15: Yeah. You talk to Ed a
4 little about the percent of asbestos or fiber or
5 whatever. Could you describe if that is either -- is
6 it a weight percent are you talking about or a particle
7 count percent or a projected area percent?

8 MARTIN HARPER: It's basically a particle
9 count that's been converted into a weight percent, and
10 that conversion factor itself is full with uncertainty
11 because you're making certain assumptions about the
12 materials. Yeah. I mean, it's a -- and of course,
13 when people report, you know, material as having, say,
14 2.4. percent asbestos -- say it's a building material,
15 okay? Did they ever report uncertainty with that
16 value? Any of the labs here report an uncertainty on a
17 weight percentage? Did anybody even try to calculate
18 an uncertainty?

19 MATT SANCHEZ: Well, I think from
20 accreditations, that they would -- you're supposed to
21 report out a coefficient of variation for ranges, but
22 that's it. It doesn't -- you don't apply those to

1 actually give an uncertainty of the actual measurement
2 reported.

3 MARTIN HARPER: I think if you actually looked
4 at the true uncertainty of the treatment, yeah. Okay.

5 MATT SANCHEZ: But the uncertainty is dealing
6 with how the methods that were designed for like
7 building materials quantify. They're either allowing
8 for just simply a visual estimation, which is by
9 definition subjective, yeah. Or you're doing something
10 like a point count where you're only counting like 400
11 nonempty points, which doesn't give you enough
12 statistical counts to have any real bite, real meaning
13 at any --

14 (Crosstalk)

15 MARTIN HARPER: Right. And some people have
16 propose a thousand counts to --

17 (Crosstalk)

18 MATT SANCHEZ: You know, it only improves it a
19 little bit.

20 MARTIN HARPER: Yeah.

21 MATT SANCHEZ: You really -- to really improve
22 it, you're gonna have to get into the tens of thousands

1 to really get the -- your counts to get a -- to really
2 get a tight measurement on that. But the other thing
3 that can affect the point counts, which is very true,
4 is if you actually go through and do point counting on
5 something that is incredibly fibrous, like a -- just
6 say like a reepa (ph) chrysolite and you compare it to,
7 let's say, a nonasbestos ampha (ph) like tremolite
8 count, the nonasbestos tremolite count is more -- that
9 would be a more accurate estimate than the real fibrous
10 material, because as you go through that area of
11 percentages, those elongated particles -- those
12 asbestiform particles either takes more area -- it
13 creates area by them being so long as part of the
14 count, so they look like they're bigger particles when
15 you're just doing it by areas.

16 MARTIN HARPER: Yeah. This occurred when I
17 looked at the arenite material that I collected from
18 Rome, and when you crush it and you look at it under
19 the microscope, it looks like it's all fibers, you
20 know; and you -- by point counting you say, "Oh, it's
21 85-90 percent fibers," but then when you calculate out
22 the size of those fibers versus the size of the glass

1 frames that are in there too, it's suddenly only 30
2 percent --

3 MATT SANCHEZ: Yeah.

4 MARTIN HARPER: -- by weight.

5 MATT SANCHEZ: And again, the higher the
6 magnification you go on your point count, you minimize
7 some of those effects, but --

8 MARTIN HARPER: Oh, yeah. Yeah.

9 MATT SANCHEZ: Because, you know, like --
10 well, you'll be able to see the two --

11 (Crosstalk)

12 MARTIN HARPER: You end up only seeing five --
13 that's right. Exactly.

14 MATT SANCHEZ: But the other issue -- point
15 that's important is all these things, because a lot of
16 times people talk about PLM being insensitive, but it's
17 really not. The quantification techniques that are
18 employed are very insensitive, but the ability for PLM
19 to observe something, that's a very sensitive
20 technique. And the real measure of a sensitivity of a
21 method is the ability to see a particle in the total
22 amount of particles analyzed. How many particles can

1 you see when you're analyzing something at 100 decks
2 first then 400 decks, compared to analyzing a bulk
3 sample by TEM where you're at 20,000?

4 MARTIN HARPER: Yeah.

5 MATT SANCHEZ: The TEM analysis, in and of
6 itself, for bulk samples, you look at so few particles.
7 It takes so much time to look at so few particles.
8 Then you do these huge extrapolations up. So
9 quantification by TEM, especially in bulk samples, is
10 highly problematic. Again, when you see something is
11 another issue; and then the identification of what you
12 see is separate from this idea of quantification.

13 MARTIN HARPER: Right. But at the end of the
14 day, if we have targets for trace analysis, we can
15 confirmed that we have met those targets by the use of
16 spike samples and round rock and (inaudible) spike
17 samples. So by whatever technique we can use or
18 whatever multiple techniques we care to use, at the end
19 of the day, we can create samples of 1 percent, .1
20 percent, .05 percent, .025 percent. We can do that.
21 You know, even though they're not homogenous materials,
22 there's enough experience and expertise in making

1 nonhomogeneous spike materials. We can do that, but
2 just give us a target, and don't ask us for zero --
3 (audience laughs) -- because there's no such thing.

4 MATT SANCHEZ: No. You're right.

5 MARTIN HARPER: A target means that there's a
6 level of acceptability. Well, don't use the word
7 "acceptability." Use the word "tolerability" so we'll
8 tolerate this much. We won't say, "This much asbestos
9 is acceptable."

10 MATT SANCHEZ: That's true.

11 MARTIN HARPER: Maybe we can say, "This much
12 asbestos is tolerable in talc because" -- and then what
13 you do is you do a risk assessment --

14 MATT SANCHEZ: Well, that's right.

15 (Crosstalk)

16 MARTIN HARPER: You know, based on that. But
17 I mean, without that information, the analysts amongst
18 are kind of blindly trying -- you know, give you what
19 you want. Figure out what you want; and then the
20 analysts will just take the best technology and best
21 expertise, and we have been, and we can give you what
22 you need or what you want.

1 MATT SANCHEZ: I think it's important too, if
2 any result -- the result is only within the parameters
3 of the test. You can't extrapolate beyond the
4 parameters of the test.

5 MARTIN HARPER: Right. That is also true.

6 MATT SANCHEZ: But -- well, I deal with a
7 world where people say, "Well, it wasn't detected;
8 therefore, it must be very small amounts." And it's
9 like let -- the test doesn't tell us that. All it
10 tells you is what that test is designed for. So if
11 people are looking at that, they have to understand how
12 that data was derived and what the scope of the data
13 is.

14 MARTIN HARPER: True.

15 MATT SANCHEZ: And you can't go beyond that.
16 The data only tells us what's in the scope of analysis.

17 MARTIN HARPER: All of these tests are
18 surrogates for actually examining particle by particle
19 every particle that goes into a can of talcum powder.
20 Everything is, you know, a surrogate because of that.
21 That's the whole definition of sampling and a sample,
22 and that adds to the uncertainty of the technique, but

1 uncertainty is inevitable. Of course, try telling that
2 to a judge or a jury. Perhaps the reason I never have
3 testified in front of the jury is because I never want
4 to admit to practicing uncertain science.

5 (Applause)

6 CATHERINE SHEEHAN: All right. So we've
7 pretty much caught up, and we are now ready to take a
8 15-minute break -- maybe 17 -- but we will be back here
9 at 11:00 a.m. In the meantime, I'm gonna find out
10 where the breakout sessions are being held, and I'll
11 also check with the people on the webinar if we
12 received any questions for our speakers.

13 (A break was taken.)

14 CATHERINE SHEEHAN: All right. Welcome back,
15 everybody. So if everybody could take their seats,
16 please. So thank you, everybody.

17 For those of you by webinar, I want to
18 introduce the next speaker who will present on
19 interpretation of data obtained from microscopy
20 measurements. Dr. Taylor Mossman is a distinguished
21 professor of pathology at the University of Vermont
22 College of Medicine, going back a few years actually,

1 has over 30 years of research, service, and training in
2 the field of environmental and occupational lung
3 disease. She has received a career achievement
4 recognition award for her scientific accomplishments
5 from the American Thoracic Society and the Wagner award
6 from the International Mesothelioma Interest Group for
7 historic contributions to mesothelioma research.

8 And I did get some information on the
9 breakouts. The breakouts will be in this room. It
10 will be partitioned into three, and we will promise
11 individual easels.

12 BROOKE TAYLOR MOSSMAN: Thank you very much,
13 Catherine, for that introduction.

14 I am going to talk this morning with one of
15 the bullet points under this session that Ann Wylie and
16 I are doing about mineral-type form inventions,
17 emphasizing on research and others in terms of
18 carcinogenic facts.

19 So I want to emphasize, in view of all we
20 heard, that there are many properties of minerals that
21 have been recognized by geologists and mineralogists
22 throughout the decades. Most recently, this volume was

1 one that Dr. Gualtieri, a mineralogist, had arranged in
2 terms of a short course on mineral fibers, again,
3 emphasizing that there are a number of properties that
4 are important. This was a short course, and many
5 individuals in this room played a role in teaching this
6 course, as well as sampling the volume.

7 I think what's important here -- and I'm not
8 getting a really good point here though. You probably
9 can see. I apologize.

10 The point I want to stress is that in the
11 summary of this pack here, Dr. Gualtieri, myself, and
12 Dr. Roggli was historically looked at fibers in lungs
13 in many individuals with disease show that if one looks
14 at just the mineralogical features of dimension, that's
15 only encompassed on one of these many boxes which Dr.
16 Gualtieri has formulated with a number of minerals,
17 giving them a relative score, in terms of toxicity, and
18 I invite you to read this volume. I think it's very
19 illuminating, and there's a wonderful discussion of all
20 of the other properties other than dimension that are
21 important in the cancer process. Several of these I'll
22 touch upon today, but again, there's a myriad of other

1 ones that have become recognized.

2 So I'm going to talk about a tumor that we've
3 studied for almost 30 years. It's called mesothelioma.
4 It's associated with exposure to high iron-containing
5 amphiboles, such as amosite and chrysolite asbestos.
6 The point I want to emphasize is that the -- and again,
7 I'm not really getting good feedback on this. But let
8 me just emphasize that we know that in this type of
9 tumor that the affected cells are mesothelial cells.
10 They occur in a contiguous mile layer, which means
11 they're a single layer that has the property largely of
12 fluid dynamics in the pleura in the lung cavity and
13 that tumors arise when long, thin iron-containing
14 asbestos fibers are able to get out to the pleura, and
15 I'll illustrate that for you in a minute.

16 So this is what happens, and we'll see if
17 these animated slides work, but the point I wanted to
18 make is that the long, narrow amphibole fibers have the
19 capacity of entering through the, primarily, inhalation
20 route through the trachea and then a series of
21 bronchiales that branch into several other smaller
22 bronchiales until they reach, typically, the end or the

1 air sacs of the lung. And here you see what happens as
2 they enter. Again, this emphasizes that the rod-like
3 shape and the dimensions of the amphibole align
4 themselves with the airways that then penetrate through
5 the airways through bronchial tubes to the alveoli of
6 the lung, and you see that here, and then it's
7 important to realize that they eventually need to get
8 out to the pleura to cause disease. And this just
9 shows how these narrow fibers, which because of not
10 only their rigidity but also some of their flexibility
11 in working themselves up to the lung, are known to
12 penetrate through the alveolar sac, and they get out to
13 the pleura, and then emphasizing that the pleura
14 consists of two membrane-like structures with this one
15 pleura and the parietal pleura, and the parietal pleura
16 is where it's thought that tumors exist in man.

17 It's important to realize that fibers are known
18 to penetrate through the air sacs, through the visceral
19 pleura, into the pleural space, and eventually come in
20 contact with a pliable pleural mesothelioma cells where
21 tumors exist.

22 It's also been widely studied there are

1 clearance mechanisms that can take these fibers, not
2 only through cells that are in the alveoli, known as
3 scavengers or macrophages, but also, lymphatics
4 naturally penetrate through and between pleural
5 mesothelial cells and then drain into everything else,
6 and this is what happens. We all got that?

7 So here you see -- if you look really
8 carefully, you're going to see fibers, and it's known
9 that a few fibers can align themselves and be cleared
10 through lymphatic channel. The problem comes when
11 there's a high-dose exposure, and you can see what
12 happens here is a group of long fibers, that the
13 stomata are occluded, that they build up, and they can
14 actually come in contact with and persist at the site
15 of tumor induction over periods of time, as long as 40
16 years, which is the average latency of these tumors in
17 man.

18 On the other hand, there's been a lot of work
19 done with inhalation of short fibers and particles.
20 It's known that they reach the air sacs of the lung
21 effectively. They also are removed by stems or cells
22 called macrophages, completely. And here we see that

1 non-asbestiform fragments are encompassed by
2 macrophages, and if they are nontoxic, they are
3 actually taken up effectively. Some of them are
4 digested. This is known what happens, for example,
5 with magnesium containing chrysotile is that it breaks
6 down within these cells; and so these cells can
7 transport the materials up through the airways; and
8 other particles, as you see, can go through the somatic
9 and drain out to the lymphatic system.

10 So the point I want to make is that certainly
11 dimensions are important in terms of materials getting
12 to the sites of tumor induction, but there are other
13 properties that become important in terms of reactions
14 that are necessary in the carcinogenic process with
15 mesothelial cells. So our work through the decades has
16 really focused -- thanks to support from the NIH, EPA,
17 Mesothelioma Applied Research Foundation, and most
18 recently, the DOD, we've really focused in our models
19 today using human mesothelial cells on the properties
20 of materials that are important in eliciting cancerous
21 effects; and what we've invariably used in our studies
22 have been crocidolite asbestos samples. We've used the

1 UICC. We've also used the NIEHS characterized materials
2 as well, and what we've shown is that crocidolite
3 asbestos fibers is the prototype, highly pathogenic type
4 that's been known to cause human mesothelioma, causes a
5 number of triggering events when it comes into contact
6 with mesothelioma cells; and this cascade of events then
7 results in the number of activation of receptors as well
8 as cascades of a number of critical protein pathways
9 that give rise to increased cell division; increase
10 survival, which are hallmarks of cancer; and other
11 stages that are necessary for a normal cell to become a
12 full-blown cancer cell.

13 I want to emphasize that oxidants are something
14 we focused on as being important and that is a result of
15 crocidolite inhalation as well as interaction with cells
16 in vitro. We've also focused on, most recently, what
17 are called epigenetic effects through things such as
18 microRNAs, which, therefore, affect the DNA to cause
19 many of these cascades into silence a number of critical
20 tumor-suppressive chains.

21

22 So what have we learned about asbestos? And

1 again, I consider myself fortunate in that I've been
2 able to interact with many of the geologists in this
3 room in terms of co-authors and supplying me with well-
4 characterized reference samples; and this is just, as
5 you know, a general scheme of the classification of
6 asbestos.

7 Oh, we actually pointed out in the 1990s to
8 the scientific community that there were actually
9 different types of asbestos with different packages.
10 We have focused because of our interest in oxidants and
11 generation of oxidants as a result of exposure to these
12 pathogenic types. We hide iron-containing materials,
13 again, blue crocidolite, and amosite, which Moscow's
14 studies have reported maybe 20 to 30 percent bulk
15 asbestos.

16 The other thing I want to emphasize is that
17 there is little experimental work with, especially in
18 vitro, with these other types of asbestos that can
19 contain iron, may not be comparable in terms of charge
20 but certainly had not been studied with regard to many
21 of the models that we've examined.

22 So the take-home message here is that through

1 the years we've discovered that the crystallite and
2 amosite have a number of different mechanisms that --
3 and I'll go back to this -- that are important in the
4 persistent release to cells as well as the generation
5 of oxidants by cells themselves. The important point
6 here is that the fibers themselves can generate
7 oxidants by cell-free mechanisms, and they also can
8 generate what's called frustrated phagocytosis and
9 generation of oxidants do the uptake by the cells. So
10 it's been shown that the oxidation state of these
11 materials is important as well as how the cell
12 recognizes them, which at low concentrations is curved
13 by natural production, antioxidants, and high
14 concentrations. We know that these methods are of
15 control or healing are curved, and we see cancer-
16 causing events. All right.

17 Inflammation. Chronic inflammation is also a
18 feature that we've looked at in our animal experiments
19 that are important in generation of oxidants. So this
20 just emphasized the differences that we've noted
21 through the years, and I'll go into our studies in --
22 that we've seen, some of the endpoints we've looked at

1 in a few minutes.

2 Here we see what happens. This happens to be
3 a lung trachea epithelial cell, so this is an event
4 whereby we use whole 3D X-clamps and corollate these
5 studies with inhalation work. We've emphasized in our
6 work that it's the long crocidolite fibers that are
7 unsuccessfully engulfed by cells who perturb and
8 produce excess oxidant release, whereas -- what is seen
9 here by TEM is how effectively short fibers and
10 fragments are taken up or engulfed by cells. If we --
11 as these advance over periods of several months in our
12 models, you see what happens with long, thin fibers.
13 Here we see -- this is a 3D model, so we see
14 inflammation. We see accumulation of macrophages along
15 the fibers. We also see that the fibers act as
16 matrices for cell division in something called squamous
17 metaplasia, which is a pre-cancerous step in
18 development of tumors.

19 So in our experiments, we've looked at a
20 number of materials. Initially, we emphasized our work
21 with chrysotile. It's asbestiform, obviously: nature
22 asbestos, crocidolite asbestos, and amosite asbestos;

1 but we also have gotten from many of our colleagues
2 non-asbestiform preparations -- in this case,
3 antigorite and riebeckite that have been supplied --
4 and we've looked at comparably in many of our models.

5 And this is just a listing of the studies that
6 we have done where we have prepared various
7 concentrations of crocidolite asbestos as we -- one
8 type of asbestos that we really emphasize is the high
9 iron-containing and oxidant-generating species and
10 contrasted that with what are called non-asbestos
11 fragments or preparations of riebeckite.

12 We began in the '80s with preparations of
13 milled material, or ground material, that we received
14 from somebody -- might ring a bell to many of you --
15 Fred Monten (ph), the U.S. Geological Survey. Others
16 we've received from different sources throughout the
17 years. The point I'd like to make is that in all of
18 our studies, unlike a number of laboratories, we've
19 also done dose responses with all of these materials
20 and have been unable to detect markers of either
21 oxidant generation of what are called genes. These are
22 early responsive genes that are causally related to

1 mesothelioma and the various protein pathways that
2 we've discovered. These have all been demonstrated
3 effectively with crocidolite asbestos but not with
4 riebeckite, and again, our preparations have contained
5 between about 1 to 6 percent of fibers that are greater
6 than 5 micron in the riebeckite species that we did
7 drain them.

8 This emphasizes, again, historically, where
9 we've proceed with our work. We've looked at cell
10 survivor proteins. We've looked at cell survival as an
11 endpoint of -- in growing response to asbestos. We've
12 looked at cell receptors that simulate many of the
13 protein pass gates that are important in abnormal
14 proliferation and survival.

15 In addition to the non-asbestos fragment,
16 we've applied -- and I'll talk about this more in
17 detail. We've done studies with the New York State
18 Gouverneur Mine -- talcs which contain 11 to 59 percent
19 fibers. Dr. Wylie and Skinner (ph) have been kind
20 enough to supply us with these materials, and we've
21 also looked at what's called a Derrick Mine platy talc
22 in many of our models. In this case, we've looked at

1 mesothelial cells, and we've looked at ovarian
2 epithelial cells. Have not seen effects of this platy
3 talc in terms of gene expression, which is time-
4 dependent and robust with crocidolite asbestos.

5 Curiously enough, in our work with
6 mesothelioma, these are all human cells -- mesothelial
7 cells and ovarian epithelial cells. We find ovarian
8 epithelial cells are very resistant to talc as well as
9 crocidolite. That's compared to the human mesothelial
10 cells that are quite sensitive to these materials.

11 So I just want to emphasize the study we did
12 with Ann in 1997. This I think is important because it
13 addresses some of the material that I knew you would
14 hear about today, thanks to previewing some of the
15 slides by others this morning; but the fact is, in this
16 study, we looked at both NIEHS samples of crocidolite
17 and chrysotile asbestos; and we looked at three samples
18 from New York. Fibrous talcs listed on the previous
19 slide. We looked at changes that signified either
20 increases, meaning increased survival of these cells --
21 again, mesothelial cells and lung epithelial cells. We
22 also looked at toxicity by looking at the decreases in

1 cell survival of these into colonies, and what we noted
2 here was that only asbestos caused significant
3 increases in cell survival, which is one of the markers
4 that we have looked at in our mesothelial cell systems
5 and not the fibrous materials, despite the fact that
6 these materials contained a very high proportion of
7 talc fibers, of tremolite that is non-asbestiform
8 tremolite fibers, and also 3 percent in one of the
9 samples of anthophyllite. And Dr. Wylie, I'm sure, can
10 comment more on the mineralogy of these materials in
11 her presentation.

12 So we went on from there to validate our
13 findings, and what we did is we looked at the
14 literature on talc exposures, and these are animal
15 studies. I emphasize here that these studies,
16 historically, were known as the Stanton Study. Many of
17 you are familiar with them, I'm sure; but the take-home
18 message is that regardless of the routes of exposure --
19 and it's very important that these studies look at
20 fibrous talc. In fact, in the Stanton and Wrench
21 studies, they looked at seven different samples, none
22 of which gave rise to mesotheliomas in their models.

1 Other studies I've listed here because they look
2 comparatively at asbestos and non-asbestos fragments,
3 and here, again, are more studies done in different
4 species using a variety of methods of administration
5 pointing out that these did not appear to show any
6 response in terms of cancers developing in animals of
7 any species with talc.

8 It's also important to realize that there are
9 a number of additional negative studies. I refer you
10 to the IARC of 2010. IARC meaning International Agency
11 for Research on Cancer. Their publications summarize a
12 number of the studies that I could not add to these
13 tables.

14 I also want to emphasize that cell studies are
15 also summarized here, and there have been several
16 laboratories, including the laboratory by Andrew (ph)
17 and Catherine and all that have looked at samples of
18 industrial talcs from Spain, from France, and from
19 Italy that have not been able to show a significant
20 increase in any marker of what's called genotoxicity in
21 vitro in mesothelial cells.

22 So what did we learn through the decades? And

1 curiously enough, this slide came from a National Party
2 of Science committee that I served on around 1980; and
3 this was one where Dr. Zoltai and a number of prominent
4 geologist, Dr. Lanberg (ph), were highly beneficial in
5 terms of educating biologists on the mineralogy of
6 asbestos; and in a take-home matter, this probably is
7 not anything that's new to any of you; but I would like
8 to emphasize that when one considers a material, one
9 has to consider more than just dimensions; but we have
10 to consider what the cell sees or what the lung sees,
11 and it sees a variety of different crystalline
12 structures, tensile strengths, chemical compositions,
13 certainly the surface area, chemistry. The charge of
14 things such as iron become important, and all of these
15 have really been related to the endpoint, which is
16 durability of certain types of asbestos and their
17 ability to not only get to the pleural but to be
18 durable there and stimulate changes that occur in
19 cancer development over periods of as long as 40 years
20 in some cases.

21 So what we learned about mesothelioma in
22 humans as well. Naturally, we compare our results to

1 human studies that emerge over time. We know now that
2 dimensions alone do not explain the ability of a fiber
3 caused mesothelioma. There, in fact, are many more of
4 thin fibers that don't cause mesothelioma in them; and
5 they indeed are different chemically, physically, etc.
6 And crystallography also varies between these and the
7 pathogenic types of asbestos fiber, so we have to take
8 that into account before looking for agents that cause
9 mesothelioma.

10 And lastly, I just thought I should provide a
11 few suggestions, apologizing that I'm not a
12 mineralogist; but I feel that as a biologist I've
13 interacted with many, and it's really helped me
14 understand that there are different mineral properties
15 that may explain the lack of carcinogenicity of non-
16 asbestiform fragments, such as tremolite, which we've
17 used in our studies.

18 We also emphasize the importance of dose
19 response in our work. It's very important if you're
20 going to assess standards or test materials in biologic
21 systems that you do dose response of a variety of doses
22 and concentrations and dose parameters, which we had

1 done in the Wylie work; and this is the only way that I
2 think you can really sort out what is happening with
3 these different types of materials.

4 And lastly, I'd like to emphasize that dose
5 response studies in animals, special inflation studies
6 are extremely rare. We have done them and shown that,
7 in fact, there's striking dose responses to chrysotile
8 and crocidolite asbestos; and low low age (ph)
9 signatures of cancer are not observed.

10 So I'd like to end here, and we'll move on to
11 Ann's presentation, which will take these observations
12 into humans and a little more about dimensions.

13 (Applause)

14 CATHERINE SHEEHAN: So any questions before we
15 move on and I introduce Dr. Wylie? We have some
16 questions? Okay.

17 GREGORY MEEKER: Well, it's a comment more
18 than a question. But amongst the materials that I
19 collected for NIOSH, there is a range of rather
20 asbestiform tremolites that vary in iron content from
21 non-detectable up to around 10 percent; and I think
22 that will be a really useful reference set to examine

1 beyond hypothesis further, and I'm just leaving it out
2 there that those materials are prepared NIOSH.

3 BROOKE TAYLOR MOSSMAN: Yeah. I meant to talk
4 to you about that, and I know we did briefly before the
5 meeting; but I think that your presentation here really
6 has illuminated sources of materials that can be well -
7 - that are well characterized that can be examined by
8 laboratories, and I really appreciate that
9 presentation.

10 MATT SANCHEZ: And, obviously, a lot of these
11 are commercial properties, which are very happy to
12 measure as a great one too. But surface area is one
13 that's been talked about. Philip Cook (ph) spent a
14 fair amount of time with it. I think it should also be
15 looked at with greater vigor.

16 Also, I wanted to ask you a bit. As you were
17 looking at inflammation pathway, how important was that
18 inflammation pathway as a precursor to the carcinogenic
19 outcomes or those physiologic changes; and have you
20 looked at, also, the fibrogenics outcome as well?

21 BROOKE TAYLOR MOSSMAN: Yes. That's the
22 finding from NIEHS and your National Heart, Lung, and

1 Blood Institute. We have looked at great numbers of
2 asbestosis and have models of asbestosis by inhalation.
3 The difficulty, as you know, is mesotheliomas take the
4 lifespan of an animal to develop, and we have not been
5 able to do those. We go out several months, and we
6 look for early indicators of mesothelial self-
7 proliferation.

8 Your point is really a very good one in terms
9 of these standpoints. Surface area you brought up, and
10 I think that is something that Ann and I looked at. We
11 actually -- now, I think I've moved the scientific
12 community to -- rather than just adding weights of
13 materials to models, that they actually adjust for
14 comparable surface areas; and you actually get a whole
15 lot of differences between fiber types much easier if
16 you can do comparative surface area on determinations.

17 MATT SANCHEZ: Thanks.

18 AUDIENCE MEMBER 1: Have you looked at the
19 Canadian chrysotile and into the Globe, Arizona
20 chrysotile? Because that's essentially pure white.

21 BROOKE TAYLOR MOSSMAN: Right. I haven't.
22 The only chrysotile that we looked at in Canada was the

1 UICC reference sample, and when we started these
2 experiments, we used -- UICC was the Canadian and
3 Rhodesian, and we also did crocidolite. Then with the
4 characterization in the NIDHS samples that were
5 characterized by Ann in the camalital (ph) paper, we
6 were able to get enough to do inhalation experiments
7 and dose response studies. So I think --

8 AUDIENCE MEMBER 1: There was a test of the
9 iron, and the gold stuff is so clean, they used it as a
10 blood filter in World War II for pongee (ph), and of
11 course, every soldier in the Pacific who was wounded
12 liked the old Arizona chrysotile.

13 BROOKE TAYLOR MOSSMAN: Yeah. I wasn't aware
14 of that, but I think -- I was somewhat disillusioned
15 before coming to this meeting because the NIH of
16 samples no longer exists; and the fact that we can now
17 get samples from NIOSH and different institutions -- we
18 miss samples -- really is going to be very helpful.

19 AUDIENCE MEMBER 2: Did you look at short
20 chrysotile too?

21 BROOKE TAYLOR MOSSMAN: Yes. We had sized
22 materials, and we didn't see any effects. We were

1 looking, again, at endpoints of self-proliferation. We
2 did not do inhalation studies with the short.

3 Yes.

4 AUDIENCE MEMBER 3: The type of particles that
5 got in through the mesothelial layer in your studies,
6 as you indicate, some of them bound to the surface in
7 some were able to penetrate the cell. Was there a
8 difference in size or composition between those
9 different types of fibers?

10 BROOKE TAYLOR MOSSMAN: Yes. There was a
11 difference in size. As Bob referred to, we gave our
12 size materials -- chrysotile. We also had different
13 size fiberglass. Preparations of size definitely was
14 an important feature in terms of cell uptake. However,
15 the iron content and the fact that the block made the
16 changes that we saw with antioxidants indicated the
17 importance of chemistry -- iron charged, iron surface
18 availability, for example.

19 AUDIENCE MEMBER 3: Thank you.

20 CATHERINE SHEEHAN: Okay. So briefly
21 introduce Dr. Wylie. Currently a professor in the
22 Department of Geology, University of Maryland, College

1 Park. She holds a BA in geology from Wellesley College
2 and a PhD in economic geology with minor concentrations
3 in mineralogy and petrology, structural mineralogy, and
4 mining engineering from Columbia University; and she
5 joined the faculty of the University of Maryland in
6 1972 where she taught courses and directed research in
7 geology.

8 So I'm going to set your presentation up.

9 ANN WYLIE: Okay. Thank you very much. It's
10 a pleasure to be here, and thank JIFSAN for inviting me
11 and Nora for all her hard work.

12 I have my name -- only have my name up there
13 because it's sort of an opinion piece, but I wanted to
14 recognize that I have work on (inaudible) Chrisantha
15 (ph). I'm working with Allen Seagreg (ph), and some of
16 the data we have, I will copy that; and some of the
17 work toward the end this fall has benefited from
18 conversations with Andrew Corechefski (ph), Andrew
19 Duane from Chemistry and Industrial Hygiene, and Mark
20 Loutel (ph) from the University of Rochester; and we
21 are working together on some of the things that I'll
22 talk about today.

1 So the question we have is amphibole. I'm
2 just going to speak about it generally. Is it
3 asbestos? You know, sometimes that question is very
4 easy to answer. Depends on the size of the particle.
5 It can be very easy to answer. It also can be somewhat
6 confusion -- confusing and not so clear on a particle-
7 by-particle basis, and I always deal in populations for
8 that reason.

9 Is it hazardous? I think that's the basic
10 question. Not so much how it formed in the absolute,
11 but is the material hazardous? What does the lung see,
12 as some people have mentioned? And how do we identify
13 it? And by that I mean something that might be
14 hazardous, and when you have to -- when you're dealing
15 with cosmetic or pharmaceutical talc, which is really
16 the topic here, then we really do need to know how do
17 we identify it.

18 Now, today I'm really going to talk only about
19 amphiboles. I'm not going to talk about anything else
20 because that's really, I think, the issue that we have
21 here before us. And this is almost the identical slide
22 that Brooke ended with, so I can skip over it very

1 quickly. But we do know that there are certainly more
2 than dimensions. I don't want to assume that that's
3 the only thing. There are many things that impact bio
4 durability, but I'm just going to talk about dimensions
5 and the dimensions of sets of data that are composed of
6 elongated mineral particles; and by that, I mean 3 to 1
7 particles. So I'm only going to talk about elongated
8 mineral particles. I use the term EMP for that purpose
9 just to describe the data set. And at the end of the
10 talk, I'll come back to the issue of fibrous talc.

11 I believe it's a good place to look at -- the
12 effect of dimensions in amphiboles because we haven't
13 seen a lot of variability in terms of their retention
14 characteristics other than dimensions in the lung or
15 their solubility or many of the other issues that might
16 impact their clearance or -- and so as a group, they're
17 pretty insoluble and have a lot of characteristics in
18 common, so we can try to isolate dimensions.

19 Well, if you knew my children, you would know
20 that -- they'd tell you that I never throw anything
21 away; and so when I was being asked to come and talk
22 about amphibole and talc, I literally went into my

1 bathroom closet, and I found a bottle -- this is the
2 god's truth -- I found a bottle of baby powder, and so
3 I brought it to my office, and I made mounds, and I
4 looked at it under the microscope. And sure enough,
5 voila, I found tremolite, and I had no problem finding
6 it. I mount tremolite in an index of refraction oil,
7 1.578. That makes talc effectively invisible because
8 it's a metal in the index of refraction, and so a quick
9 scan of a large number of particles will show you
10 immediately where you have high index material like
11 amphibole. You can see talc platelets on end. They
12 also stand out because they have a very low index, but
13 this is a very easy distinction to make.

14 And I think our basic disagreement about
15 things and why we're here is that: Do we accept the
16 counting criteria that are used to assess the magnitude
17 of exposure to asbestos in environments where asbestos
18 is known to occur? We developed a whole methodology
19 for protecting worker and for making sure buildings
20 were clear when we knew asbestos was there. Do we
21 accept those as the definition for asbestos? And
22 that's the crux of the problem.

1 This is not asbestos. This is just a piece of
2 rock. I mean, you look at it under cross-colors you
3 see that it is a fairly uniform material. It's not
4 composed of fiber bundles. It's not asbestos. It
5 can't even be inhaled. This is 19 by 83 micrometers.
6 You can't inhale it. It's not going to braid up when
7 you put the powder on your body to make a lot of other
8 little particles out of it. So this is not -- to me
9 this is not asbestos, and I don't think I'm gonna get a
10 lot of disagreement about that from anyone in the room.

11 If it's not asbestos and it meets the 3 to 1
12 and longer than five, then how do we approach the
13 problem? How does FDA approach this problem? I think
14 that's the crux of the matter here. We need a
15 different definitional characteristic for tremolite if
16 we are going to enable the identification of asbestos
17 or hazardous particles in talc.

18 I'm hoping this next slide shows up. I've got
19 a new camera, and I'm not so sure. It's okay. Now,
20 this is a sample of tremolite asbestos. Art Langer, you
21 gave this to me, gosh, a zillion years ago. It comes
22 from Metsovo, Greece, where there's a high

1 incidence of mesothelioma and other lung diseases among
2 the residents of four villages in Greece. Art reported
3 on it, and it's tremolite, and it's asbestos; and it's
4 about the same size particle, about 11 micrometers wide
5 and 77 micrometers long. And there's no question that
6 this is asbestos, and even if this is just a -- not as
7 nice as those electron microscopy pictures, when you
8 look at it under the cross-colors, you can see that
9 it's composed of lots and lots of little fibrils, and
10 they break up easily just like spaghetti and have all
11 the characteristics that make asbestos, in my mind,
12 dangerous.

13 But can we tell these forms apart? And I will
14 grab, there are many variations between this and the
15 one I showed you before in terms of habit but not in
16 terms of relative abundances. Almost all the amphibole
17 that makes up the crust of the earth and in the United
18 States -- I would say that's between 6 and 10 percent
19 of all rock is made of amphibole. Almost all of that
20 is just ordinary garden-variety material that will form
21 cleavage fragments if you break it up. That's just --
22 it's not uncommon, but it is uncommon -- it is rare in

1 terms of its abundance, and any of the other forms are
2 there also. You can find them. There's nothing out
3 there you can't find, I have learned, but I'll keep
4 going.

5 So I want to talk about dimensions. I want to
6 talk a little bit about width and length. Where are we
7 going here? So as Brooke I think has well summarized,
8 those particles that are known to cause asbestos-
9 related diseases, where we actually have it in human
10 populations. We have narrow widths on long fibers. It
11 is the narrow width that makes asbestos flexible. You
12 can actually bend any rock if you can make it long and
13 thin enough. That's the truth of the matter. So it's
14 the relative proportion -- the flex, the width -- that
15 gives flexibility and people are so tired. I wrote a
16 whole paper on this, this great mineralogist that was
17 mentioned earlier.

18 Width and density control the aerodynamic
19 behavior of fibers. Width controls the penetration
20 potential of fibers deep into the lung and access to
21 the pleura, and migration through fluid vessels in the
22 body is controlled primarily by breadth; and when I say

1 very narrow, I'm talking about fiber rates that range
2 from less than .4. I'd say around .35 to .03, which
3 are about the narrowest fibers that I've seen reported
4 in the literature.

5 Now, length -- again, we look at length and we
6 know that, as Brooke described very clearly, the short
7 fibers are removed by a variety of mechanisms. The
8 long fibers persist, and almost everyone that has
9 studied the issue believes that long fibers are more
10 important in the carcinogenic response than short.
11 We find abundant long fibers in lumber and stumps. The
12 long fibers appear to be preferentially retained in the
13 lungs. The short fibers are removed, and of course,
14 ultimately, for the work I'm going to talk about a
15 little bit later, it's important that our occupational
16 exposure, our risk analysis, all the things that we
17 depend upon to understand the carcinogenicity of
18 mineral fibers are based on exposures to long fibers --
19 L5. I call them "L5." I got tired of saying "length
20 greater." So L5 fibers, that means longer than five.

21 And the -- there is, however, a conundrum that
22 we face, and that word was used before. I hope I'm

1 using it properly. Whereas, the long fibers are
2 associated with disease, the short fibers are much more
3 abundant. The mobile fiber lengths for crocidolite,
4 that 1 to 3 micrometers; amosite, 1 to 5; Libby 1 to 4;
5 and so forth. So there's lots and lots and lots of
6 short fibers, but I'm gonna focus on the long ones for
7 all these reasons that I described. I do treat the
8 widths characteristics of long and short fibers
9 differently for that reason.

10 So in the court cases that are in front of us,
11 the Davis set's been entered in evidence. It's part of
12 the public record. I took it, and I plotted it, so I
13 wanted to see from my own mind what is it exactly that
14 we're talking about in talc.

15 And so these are L5 elongated mineral parts.
16 They meet 3 to 1. They're longer than five, and they
17 were -- the data was provided by Longo (ph) in 2017;
18 and what we see here is for these long fibers. You see
19 that there's a range in fiber widths. It's actually
20 fairly uniformly divided between .2 is the narrowest
21 fiber recorded. There are no .1 fibers in that data
22 set, and they range the -- I put the mode on there --

1 it's hardly a mode, but at least it's the highest value
2 -- at .4, but they stand rather regularly over to about
3 1.2 micrometer, and then there's another bump out there
4 at 1.5. Now, I want you to remember the shape of this
5 curve because I'm gonna come back to it a little bit
6 later.

7 I know that Metsovo, Greece tremolite asbestos
8 that I showed you, this is the width distribution. I
9 thank you Allen (ph) for these data, and you can see
10 that the mobile width is .175, and this is a very
11 uniform material. It's remarkably uniform. It has
12 virtually no fibers braids, and that's .4. S little
13 tiny bit out there. There's always going to be those
14 things. It's very, very narrow, and it doesn't look at
15 all like that other sample, and I want to show you
16 putting them side by side on the same scales just what
17 I mean when I say they don't appear to be the same at
18 all. And so this material has a wide long range and
19 low abundance of a lot of different material. This
20 material has a very narrow range and a very high
21 abundance -- a small number of widths.

22 So we have what we know about asbestos as a

1 human carcinogen. Comes from exposure to asbestos in
2 human population, in mine population, industrial
3 workers of all sorts; but I want to look then -- let's
4 look at -- compare what I just showed you to what we
5 actually know about what asbestos is like. And I like
6 this slide very much because these data come from Shedd
7 in 1985, the Bureau Mines. She measured
8 extraordinarily carefully. You had very high
9 magnification. A lot of different crocidolite samples,
10 and the one on the left shows you that there are molds
11 of crocidolite that are very, very tiny -- .03 in width
12 and the one from the Cape there is about .05. You
13 know, mostly, you don't know that that's there because
14 the way we do measurements -- a part of the
15 measurements is we use wide bins when we plot
16 frequency. So this and that, those are exactly the
17 same data. There's no difference in those two data
18 whatsoever. It's just that this is plotted at a very,
19 very narrow bin width, and I wish that we had data like
20 this on amosite. I wish we had it on a lot of things
21 because they -- biological potencies of those very,
22 very narrow fibers, it's like it was rather poorly

1 investigated.

2 So this -- most of the width distributions
3 that I can show you have bin widths of about .1
4 micrometers, and so you'll see. If that's there, I
5 don't know. We'll see what I'm going to show. It's
6 like this, but I do want to point out that virtually
7 every fiber in these samples is less than .4
8 micrometers in width and the abundance of particles is
9 the greatest, less than .1.

10 Now, it's also very important for us to
11 remember that just because we call something
12 crocidolite or tremolite asbestos or whatever, that
13 does not tell you much about it because mineral samples
14 are location specific. There's no ideal one of any of
15 these things, and these are four different locations
16 where crocidolite asbestos is mined; and the first two,
17 again, these are single individual samples, are from
18 the trans -- I'm sorry -- from the Cape and from
19 Australia, and they have the very narrowest widths,
20 .05. And then when you move into the Transvaal, you
21 can see that the width -- the modo (ph) width is much
22 wider. It's still pretty narrow but much wider. And

1 then when you got to Bolivia, which they are still
2 mining crocidolite down there, by the way, you see a
3 much different kind of distribution.

4 In 1971 there was an article published in
5 Nature and -- by Timbrell, Grifferson (ph), Pooley,
6 1971 who -- the title of the article was The Role of
7 Fiber Width in Mesothelioma, and at that time they were
8 looking at mesothelioma among the mine populations in
9 the world, and they didn't find any in the Transvaal.
10 Now, the Transvaal doesn't just mine crocidolite. The
11 major asbestos mine there is amosite, and these widths
12 are a little bit wider than this. But for the Cape and
13 Hamersley that the widths were much wider, and they
14 postulated that it is the width of the fibers in South
15 Africa -- these two locations -- that explain this huge
16 abundance of mesothelioma in the Cape and its lack in
17 the Transvaal. I think they had one case. Somebody
18 might be able to tell me another. Reference that for
19 prep.

20 And then I'm gonna look again at comparing. I
21 just picked one of these asbestos populations from
22 Hamersley, Australia. Again, this is the Shedd data,

1 and this is data from our lab, and this is the
2 California riebeckite. And I want you to look at the
3 shape of the distribution, a large number of evenly
4 abundant particle sizes and width, a little bit --
5 another big bump out here a little bit further. This
6 is exactly the profile of those tremolite particles
7 that Belongo (ph) presented as coming from a platy
8 talc.

9 So let's look at some of the other types of
10 asbestos that we know have a potential to cause
11 asbestos-related disease. This one was characterized,
12 again, by my lab by SEM. I think -- I wish I had done
13 the TEM, but I was young and stupid; and here you can
14 see that we have a mode at about .33, and then there's
15 a shoulder on this width. They may be two independent
16 sets of data there, two modes that are just not clearly
17 defined. There's certainly a couple more as we go out.

18 Amosite has very fine fadders. I see a .1.
19 Just about 6 or 7 percent in this particular profile,
20 and at .2, there's 15 or 16. So there's a lot of
21 narrow fiber. There's a lot of white fiber. Amosite
22 is very interesting. Mineralogical studies have shown

1 that there is actually -- there are -- other than
2 amphibole minerals that sometimes form between the
3 fibers that tend to glue them together, and there is a
4 structural continuity across fibers; and so I think
5 amosite doesn't break apart quite so readily, but it
6 does indeed have these very, very narrow fibers that
7 are characteristic of asbestos.

8 Libby. Okay. So mesothelioma is known from a
9 Libby and these data were gathered by MRI in a study
10 that was done a long time ago. They were extracted
11 from the ore, and you see a pattern; and by the way,
12 this pattern looks exactly the same as the pattern of
13 the amphibole in the air around the town of Libby that
14 was collected by EPA not all that long ago. So this is
15 a very stable cross-section, here, frequency diagram.
16 I'm not -- I have numbers of fibrous elements exactly
17 the same. So this is at .34. We have -- we have
18 another bi-modal distribution. Like this beginning to
19 show an amosite, but we can clearly see it here, and
20 then it will kind of lump out further.

21 This second may be a courser fiber. It may be
22 two different periods of fiber growth that have

1 produced this. It could have broken fragments in
2 there. I'm not totally sure what it is, but that --
3 this profile is very characteristic.

4 And we've talked about Italy. So the
5 epithelia, there's mesothelioma among the people who
6 worked in the quarries there. These are data from
7 Paoletti (ph) and Bruny. They published their data in
8 charts, and I copied it, so I'm not totally -- well, I
9 think my arrow copy is .02. So I think these are
10 pretty good representations of what they show, and
11 again, you see kind of the same sort of thing. You see
12 a lot of very narrow fiber -- .25. You see a secondary
13 peak at .5 and another one at .75 and then one a little
14 bit further down.

15 And finally, this is Pokela , Finland.
16 Asbestos was mined there for, I don't know, hundreds of
17 years, and it stopped production in the year of 1970s.
18 At that time there was no -- and even into the '90s
19 there were no mesotheliomas at all reported from
20 Pokela. The population there has a -- the recent
21 publication where there are some mesotheliomas
22 reported. I don't know what that means since it's

1 been, you know, 40 years since the mine closed; but
2 nonetheless, I'm not sure about the mesothelioma
3 potential for this particular anthophyllite, but I
4 would predict that it should, based on this. You can
5 see it's got very narrow fiber in it. It has this bi-
6 modal distribution, and there's a lot of characteristics
7 that are similar to the ones that we have seen.

8 So if I were to summarize, what does the width
9 look like in asbestos, I would say that we have one
10 type, which is like crocidolite and that Metsovo
11 tremolite asbestos where we have 50 to 60 percent of the
12 fibers that are longer than 5 micrometers. Now, I'm
13 only talking about longer than 5 micrometers and the
14 percentages are all those particles that start out at
15 least at 3 to 1. 50 to 60 percent are less than .2, and
16 amosite and -- we have the dimensions of crocidolite
17 present, but generally speaking, the width is a bit
18 larger.

19 We move onto Libby and to Pokela and Italy, we
20 see these bi-modal distributions. We see the presence
21 of these very narrow fibers, in decreasing proportions

22

1 perhaps, but they do all have particles of width less
2 than .2. So if I'm looking for asbestos, I'm gonna
3 find out -- I'm gonna look for what's always there.
4 It's always less than .2. It's always there, and so if
5 you're gonna call something asbestos, you better have
6 particles in there that are longer than 5 and less than
7 .2.

8 Now, does all this matter? Does it make any
9 difference whether these particle populations are
10 different? Does it matter? And the only way we know
11 is to look at the patterns of disease among the mining
12 population and mesothelioma mortality. Most of our
13 studies are done from mixed exposures, you know, where
14 you have four different kinds of asbestos or an unknown
15 exposure to asbestos -- workers and that sort of thing.
16 But there are estimates of mesothelioma potency, and
17 the measure which I'm just referring to, they often
18 refer to as RMeso, and that's the percent of all
19 expected deaths per fiber -- per fiber, and that's by -
20 - per fiber. I'm talking about the ones that are
21 measured for occupational exposure, longer than 5 and 3
22 to 1 expectation, so the sack per fiber, per cc, per

1 year. So that's the measure, and Hodgson and Darnton
2 published some mineral-specific values for RMeso, and
3 Garrett and Castillo (ph) have updated these data. The
4 Journal of Toxicology and Applied Pharmacology has a
5 volume coming out very shortly -- I'd say within the
6 next three weeks -- from a conference that was held on
7 this topic in Virginia a year ago, and this paper is in
8 that volume. So it's something certainly to look for.
9 A lot of them are -- papers are already available
10 online.

11 And so they published an update on crocidolite
12 and amosite. They added the Libby and the mining
13 populations at Homestake, South Dakota; and Homestake
14 is the largest and oldest active gold mine (inaudible).
15 It's a great place to go to. I like (inaudible), but I
16 like it anymore. But the miners there mine deep
17 underground mines in a rock that's basically made of
18 grunerite and quartzs. And so they were exposed to
19 these particles, and we do know that there is -- has
20 been no asbestos related diseases in that population.

21 I think there will be additional studies come
22 available that we can use. And what do I mean by

1 "being able to use?" Exposures to a single mineral.
2 And what do they show, and I'll show you some real
3 data, but I just want to be sure that the point is
4 clear. They show that for the same occupational
5 exposure as measured in fiber per cc year that there is
6 a great difference in mesothelioma mortalism from
7 location to location, minerals content, and that must
8 be reflected one of these or more characteristics. It
9 has to reflect dimension or durability, composition,
10 and common structure. It should have been right there.
11 It should reflect something that's different from
12 location to location.

13 So here are the data. These are from Garrett
14 (ph), Brad (ph), and Custor (ph). Asbestos type and
15 location. Now, there's a lot of assumptions should
16 come into some of the data that I'm gonna show you, but
17 these just come right out of the paper. You can read
18 it yourself, and I'm giving you the RMeso for overall
19 crocidolite, and that's from the Cape and Transvaal.
20 So for those two locations the overall -- and they
21 published one for the Cape, and they published one for
22 Hamersley and they -- you know, they have several; but

1 I averaged these, and they have averaged them, so I'm
2 giving you the average. It's 0.451 and that's the --
3 95 percent confidence intervals are shown there.

4 Amosite in the Transvaal, look how far that
5 drops. It drops way down, 0.09. Winchite and
6 Richterite asbestos from the vermiculite workers of
7 Libby, Montana, 0.028. Drops down. Overall chrysotile
8 0.0012. I'm going to talk about that, and we're about
9 to be perplexed with some of the things that Brooke
10 talked about. It's a different mineral. We usually
11 can't compare them.

12 And then fragmented grunerite from Homestake
13 gold mine in Lead, South Dakota. This is not asbestos
14 and there is no excess disease, so they have RMeso at
15 zero.

16 So what do we do with those data? Well, we
17 need an index for the toxicity of durable mineral
18 fibers. What index can we use that we can compare and
19 try to understand this mineral difference? And I got
20 three up here. There might be a lot of other ones.
21 Litman (ph) has suggested that in order for minerals to
22 produce mesothelioma it has to have a width less than

1 about 0.15. Stanton used 8 micrometers and 0.25 in
2 width, and I dreamed up another one here. Longer than
3 7 and a width less than 0.4, and I have -- I'm using
4 that one. I'm gonna show you some data from that one
5 because Fred Pooley, in his studies of lung tissue and
6 what particles actually get to the pleura, has shown --
7 and this paper's coming out in this volume --that these
8 7 micrometer particles long are sitting right there at
9 the surface of the lung waiting to move into the pleura.
10 And Lance (ph) et al. published their assessment that
11 particles have to be less than 0.4 micrometers to make
12 it to the pleura. Now, we can argue about those. I'm
13 not sure these are the right, but I've got three here,
14 so let's look and see how they work. It could be added
15 that I hope our work, as we go forward, will improve
16 this.

17 So what we have plotted here is the total
18 fiber in the exposure and what proportion of that fiber
19 meets certain width definitional criteria. So let's
20 just take this first gray triangle there. That is for
21 length greater than 7, width less than 0.4. That's for
22 crocidolite, and I've averaged crocidolite at eight

1 populations, so I'm happy to -- it's a way to gain
2 (inaudible). Anyway, there it is. So it's 58 percent
3 of the crocidolite fiber fall in that category. For
4 amosite, it's about 30 percent. For winchite,
5 richterite asbestos from Libby, it's at 17 or 18; and
6 for Homestake, it's zero. But that is with a simple
7 regression line on there, and put it just right through
8 all those, and so that quotes the percent expected
9 deaths against a dimensional characteristic of a
10 population; and I did that for the length greater than
11 7, width less than 4. I did it for width less than
12 0.15. I did it for length greater than 8, width less
13 than 0.25.

14 So in the fiber per year, this tells you
15 something about what that fiber that they were
16 breathing in actually looks like. It isn't a bunch of
17 particles that are 5 micrometers long and 1 micrometer
18 wide. There are much different from that, and they
19 vary among these native sacks, which I think is a --
20 the reason why the mesothelioma potential varies. The
21 0.85 and the 0.15, they almost fall on exactly a
22 straight line. They are very, very similar. The R

1 squares should be something like 98 percent, and they
2 put these when you only have a points. You only need
3 two to get 100 percent now. (Audience laughs.)

4 So let's try -- can we use this to predict?
5 Can we take a curve like this and predict mesothelioma
6 outcome? So I've taken three samples I'm gonna show
7 you. One is in Metsovo, Greece, where we know there's
8 mesothelioma. One is Pokela, where we're not so sure,
9 but if my medical (inaudible) would see, what would
10 they predict. And then I've taken the data from Italy.
11 What does it predict in terms of -- at home, I don't
12 know how to plot error and square in the Excel. I'm
13 old and really backward about all that, so I asked a
14 friend of mine to do that for me. I have all the
15 errors. I just want to show you what the errors are in
16 these points. So these are one standard deviation in
17 the percental fiber and 95 percent confidence interval.
18 Just want to be sure. We talk about error earlier.

19 All right. So here are these three curves,
20 and Metsovo, Greece tremolite plots on these three
21 different curves, and it plots at an average of about
22 0.3 RMeso, so you know, something in there. By all

1 these criteria it should cause mesothelioma. Of
2 course, we know it does. With young Lidia (ph), in
3 Italy, well, that one is around 0.2 expect for the
4 width less than 0.15, and it's way down here in the
5 lower corner. There were no data from that chart I
6 copied of particles that were less than 0.1 micrometers
7 in width, so I'm not 100 percent sure about the quality
8 of that data point. And then Pokela, Finland, they
9 plot at about the same level as well. Just a little
10 less than 0.1.

11 Okay. So how do we use all that information
12 to help the FDA? That's the question. This, again, is
13 from Metsova; and under PLM, do I have any trouble
14 telling this from that? I don't think so. I don't
15 think anybody would have any problem. This is composed
16 with a zillion fibers that are less than 0.2
17 micrometers in width. I mean, it is a material that
18 will come apart. If this were in talc and you rubbed
19 it on your body, I'm not sure you wouldn't release a
20 lot of this fiber. You might start with a certain
21 number. You might end up with a lot more. I think
22 when you inhale fiber particles that it's aggravating

1 your lung. So I think there's a lot to be said for the
2 health effects of asbestos because of the habit that it
3 forms, and it certainly is predicted by my analysis
4 that this would be highly carcinogenic. No problem --
5 this is a PLM. This particle is 18 micrometers wide.
6 It didn't come out from a talc deposit. Here's another
7 particle from that bottle -- my children's baby powder
8 -- and it's not asbestos. It isn't a fiber bundle. It
9 can't disaggregate. It can't be inhaled. Nothing can
10 happen to this that I know of that has any health
11 hazards associate with it whatsoever, none. And
12 there's no confusion about a particle this size, about
13 whether or not it's asbestos, using PLM. By PLM, it is
14 unambiguous.

15 AUDIENCE MEMBER 1: Did you throw out the
16 bottle?

17 ANN WYLIE: Pardon?

18 AUDIENCE MEMBER 1: Did you throw out the
19 bottle or keep using it?

20 ANN WYLIE: Well, it's -- my children are in
21 their 40s.

22 Okay. So the analysis issues in cosmetic talc

1 I think are the crux of the matter. And we ask: Is
2 the amphibole in talc -- is it asbestos? Does the talc
3 contain chrysotile? And how do you distinguish
4 anthophyllite from fibrous talc? So let me just make a
5 few comments on these things.

6 Okay. You see amphibole asbestiform. Well,
7 the talc that I looked at under my microscope last week
8 or week before -- week before Thanksgiving, actually --
9 the particles were huge. I mean, we're talking about
10 70 micrometers. Wow, these are huge. And these talc
11 particles were gigantic. I don't know what I was
12 expecting. Why we would have gone to the TEM, I'm not
13 totally sure. Almost everything that I saw in this
14 bottle was very, very large; and so polarized light
15 microscopy is great for this kind of thing. You can
16 see fiber bundles no problem, and they're going to be
17 there -- I contend that if it's amphibole and it's
18 really asbestos, they're going to be present in these
19 large sized particles. They don't just all break up by
20 themselves. The talc does. Remember talc is the
21 softest mineral known. If it's not breaking up into
22 tiny little particles, I don't know why the tremolite

1 would. But if we go to the electron microscope and we
2 count 3 to 1 long, width 5, what about -- how do we
3 deal with that? How do we look at those data? And I
4 think you have to ask at those data whether or not
5 you've got particles that have widths less than 0.15.
6 Do you have lots of particles that are longer than 8
7 and less than 0.25? Do you have a lot of particles
8 that are longer than 7, less than 0.4? I mean, are
9 these particles that are asbestos-like present in the
10 sample? If it's chrysotile -- well, I would ask: If
11 there's serpentine found in talc, is chrysotile evident
12 by light microscopy? Chrysotile asbestos is just like
13 amphibole asbestos in the sense that when it occurs as
14 asbestos in veins, it seems you should be able to see
15 this no problem. If it's dispersed -- if it's like a
16 mass fiber deposit, sort of mass fiber -- chrysotile
17 plus talc, you'd have to go with the TEM, but I don't
18 know of any assurances like that. Now, some of the
19 rest of you may. I just am unaware of that occurrence.

20 I found this in that same bottle of powder
21 that -- I swear it was there. And this is fibrous
22 talc, and I know it's fibrous talc because the indices

1 of refraction are too low for it to be amphibole.
2 They're not even close. It also has an extraordinarily
3 high birefringence. In other words, the indices of
4 refraction parallel and perpendicular to this bundle
5 are vastly different and the material shows up under
6 polarized light microscopy without a problem. It is
7 actually so simple under a PLM to tell fibrous talc
8 from anthophyllite asbestos.

9 Let me just -- so let's talk about some of
10 these issues because I see this issue all the time.
11 People talk to me about this. Why is it a problem? It
12 appears to me that by chemistry and morphology that the
13 grains of fibrous talc and anthophyllite asbestos look
14 an awful lot alike by SEM (inaudible) 1:14:55.1; and
15 they look very, very different by optical, and the
16 reason for that is that optical microscopy is sensitive
17 to the water content. Water content lowers the
18 density. When you lower the density, the indices of
19 refraction go down. But TEM and SEM are insensitive to
20 the water, and so people confuse them all the time by
21 just looking at chemistry. As I've said before you can
22 easily tell these two apart.

1 Now, I've talked to a number of TEM
2 microscopists and asked, "Why do you have this problem
3 all the time of fibrous talc being called anthophyllite
4 asbestos?" And they said that in ISO, methodologists
5 that -- not always when you have two minerals in that
6 similar composition that are constantly present, not
7 only do you look at the zone access pads for
8 consistency, whether it's tremolite or anthophyllite,
9 but you also want to evaluate them for inconsistency
10 with the crystal structure of other minerals of similar
11 composition and this is simply not done. It is not
12 evaluated. It used to be that -- just the 5.3.
13 Instant spacing got the definition of anthophyllite,
14 and then we started getting a few zone access patterns,
15 but they are not necessarily specific for
16 anthophyllite. They may be consistent, but they may
17 also be consistent with talc and, therefore, do not
18 provide the necessary distinction. I know this can be
19 done, but I think it is an extremely difficult
20 proposition. And those of you who deal with electron
21 microscopy can comments on that in a little bit more
22 widely.

1 Well, I was asked weight percent versus
2 particle number. Boy, there's a really different way
3 of looking at things. I don't think you should begin
4 an analysis for asbestos unless you know it's there. I
5 just don't think so, and you can tell that it's there
6 by looking for evidence with fiber bundles, scanning
7 the slides by PLM. You have some indication that you
8 have asbestos present by mechanisms that we know are
9 reliable before you began counting individual
10 particles.

11 Normally the levels are very low in tremolite,
12 in top material; and that is a consistency -- there's a
13 possibility of then homogeneo (ph); and we had a little
14 earlier discussion. Someone said they looked at
15 20,000, and there wasn't any; and then someone else did
16 some concentration, which is a very good way to abuse
17 PLM, by the way. I think it could be sample
18 inhomogeneity at those very low levels. But PLM, you
19 can -- particularly if you concentrate, you can get as
20 low of a sensitivity as you want. It just depends on
21 how much material you want. Really? And how much time
22 you want to spend. But 0.1 or .01 percent BLM is

1 pretty easy.

2 Remember, the mass is in the large particles.
3 It's not in those little tiny particles. They don't
4 have any of the mass. It's in the big particles. We
5 have particles that are 100 micrometers wide, and we
6 are trying to measure the mass of a component with the
7 little particles that are 1 micrometer? The mass is in
8 the big stuff.

9 Now, fiber number, that is a very complicated
10 approach. I don't think that it is helpful in terms of
11 estimated percentages of anything. I don't -- I think
12 there's a great deal of difficulty and reproducibility.
13 I'm going to leave it to the TEM people to comment on
14 this. What are you going to count? What do you
15 measure? If you use TEM or SEM and you measure fiber
16 number, I would argue that you must record the length
17 and the width of every particle that you measure so
18 that you can evaluate the population for toxicity, and
19 that would be the recommendations that I would have to
20 give you. Thank you.

21 (Applause)

22 CATHERINE SHEEHAN: Thank you very much.

1 ANN WYLIE: You're welcome.

2 CATHERINE SHEEHAN: So any questions? We got
3 questions?

4 AUDIENCE MEMBER 4: Yes. Often when we're
5 looking at talcs that have these amphiboles in them,
6 what we're seeing aren't necessarily singular
7 structures. We often see bundles, and it's difficult
8 to actually determine what we're going to use for the
9 width in a bundle if you have a bundle that has, say,
10 some fibers that are 0.3 and some fibers that are
11 particles within that bundle that are less than half a
12 micron. How would you address that when you said you
13 should be measuring the aspect ratio of every particle
14 by EM?

15 ANN WYLIE: All right. I never measure aspect
16 ratio. Aspect ratio is an absolutely useless
17 parameter. It's dimensionless. It has no value.

18 AUDIENCE MEMBER 4: Wake me up.

19 ANN WYLIE: So I really -- I feel really
20 strong about that. Well, when you look at all of these
21 distributions, we all had that problem. We have it in
22 every distribution that's ever been done, but in terms

1 of particle -- you just take the width. Just take the
2 width. Whatever it is, take the width. Of the bundle,
3 whatever, take the width; but you should have --
4 asbestos easily disaggregates by hand pressures. It's
5 one of the definitions. It easily disaggregates, but
6 you're gonna have a lot of the other things in there,
7 and I wouldn't worry about that one bundle. I would
8 worry more and measure more those individual particles
9 that you see which are by far more abundant than the
10 one particle that you're talking about. That's been my
11 experience.

12 AUDIENCE MEMBER 4: Well, my question was,
13 basically, if a bundle is defined as three or more
14 fibers, parallel each other, separated by less than the
15 width of one fiber and those individual fibers have
16 different widths, how do you determine a width of a
17 particle when you said that ever particle must be
18 measured for its length and width?

19 ANN WYLIE: I would measure the bundle, as I
20 told you. I mean, all those populations that I've
21 shown you -- all right. There is thousands and
22 thousands and thousands of measurements, and whenever

1 there was a bundle, we measured the width of the
2 bundle. All right? Because the number of those
3 particles that are individual far out -- exceed -- and
4 that's why you always have tails. That's why you
5 always have tails on distributions of asbestos. You
6 don't always just -- it doesn't just end at .1 or .2
7 micrometers. It's all -- the crocidolite decided it's
8 so readily that you tend to have much shorter tail on
9 crocidolite. All right? For me, I (inaudible) why
10 it's so dangerous because I think it would disaggregate
11 under any circumstances, but the -- you measure
12 whatever you see there, and then -- that's what all of
13 these are based on. We never try to say, well, what
14 about those individuals that make that thing up? Never
15 tried to do that. So all the data that I'm showing you
16 here, it's just every particle however it presents --
17 bundle, no bundle -- are what makes these data. That's
18 what I've showed you, or that's how we've dealt with
19 it.

20 AUDIENCE MEMBER 5: Just a comment, actually.
21 Showing up. If you can't do magnification better and
22 better and you keep chasing zeros, you can end up

1 increasing the number of fibrils or fibril masses gone
2 to the individual fibril. Now you've got millions
3 where you only saw one bundle to begin with. The end
4 is sitting right here. Just measure what's there, not
5 the individual separations.

6 ANN WYLIE: Yeah. Next question.

7 GREGORY MEEKER: I appreciate what you said at
8 the end about measuring individual by TPM the
9 dimensions, and then you went on and said something I
10 think was wrong.

11 You said because then you can calculate from
12 that the toxicity, and I guess you were getting it in
13 mass, and mass is really irrelevant in toxicity. It's
14 the number of individual small fibers that are gonna
15 reach the lung. Because as you said earlier, 70 micro-
16 like fiber never going to reach the lung, but it --

17 ANN WYLIE: Right.

18 GREGORY MEEKER: -- has a huge mass. It's
19 gonna overwhelm millions of other fibers.

20 ANN WYLIE: That's right.

21 GREGORY MEEKER: As Roe (ph) said 40 years
22 ago, .25 percent in talc, it still had billions of

1 fibers.

2 ANN WYLIE: No. I agree with you. I don't
3 disagree with anything that you said, and I think that
4 you misinterpreted. If you're gonna measure particles,
5 you're not going to be calculating mass. I mean, that
6 would be fiber number, and that's where I think you
7 measure everything; and I think it's a very complicated
8 to extrapolate from TEM print to an entire ball of
9 talc. But nonetheless, I think what you're measuring,
10 measure everything; and then what I met my toxicity, I
11 think that you have to have asbestos-size particles to
12 have asbestos-related disease. Now, that's my opinion,
13 but -- so I would say that if you don't have
14 populations of particles that have widths less than
15 0.4, then -- and I mean 0.35 measured or less --
16 usually there's a 0.05 error -- then it's very unlikely
17 that you're going to have the kind of toxicity that we
18 see with amphibole -- of crocidolite. Now, that --
19 that's my opinion, and you know, it's not something --
20 and I say it is that based on some of the work that I
21 just showed you why I think that way, because I didn't
22 get to see dose response on those sized particles.

1 AUDIENCE MEMBER 6: I wanted to put in a good
2 word for aspect ratios. (Audience laughs.) One of the
3 biggest that we found useful with aspect ratios is that
4 as you look up populations of non-asbestos fibers and
5 asbestos fibers, the diameter of the asbestos fibers,
6 the width stays pretty narrow. So as they get longer,
7 the aspect ratio jumps up, and it doesn't happen with
8 non-asbestos fibers. If they get longer, they get
9 fatter, so their aspect ratio goes flat.

10 ANN WYLIE: My experience has been exactly the
11 opposite. The longer they are, the higher the aspect
12 ratio concluded fibers, and I've got a lot of data
13 published that shows that.

14 AUDIENCE MEMBER 6: Compared with asbestos?

15 ANN WYLIE: No.

16 AUDIENCE MEMBER 6: That's the comparison I'm
17 making.

18 ANN WYLIE: No. As you -- if you take
19 ordinary tremolite and crush it off, when you look at
20 the smaller particles, the aspect ratios will be last,
21 and it isn't until they get longer does the aspect
22 ratio increase. So I don't like aspect ratio, because

1 when we see populations and you compare two populations
2 up here on aspect ratio, you do not know what the range
3 of length over which those particle populations
4 represent. And so one of them might represent
5 particles from 2 to 100, and one might represent
6 particles from 1 to 20; and that might be very, very
7 different; and we're not comparing apples and apples in
8 that way. Aspect ratio can be very misleading.

9 AUDIENCE MEMBER 6: We were building the size
10 distribution and then we're comparing the aspect ratios
11 of the two populations, so you know what the lengths
12 are.

13 ANN WYLIE: As long as you compare aspect
14 ratio over the same length range, then I think it has
15 some validity for comparative purposes; but if you
16 don't have the same length range, then you are not
17 comparing apples and apples.

18 AUDIENCE MEMBER 6: I agree.

19 AUDIENCE MEMBER 7: I've got one question
20 along these lines. Has it been determined if someone
21 said reason or bundle, what happens over time to the
22 bundle in the lung? Did they -- are they -- do they

1 come in a case like at Cenegenics? Are they individual
2 fibers? Does anybody know?

3 ANN WYLIE: Well, maybe, Brooke, you can
4 answer. Most of the data I've seen shows single
5 fibers.

6 BROOKE TAYLOR MOSSMAN: Yeah. I think a lot
7 of the original work on the fiber breakdown in bundles
8 was done by Bob (ph) a long time ago, in the 1960s; and
9 he did show that even long asbestos fibers in
10 Crocidolite-enticed talc broke in.

11 AUDIENCE MEMBER 7: Okay.

12 ANN WYLIE: There was a wonderful study by
13 Coffen (ph) on, apparently, actinolite in rats, and
14 they -- I think they did inflation. I'm pretty sure.
15 And then they killed the rat slowly over a long time,
16 and looked at the populations; and with time, the
17 numbers of fibers in the lungs increased. And that
18 shows you that those bundles were breaking up. So I'm
19 pretty sure that that's my answer.

20 AUDIENCE MEMBER 7: Uh-hum.

21 CATHERINE SHEEHAN: Hunthro (ph).

22 AUDIENCE MEMBER 8: I've had, I guess, a

1 unique opportunity with my association with Dr. Dodson
2 to have analyzed postal valves and lung tissue samples,
3 and it was interest. Your width is, I think, spot-on
4 is what I see; and I can show you data because we have
5 compiled length and width. Where I would take
6 objection is the greater than five. The vast majority
7 of fibers that I find are actually not less than 0.4
8 but probably less than 0.25.

9 ANN WYLIE: In width?

10 AUDIENCE MEMBER 8: In width. And less than 5
11 in length.

12 ANN WYLIE: Yeah, I know. That is the
13 conundrum about length, and I don't understand that;
14 and every population I have ever seen or looked at has
15 the most abundant fiber tests in 5 micrometers or less.
16 So there's no question about that, and that is a
17 problem, a conundrum is something I don't exactly know
18 how to deal with; and I know how Dr. Dodson feels, that
19 this is important; and particularly, I think it's going
20 to be important today; it will be important in
21 inflammation; it will be important in asbestosis; maybe
22 it will be important in lung disease; but for

1 mesothelioma, I'm not so sure.

2 AUDIENCE MEMBER 8: I could hear him in my
3 head. (Audience laughs.) The question he's asking is:
4 How long does it have to be in there to start the
5 process?

6 ANN WYLIE: That's a good question. I just
7 use five because all our exposure data is five, and if
8 I'm gonna use data that suggests the variability of
9 your potential to get disease, I have to use it on the
10 basis of fiber, measure, and exposure.

11 AUDIENCE MEMBER 8: Exactly. That's just on
12 the occupational exposure is all five. So we don't
13 have that data --

14 ANN WYLIE: Right.

15 AUDIENCE MEMBER 8: -- to be able to -- you
16 know, the data that I've been able to find shows that,
17 yeah, the majority of the population is less; and it
18 matches very closely what we find -- what I've been
19 finding in human lung tissue.

20 CATHERINE SHEEHAN: Okay. We're cutting into
21 our lunchtime now, so we can take one more question. I
22 see two hands up. Okay, Aubrey (ph).

1 AUDIENCE MEMBER 9: Yes. I thought your
2 analysis was really interesting trying to look at the
3 differing sizes and shapes related to mesothelioma, and
4 obviously, at the beginning of that exploration into
5 the arenite populations and other populations --

6 ANN WYLIE: Yeah.

7 AUDIENCE MEMBER 9: -- as well; and obviously,
8 the worker populations are selective, so I think that
9 would be commercial asbestos.

10 Have you also been trying to look at other
11 health influences as well? Lung cancer, fibrogenic,
12 interstitial lung disease, fibrogenic pleural lung
13 disease because they -- there's different sensitivity
14 to different size and shape with respect to the other
15 health influences, and they're just as important as
16 mesothelioma.

17 ANN WYLIE: Oh, the anthophyllite workers in
18 Pokela margin -- the population was full of asbestosis
19 and lung cancer. And so there's no question in my mind
20 it's -- the certain area of anthophyllite is very high.
21 Timbrell did work on surface area and demonstrate very
22 clear to my satisfaction that he can explain asbestosis

1 on the basis of the high surface area of anthophyllite.

2 So, yes, I absolutely --

3 AUDIENCE MEMBER 8: We actually do those same
4 kind of analysis.

5 ANN WYLIE: Absolutely. Now lung cancer is
6 very hard because the data that have been shown by
7 Garret, Brad, (ph) and Castillo (ph), and Hodgson and
8 Darnton show no correlation, no variability that I can
9 call against dimensions. So I don't know. Lung cancer
10 I don't understand. There's a lot of factors there,
11 and it's not just a dimensional argument.

12 AUDIENCE MEMBER 9: You know, stop and shield
13 or --

14 ANN WYLIE: Yeah. Yeah. No. You know, I
15 don't.

16 CATHERINE SHEEHAN: Okay. I hate to break
17 this up, but we have to move on. So lunch is from 1:30
18 to -- I'm sorry -- 12:30 to 1:30. I see they're
19 setting up the buffet outside, but most importantly,
20 the breakout sessions are going to convene in this room
21 divided into three. Recall that you signed up for two
22 of three sessions, so come back and be prepared to know

1 which of the sessions you have signed up for or we will
2 have chaos.

3 The co-moderators for Session A on tech methods
4 is now Robyn Ray and Frank Ehrenfeld. The Session B,
5 measurement criteria, the moderators are Ann Wylie and
6 Art Langer; and then the third session on interpretation
7 of testing data is Brooke and Matt Sanchez. So
8 everybody knows where to go after lunch.

9

10 (A lunch break was taken.)

11 CATHERINE SHEEHAN: So what we're gonna do now
12 is if everybody can come back into the main room. We
13 are going to begin with a report-out by session
14 moderators. The report-out will last for 45 minutes,
15 and so we'll do the math. Here, we have three
16 sessions, so we have to stick to our 15-minute time.

17 So I will begin with Session A, if I could
18 have Frank and Robyn. If they can come up and share
19 their report-out.

20 When we're done with the three report-outs for
21 Sessions A, B, and C, we will then go into a discussion
22 questions for the moderators; and that will last half

1 an hour, 30 minutes. So we should be out of here --
2 basically, we should be done by five o'clock; but I
3 will finish off 15 minutes with closing remarks and
4 next steps. So --

5 FRANK EHRENFELD: Can we have ten minutes to
6 put our ideas together here?

7 CATHERINE SHEEHAN: Okay. Do you want to go
8 second? Which of the sessions -- A, B, or C? Who
9 wants to go first?

10 FRANK EHRENFELD: We're just putting our notes
11 together.

12 CATHERINE SHEEHAN: You're putting your notes
13 together.

14 FRANK EHRENFELD: I thought we had more time.

15 CATHERINE SHEEHAN: Yeah, I was given the
16 instructions to get this thing moving, so if you're not
17 done, we don't have any choice.

18 FRANK EHRENFELD: Okay. Here we go.

19 CATHERINE SHEEHAN: You're good?

20 (Background chatter)

21 FRANK EHRENFELD: We seem to be down a few
22 people. Do you want me to get some more people back in

1 the room once you --

2 AUDIENCE MEMBER 10: I'll grab them.

3 FRANK EHRENFELD: We'll do that.

4 (Background chatter)

5 Okay. Folks, I think we're ready to go here.

6 I want to summarize for our Session A today. Session

7 A, this is our charge is before you on the screen.

8 Martin added his. And so we were charged with what

9 test method for the analysis of talc and mineral fibers

10 in cosmetics -- it was very specific -- where asbestos

11 is not there and the word "cosmetics" are there. So we

12 sort of specified that as we went through this.

13 And, again, here we are again. I will tell

14 you that we had a lot of assistance putting these notes

15 together, this presentation, from Robyn Ray who is the

16 special projects manager for asbestos for EMSL; and

17 again, I'm Frank Ehrenfeld. I'm the laboratory

18 director at IATL in New Jersey as well as the chair of

19 ASTM D2207.

20 We started by asking for a show of hands as to

21 who our audience was, and so we discovered that we did

22 have a number of geologists. We had a number of lab

1 rats that specialize in various traditional
2 technologies and techniques. We had XRD represented
3 several times over, a number of light microscopists and
4 electron microscopists present. We had those who were
5 familiar with some of the medical epidemiological
6 background of the subject as well as a toxicologist in
7 the room. Everybody should have a toxicologist in the
8 room when they're meeting. We also had those who were
9 involved in the regulatory community.

10 We had a number of things that we wanted to
11 consider, including about the matrix of the material.
12 Some matrix considerations were discussed. We can even
13 look at an overview of that.

14 Is this something that is a talc deposit, and
15 what analytical methods might be appropriate for that
16 versus what analytical methods and techniques would be
17 appropriate for talc in a product? Obviously, our
18 charge was cosmetic, so a product.

19 We talked about some of the products
20 themselves, to what extent would they be used. Was it
21 something that was bound in waxy matrix like lipstick
22 or something that, perhaps, was more materially that

1 could be readily airborne like a talc?

2 We also talked about the lack of reference
3 standards and calibration standards. We talked about
4 all of these various analytical techniques in detail.
5 One of our core conclusions was that no one analytical
6 method shall trump another and that you must have
7 either complimentary or a suite of analytical methods
8 in order to be able to confirm these minerals in those
9 matrices.

10 Under the term "other," we actually had a
11 couple other things proposed for -- to overcome certain
12 challenges, including SEM OSHA analysis using EDS --
13 thank you, Greg, for taking me back to my days as a
14 graduate student at Lehigh -- as well as ICP mass spec
15 to look at some of the chemistry of the minerals as well
16 as the matrices.

17 Under "prep options," we were reminded by Chris
18 Weis, our toxicologist. Careful about prepping your
19 sample. Do not create anything if you can get away with
20 it, and don't diminish or demolish or dilute anything
21 that might already be in there. So careful not altering
22 the material as it is received for

1 a laboratory -- in the laboratory.

2 We have other takeaways regarding prep
3 options. We talked about various modernization
4 techniques. We talked about the disadvantages of
5 knowing -- and everything you see here on the slide, we
6 talked about it at least in some length.

7 We also talked a great deal about, okay, once
8 it's under a light microscope or in the XRD or under
9 the SEM or TEM, to what extent are you going to -- I
10 don't want to use the word "limit" an analysis but to
11 extent -- or to tolerate some limit, to put it in
12 Martin's terms. But we thought that the best idea was
13 to analyze everything so the microscopist would never
14 have to put that sample back into a stove and if
15 there's a particle there that can be analyzed and the
16 dimensions recorded and the chemistry measured and the
17 fraction pattern obtained and documented, that you do
18 it right there and then. Don't have to go back and do
19 it.

20 One of the other filters that we mentioned a
21 couple different times had to do with an unknown or a
22 certain tie it up here. We also asked repeatedly about

1 those who had experience analyzing these materials, and
2 a number of hands went up as well. So the room had a
3 lot of experience in it.

4 What we said we would learn some of the
5 lessons from the morning sessions, and I proposed that
6 we filter our comments through these couple points that
7 were made by Greg Meeker -- two of these points -- Ann
8 Wylie, Martin Harper, while in the hallway, and others.

9 Greg said, "Is it possible to protect public
10 health without regulating everything?" So we had to
11 think about that, to what extent. You know, where's
12 your cost-benefit analysis? If you're doing an
13 analysis of material, do you want to analyze
14 everything? Do you want to have that boxcar of an ore
15 deposit pull up and somebody say, "Okay. Tell me what
16 this has or does not have in it" or, "Here's a thimble
17 full of material. We need your analysis to proclaim
18 the asbestos or mineral fiber content of this boxcar of
19 material"? So all that stuff we considered. So to
20 what extent is public health going to be protected
21 without regulating everything?

22 Another comment that filtered our

1 conversations had to do with geologists used to own the
2 definition of asbestos, and it has been -- and those
3 definitions have now been turned over, for better or
4 worse, to the legal community.

5 Greg had another important statement that we
6 used to filter our discussion, which is: "What does
7 the lung know?" So regardless of how you might define
8 a particle or a fiber, what does your lung have to say
9 about it?

10 Make sure I have all of these out of the way.
11 We were also concerned about it turning into a
12 discussion about asbestos definitions, and we at some
13 point there was at least some murmur of consensus about
14 the fact that the initial definitions of "asbestos" had
15 to do with materials that were intentionally formulated
16 with these minerals for building materials and other
17 such things and if there are other products that might
18 be contaminated with these minerals or coming up out of
19 the ground that they may not -- that we need to maybe
20 create another definition for them. Those are some of
21 the filters.

22 Again, the main points to take away from our

1 discussion, use multiple techniques and technologies.
2 Make sure that your prep is sound and not either
3 removing anything that you might detect or creating
4 something that you're going to be counting. And also,
5 if you're gonna analyze something, take the time and
6 analyze everything so that 20 years from now they can
7 use that data and not have to reinvent the wheel.

8 And again, we had a lot of minor points that
9 will eventually come into a summation that we'll submit
10 to JIFSAN.

11 And any questions before I'm done with your
12 little synopsis there? Yes sir.

13 AUDIENCE MEMBER 1: Did you discuss a possible
14 combination of these techniques, whether these or some
15 of the others that you mentioned, that could be used as
16 an additional screening process that could --
17 identifying risk, maybe be a way of identifying talc
18 that was reasonably safe and should be making in our
19 commerce, you know, based upon, you know, what our IHHE
20 or one of the risk assessments we come up, give us some
21 number to hit on; but what I'm looking for here is a
22 screening protocol that might be a little over

1 sensitive, but if it gave false positives, bam, then
2 you go ahead and do the additional confirmatory
3 analysis to get rid of it.

4 But what I'm looking for is an initial
5 screening protocol that would give us, you know, a high
6 -- relatively high confidence that whatever product got
7 through was safe for the public.

8 FRANK EHRENFELD: Okay. That's a long
9 question. Let's see if I can get it down to its bare
10 components there. The last thing was like, hey, with
11 this screening protocol, can I have a high confidence?
12 But that may be counterintuitive there -- screening and
13 high confidence, right? However, we did bring up at
14 least the term that: Now, what would you use first? Is
15 there an order you'd use these analytical techniques?
16 Is one better than the other? Can you just go straight
17 to this analytical method? And the answer over and over
18 again was, "No. You need to use a suite or use multiple
19 confirmatory techniques."

20 Nobody was too confident with using a
21 screening method outside of using light microscopy at
22 least on the ore deposit side of things, only cosmetic

1 products -- finished product side of things. Obviously
2 there would have to be a lot of prep involved, and
3 then, again, you're losing some of the pool --

4 AUDIENCE MEMBER 1: That's a whole -- that's a
5 whole different.

6 FRANK EHRENFELD: Yep. I may not have answered
7 your question, but at least some of those elements were
8 discussed. Again, most of the comments that we shared
9 also related to the morning sessions.

10 Sean.

11 AUDIENCE MEMBER 2: We discussed XRD and PLM
12 as valid screening pools that have advantages and
13 disadvantages, but I thought we had agreed a group that
14 some form of electron microscopy was needed for final --
15 or at least quality assurance.

16 FRANK EHRENFELD: Yeah. And with that, we
17 also discussed measuring the width of various suspect
18 minerals, and so TEM would obviously need to be used
19 for that, with the limitations of light microscopy, in
20 order to collect the data that might have pertinent
21 biological information. TEM would have to be used.

22 Any other questions? Okay. Thank you very

1 much.

2 (Applause)

3 Of course the secret weapon of our session was
4 Art Langer, so we had a wonderful broad-ranging
5 conversation about all sorts of things.

6 Our goal was to establish concurrence on a
7 morphological criteria for the identification of
8 mineral fibers in cosmetics containing talc, and so the
9 things that I think we did agree on was that the longer
10 than 5, aspect ratio 3 to 1 gives you -- may give you
11 false positives. All right. So although it will patch
12 her what we're interested in, in an analysis, it would
13 necessarily -- or likely give you false positives if
14 both fragments and asbestos was present.

15 We also noted that 3 micrometers is the limit
16 of respiration for fibers, and so that's an important
17 limit on what should be included if respiration is the
18 method of entry.

19 Someone asked if you could get talc through
20 the skin. I don't think we were experts enough to
21 answer that, but I think it was raised. We then agreed
22 that particle morphology using this standard method for

1 assessing asbestos exposure will exaggerate, or may
2 exaggerate, asbestos fiber counts.

3 We agreed that the analysis should look at and
4 focus on particles longer than 5 micrometers, and we do
5 not accept coal without dissent, that it's only long
6 particles that we should be worried about; but what
7 we're looking for is an index and an indication that we
8 have fiber present. And since all of our risk
9 assessment and everything that we know about how these
10 minerals were likely to behave are based on that, that
11 analysis should focus on longer than 5 micrometer
12 particles.

13 We also believe that the FDA has an
14 opportunity for a method of analysis of a bulk
15 material, that there is no reason to apply a method
16 that was used for air sampling and environments known
17 to contain asbestos to bulk analysis, that that leak is
18 not necessarily warranted; and we urge the FDA to think
19 creatively about what else they could do to try to
20 develop a method in bulk -- criteria for bulk
21 materials.

22 We agreed that false positives by just simply

1 conventional counting can be enhanced by using more
2 than one type of instrumentation. Polarized light
3 microscopy is an advantage over phase contrast, that
4 electron microscopy gives us another set of data by
5 which we can make the analysis; and so I think we concur
6 with what was discussed earlier. These -- the analysis
7 would benefit significantly in bulk materials by heavy
8 liquid separation, that we should use it. We use light
9 microscopy. It should be polarized light microscopy.

10 We agree that we need -- if we're using
11 electron microscopy, we need to establish a set of data,
12 a certain number enough to feel that a mode has been
13 established in width. So we measure a large enough
14 population in order to establish a width mode so that
15 that can be compared to known asbestos populations to
16 enhance the certainty of the definition -- of the
17 identification.

18 We had, I thought one, a very interesting
19 discussion. It was a little bit outside our direct
20 charge, but the question would be: At what level can we
21 tolerate a mineral fiber in talc?

22

1 And I think Martin had a really good idea to
2 use some of the risk assessments that have been done at
3 Libby. We know exactly what Libby looks like. There's
4 enough information in that analysis that they establish
5 a safe level and that that might be used to help
6 establish a tolerable limit for analysis, and an
7 analyst has to have a detection limit. They have to
8 have a level below which you can't prove the absents,
9 and so we need something. We need some limit that we
10 work toward in the analytical community no matter what
11 criteria that we apply.

12 Anything else? Anybody from our group, again?

13 Okay.

14 (Applause)

15 MATT SANCHEZ: All right. I'll tell you
16 excuse my computer up here. It's limited space, so I
17 took my notes on here.

18 I would like to excuse Brooke Mossman. I'm
19 pitching when you can go to her as a co-moderator of
20 one of the sessions, and then Brooke Mossman had to
21 leave to catch a plane, so I'm -- I don't know. I'm
22 just pitching and gone. (Audience laughs.)

1 The goal that we are given, which I learned
2 about two days ago, was to establish a consensus on the
3 interpretation of microscopy measurements for mineral
4 fibers in cosmetics containing talc. I would --
5 fellows kind of liked my show. There was a lot of give
6 and take with the participants. I'll do my best to
7 summarize kind of what I thought I said and then also
8 based upon some of the questions for those that were in
9 the other panel -- or in that one meeting.

10 Before I do that, I would just recommend, if
11 you haven't yet, there have been two stimuli articles
12 published by the USP, the different expert panels
13 working on testing talc for asbestos. I think it was -
14 - the discussions in both of those are very relevant to
15 everything we've discussed today, and it also gives an
16 idea of the talc expert panel, which is working on
17 analytical methods, the direction we're going. There's
18 some information about where we're going with that, and
19 we'll be more forthcoming, too, in the coming year I'm
20 sure.

21 One thing that I noticed from the morning
22 sessions is nobody defined a mineral. I found that

1 interesting because in any of the interpretation of
2 microscopy data, or any analytical data dealing with
3 minerals, you need to make sure that you've collected
4 enough data to identify them. So this is a basic
5 working definition of the mineral. This is where you
6 get "a natural occurring solvent." It's going to have
7 a crystal structure. It's crystal in it. It's gonna
8 have a chemical composition. You can measure something
9 that's consistent. So depending on however you're
10 looking at the sample, whatever kind of technique
11 you're using, be it XRD -- XRD's not going to tell you
12 anything about the composition of what you're looking
13 at. It will tell you what crystal and phases are
14 present. When you're looking at PLM, PLM's not going
15 to tell you anything about the composition directly.
16 Based upon refractive indices in the amphibole, you can
17 make some inferences.

18 There was a lot of -- you know, Ann rightly
19 pointed out that anthophyllite and thallophe, PLM,
20 that's child's play to tell those apart by refractive
21 index. However, I mean, you move into things like
22 tremolite and anthophyllite, if they're not

1 asbestiform, you're dealing with an extinction-angle
2 difference. You can tell them apart by the distinction
3 angle, otherwise you can't.

4 When you're dealing with a phase like
5 cummingtonite and actinolite, you're never going to
6 tell those apart only by optical data. So if these
7 specific mineral species of interest are important, the
8 optical data could get you pretty far; but if you're --
9 you may be assuming something incorrect if you just
10 call it actinolite. There could be something else.
11 And I will say that in historical talcum powders that
12 I've been testing over the past year, we are finding
13 cummingtonites that historically were reported as
14 actinolites and tremolites. So that is a -- from a
15 historical perspective, that is something that is real.

16 And so just moving on, when you're -- so when
17 you're evaluating data, it's critical to understand
18 what these instruments can and can't do on
19 identification. I spoke -- I'm trying to think it
20 here. So sorry. I'm gonna follow my notes.

21 One of these -- we were pushing for in the USP
22 expert panel -- maybe I'm speaking for them, but what

1 I'm trying to push for is the data that's reported with
2 any test report would contain all the information
3 necessary for third parties to be able to independently
4 verify the results. What that means is, if it's the
5 PLM testing, there will be photographs of the particles
6 and plane-polarized light in different directions with
7 the -- so you can see the Becke` lines or dispersion
8 stain colors, however you're doing that, where you have
9 imagines showing what the extinction angle if one was
10 observed was, when you have imagines to see what it
11 looked like, you know, signing and longation, all these
12 different measurements. I require that those things
13 all be reported because through all those pieces of
14 information that an analysis is supposed to be doing,
15 you can then understand what the data actually means
16 and whether there's been misinterpretation on the
17 laboratory side.

18 The same holds for any kind of a TEM analysis.
19 The different issues with TEM make it much more
20 difficult. They're not more difficult. I know it was
21 said earlier that somehow PLM is not sophisticated, or
22 it seemed to be implied that, and that's just not true.

1 Minerals are very complicated. The technology and the
2 science and the physics behind polarized light
3 microscopy are also very complicated. They're very
4 robust within their limitations.

5 The same goes for TEM. TEM has very wonderful
6 things that it can do. Martin Rutstein mentioned this
7 idea of this 5.38 row spacing by, you know, TEM
8 analysis to somehow confirm an amphibole. Talc has
9 that. Sepio has that. There's a -- any bio pyro glass
10 (ph) -- that's a new term for everybody -- will have
11 those 5.38 in row spaces. That does not make them
12 amphiboles. That does not make them asbestos.

13 So whenever these issues are coming up in TEM
14 data, the SAED data that's collected must be robust
15 enough that you have zone axis to fraction work -- and
16 this is all spelled out in old documents from the EPA.
17 This is also spelled out very precisely and good by the
18 ISO Methods by using TEM, but when you need that zone-
19 axis work -- and then the zone-axis solution needs to
20 be specific to the mineral you're identifying. There
21 are a lot of zone axes for different minerals that will
22 be the same, so unless you have a unique solution, you

1 cannot say you've identified that mineral. A caution -
2 - a cautionary note, that most -- I can't speak -- in
3 my experience, I'll leave it at that, a lot of asbestos
4 testing labs by TEM only have crystal structures
5 provided to them through NVLAP which does not include
6 the crystal structure of talc. So how is the lab
7 supposed to analyze talc for asbestos if they can't
8 differentiate by electronic fraction talc and
9 anthophyllite? I'll just leave it at that.

10 There was a lot of comments from the audience
11 there. The questions, a lot of them revolved around
12 almost like surrogate techniques to measure for
13 asbestos content or amphibole content. One of the
14 discussions revolved around using, you know, calcium as
15 a tracer for maybe a tremolitic or at least a calcic
16 amphibole. I did my best to try to deal with those
17 issues. You know, talk about using iron. There's just
18 issues if you're trying to do a certain chemical
19 solution for these things, and I hope I explain this
20 well enough that that was clear. I think we're stuck
21 with doing microscopy on individual particles for the
22 most part.

1 Some of the discussion dealt with the
2 quantification revolving trying to do techniques to
3 concentrate, like, amphibole phases from talc, which
4 can be done in a variety of ways. There's pros and
5 cons to doing that, but I tried my best to discuss what
6 those are; and really, I think from an idea of getting
7 better quantitation, I think there's a lot of merit to
8 doing concentration techniques once you've identified
9 whether something is there to know how much is there.

10 But you know, for an example, if you take 10
11 milligrams of talc, put it in a heavy liquid separation
12 and, you know, do your thing and then look at the
13 residues, that's the same as just looking at that 10
14 milligrams of talc but actually by PLM, which you can
15 do rapidly and quickly. So there -- but from a
16 quantitation perspective, to be able to remove the
17 nonamphibole from those components, you can get a much
18 higher idea of the quantitation, get a much lower --
19 much more sensitive burden. Accurate quantification is
20 best by using those kind of techniques at the expense
21 of, you know, doing nothing about chrysotile, if it is
22 present or not.

1 There was a lot of talk about the idea --
2 especially from the FDA groups, there was an idea of,
3 you know, having a rapid and also reliable testing and
4 screening of these materials. My recommendation was
5 for rapid testing, I think PLM is the best. We can do
6 it on site if you were equipped to do it, but again, I
7 agree with what was said earlier. I think doing
8 multiple approaches is necessary here. There's a lot
9 of -- a lot of nuances, and having other techniques,
10 they complement each other. Where you have
11 contradictions in the data, you need to resolve those
12 contradictions, and a lot of times other techniques
13 will be able to allow you to do that.

14 There was also some discussion of the
15 cosmetics, and I think Frank Ehrenfeld already mentioned
16 that -- the idea of removing, you know, waxes or binders
17 from them. The amp flows are there. I think that would
18 have to be done before you analyze reliably. Those
19 things could mask and make it difficult to measure
20 pertinent properties of those particles for
21 identification.

22 I think I -- I think that was all my notes I

1 had. I don't know if anybody that was in the group had
2 anything to add. Did I miss anything important?

3 AUDIENCE MEMBER 3: Ross (ph)?

4 MATT SANCHEZ: Yes.

5 (Crosstalk)

6 AUDIENCE MEMBER 3: Were you enshrined in
7 doing much with UBSD?

8 MATT SANCHEZ: Yes, we have.

9 AUDIENCE MEMBER 3: How is that going?

10 MATT SANCHEZ: I mentioned UBSD in the
11 session. It's going well sometimes. The beautiful
12 thing about UBSD is it either works right away or it
13 doesn't work at all. The other issue with UBSD
14 techniques is it's very dependent on anything on the
15 surfaces.

16 AUDIENCE MEMBER 3: Other than just --

17 MATT SANCHEZ: We've been doing them -- it's
18 best to do them uncoated, so we haven't --

19 AUDIENCE MEMBER 3: No. I mean the ion
20 sputtered.

21 MATT SANCHEZ: Oh, we haven't got that
22 sophisticated from that perspective. Most work
that

1 Brian (ph) did for his PhD work was using filter
2 preparations and then using geometry is where they were
3 actually transmitting with the transmission -- it's not
4 back scatter anymore but it was a transmission mode for
5 the diffraction pattern generation. We've been trying
6 to take that into -- what we're doing now, we're
7 isolating individual particles that we see, like, on
8 PLM, removing those, putting them on the SEM, getting
9 the compositional information, then obtaining the
10 diffraction information at UBSD; and we're probably
11 about an 85 percent success rate doing it that way.
12 And we've seen some -- yeah, well, we can talk about
13 that later, but -- so we're having success there.

14 One of these we're trying to do is actually
15 tie in the UBSD to the automotive analyses on SEM, but
16 we're not doubting much -- we're having difficulties at
17 that. That's far off, I think, before we can merge
18 those technologies.

19 AUDIENCE MEMBER 4: Have you had success with
20 all the different asbestos types or --

21 MATT SANCHEZ: No. I would defer to Brian's
22 PhD and publications. Brian Bannon (ph). Sorry. He's

1 a colleague of mine at RDAG Group. From my
2 recollection they -- there's issues with the -- there's
3 a few issues. When you're using the transmission mode,
4 you have much better spatial resolution; but if the
5 individual fibers are very, very fine -- I don't
6 remember where that was, whether it was .1 microns; and
7 then for somewhere, there was just no signal from them
8 -- the UBSD technique.

9 It does not work at all with crisapa (ph)
10 because of that scrolled structure. It just looks at
11 more of just pretty much IBSD work, but for, you know,
12 single crystals of amphiboles that are, you know, big
13 enough for the spatial resolution to work, you can
14 usually get that from that, assuming there's no
15 coatings or something on the surfaces.

16 AUDIENCE MEMBER 5: You mentioned
17 cummingtonite. On the TEM, is that just too complex or
18 too similar to, you know -- can you still do
19 diffraction there to identify them?

20 MATT SANCHEZ: Well, absolutely. I think the
21 -- cummingtonite, for those that don't know, it's a
22 magnesium amphibole.

1 AUDIENCE MEMBER 5: So --

2 MATT SANCHEZ: And the number of the formula
3 would be $Mg_7Si_8O_{22}OH_2$. So compositionally it would be
4 the same, or potentially the same, as any anthophyllite
5 you would encounter. The difference between them is
6 cummingtonite is part of what's called a monoclinic --
7 it's part of a monoclinic system. It has different --
8 it has a different crystal structure. Because of that,
9 it has different diffraction properties than
10 anthophyllite. So if you're doing the electron
11 diffraction correctly and understand the differences in
12 the space groups, you can make those distinctions
13 whether it's an orthorhombic amphibole or a monoclinic
14 amphibole. This is not something that is routinely
15 done by any laboratory that I know of in the asbestos-
16 testing world.

17 AUDIENCE MEMBER 5: Pretty straightforward for
18 anthophyllite. It's orthorhombic. Cummingtonite, its
19 structures collapse because of the iron in it. It has
20 more iron than anthophyllite.

21 MATT SANCHEZ: What do you mean? Well, you
22 still have to collect data and make the measurements

1 and do the indexing; but the real difference there is -
2 - the important differences are the differences in the
3 space groups between the monoclinic amphiboles and the
4 orthorhombic amphiboles.

5 AUDIENCE MEMBER 5: That's what defines them.

6 MATT SANCHEZ: I'm sorry?

7 AUDIENCE MEMBER 5: Yeah. That's what defines
8 them. That's what differentiates them.

9 MATT SANCHEZ: Yeah. But the issue is
10 understanding what those are and how those -- and how
11 those result in the diffraction patterns to make the
12 appropriate determination. I think that's beyond my
13 topics here today but --

14 AUDIENCE MEMBER 5: All I'm saying that
15 there's no cummingtonite asbestos.

16 MATT SANCHEZ: I don't know. I've never seen
17 it, but cummingtonite is a real -- it's a real
18 amphibole, so --

19 (Crosstalk)

20 All right. Anything else? All right.

21 (Applause)

22 CATHERINE SHEEHAN: So I think now we can move

1 into the next session, which is questions, discussions
2 for moderators. So I know we don't have chairs here,
3 but moderators now can take questions from the
4 audience.

5 So any questions, discussion points? Yes,
6 Gary (ph).

7 GREGORY MEEKER: Did I understand in your
8 group you decided to eliminate any airborne --

9 ANN WYLIE: No.

10 GREGORY MEEKER: -- (inaudible)?

11 ANN WYLIE: In fact, there was discussed -- it
12 was discussed -- we weren't doing the testing methods
13 per se, but it was mentioned by several that
14 aerosolizing the samples might be a useful thing to do.

15 GREGORY MEEKER: Okay.

16 ANN WYLIE: Okay. So it wasn't -- but it
17 wasn't our -- that wasn't our charge.

18 GREGORY MEEKER: Yeah.

19 AUDIENCE MEMBER 6: So I think we've talked it
20 out, and there's really an uncertainty, problems. I
21 think we discussed this at ASTM and definitely at USP.
22 You have what -- you'll see some of the special, but

1 necessary to keep, certificates. You want a de minimis
2 sample on some of your reference materials, and that's
3 important when you're taking a sample for analysis.
4 Whether you take 10 milligrams or 1 milligram, are they
5 the same? You have to establish that somehow,
6 somewhere that when you take on a semplet (ph), if you
7 don't do duplet, triggerclet (ph), or even for
8 analysis, in order to rule out and analyze it, we have
9 to also approach it from that perspective. And you can
10 say, "Well, it's a fine cosmetic talc or pharmaceutical
11 talc." Okay. Granted that helps in some situations,
12 but if you're looking at maybe the courser talcs, you
13 do have a situation where you have to think about how
14 you're subsampling and what would really be of the de
15 minimis sampling before you put it all on diffraction,
16 PLM, or Tega (ph). So I just think that should be
17 brought out.

18 CATHERINE SHEEHAN: I'll give you mine just in
19 case.

20 MARTIN HARPER: Sure. I got a couple of
21 comments. And one is the availability of proficiency
22 test samples. I mentioned the HSE's schemes that they

1 occasionally have talc in -- as the material; and I've
2 mentioned also through ASTM that there's a couple of
3 initiatives to do some inter laboratory studies, but
4 they like you to be one-offs, I imagine. Now, it's
5 perfectly possible to go along to a PT producer in the
6 US and request a PT sample be added to one of their
7 programs. In fact, I'm thinking of the American
8 Industrial Hygiene Association, that bulk asbestos
9 proficiency testing program. It's -- you know, their
10 provider is similar to the, you know, NVLAP provider.
11 I mean, if you wanted a proficiency test sample of talc
12 contaminated with different materials at different
13 levels, these can be put together. I mean, obviously
14 there's a cost involved in the start-up. You know,
15 there's a cost involved in participation in the program
16 too, and American Industrial Hygiene Association, pack,
17 LLC, may be willing to invest money in the creation of
18 the samples, knowing that they'll get it back from the
19 participants later, or there might be, you know, a
20 government agency that would, you know, put a grant
21 together to enable them to get them. I think it's a
22 really, really useful thing to do because labs need to

1 know what their capabilities are -- what their true
2 capabilities are, and you just can't get it by
3 guesswork.

4 And as it corroborates with that, I also want
5 to ask that if anyone has, you know, an electron
6 microscope with an EDS, please, please calibrate it and
7 calibrate it on the right kind of materials. You know,
8 reference tremolite, reference actinolite, and please
9 check the results of those calibrations because, you
10 know, I've seen results where the actinolite
11 calibration stat, it was off by 20 percent from 30
12 percent from the reference composition in the missed
13 sample. So you know, this is something that I beg the
14 labs to do.

15 CATHERINE SHEEHAN: Is it on her?

16 GREGORY MEEKER: Could I just -- I'll walk
17 through quick. He got EIRONG glass -- EIRONG glass,
18 secondary stick will do for SEM.

19 AUDIENCE MEMBER 7: Martin, to that point,
20 Session A, we talked about standards as well, on the
21 calibration standards but also reference standards, of
22 course; and our biggest obstacle, perhaps, was the fact

1 that -- can we get standards formulated to match a
2 cosmetic product? We can get Loan Pine. We can go and
3 -- Money Lab's represented here today and others that
4 are at least of that status would, you know, have in
5 their library of standards all these minerals; but I
6 don't necessarily have something that I could call a
7 reference material for a base, foundation, cosmetic,
8 something or another or -- so either can the industry --
9 so can USP say, "Hey, manufacturer, can you supply the
10 base formulation of this stuff and then can it either
11 be spiked or -- we're looking for that bulk matrix
12 material, not just the mineral fiber itself."

13 CATHERINE SHEEHAN: Happy birthday. No?
14 Okey-doke.

15 AUDIENCE MEMBER 8: Regardless of the chemical
16 composition, the various amphiboles and talc and things
17 like that, Matt, I believe you mentioned in our session
18 that there was a study that looked at the general
19 elemental composition of various talcs around the
20 world. Is that the only study available on that
21 subject?

22 MATT SANCHEZ: I think it's the most inclusive

1 for sure. I know in the -- what is it? The
2 International Agency on Research for Cancer? I don't
3 bet that -- they had -- they had some bold compositions
4 presented in there from citizens from different top
5 areas that produced, but with Marian Dosone (ph) at the
6 Smithsonian Institute, they went to different talc
7 mining areas; and other gentleman researchers was in
8 academics and did a lot of work in talc and assembled a
9 huge collection of talc from all over the world,
10 different mines; and they made a first passthrough
11 that, characterizing those things, bulk composition and
12 some other work using both XRF techniques as well as
13 EPMA or electro microprobe analysis. And they did some
14 cluster analyses in trying to look at some correlations
15 in that paper, but that's the most widespread study I
16 know, gosh, from everywhere, as many locations as
17 possible.

18 AUDIENCE MEMBER 9: Roughly, what sensitivity
19 do those methods have?

20 MATT SANCHEZ: I don't know. They did run
21 everything by pattern straight fraction as well to
22 identify the mineral phases, but then they were going

1 through and doing -- it will be sold out for -- the
2 chemical analyses, I don't recall, but they were doing
3 a lot of trace element levels down, parts per million,
4 maybe even parts per billion levels. They were using
5 the Research Institute over at Washington State
6 University of Pullman to do a lot of elemental analysis
7 that way on the bulks.

8 When they got into doing the microprobe work,
9 it was -- those would have been particle specifics that
10 they would have identified beforehand; but as far as
11 the chemical compositions, that's very precise data of
12 a large suite of both major and minor and then trace
13 elements.

14 AUDIENCE MEMBER 9: Thank you.

15 CATHERINE SHEEHAN: All right. Were there
16 questions? No? Going, going, gone. Okay.

17 So I move to close the session if nobody else
18 has further questions, and we can now go into the
19 closing remarks and next steps.

20 So these are my closing remarks, not USP's,
21 but my first closing remark is I wanted to thank
22 everybody that has come to this meeting today

1 representing us from industry, regulators, and academia
2 because I think it really did give us that
3 brainstorming at first. There's a lot of themes,
4 definitions, and measurement, structure, composition,
5 shape size. It was a soup of nomenclature, and from
6 that, there was a lot of questions I felt, and I
7 thought they were very fundamental questions. Do we
8 have a definition of what we are testing for? We just
9 heard many, many times, "Define the mineral. Define
10 asbestos. Who owns the definition?" We talked about
11 revising the definition. Perhaps it may need to be
12 revised. Secondly, in terms of definitions: "What are
13 we really looking for? What do we want to test for?"
14 I think these are fundamental as we go into the big
15 task of developing method and limits.

16 I think the second theme common throughout the
17 morning session speakers and the sessions was that we
18 were really looking for a standardized approach that
19 labs can follow. I think the consensus was that there
20 is a toolbox out there. No one method will suffice,
21 but which ones do we used and for what? We also talked
22 about what is the right reference standard, that that

1 was important as well.

2 So there were my general closing remarks in
3 terms of what, you know, we discussed both in the
4 morning and afternoon.

5 So in terms of, I think, next steps -- because
6 I believe there's a lot of unanswered questions of
7 those that I mentioned; but to start the ball rolling,
8 in terms of next steps, I think it's important now that
9 there's a lot of information shared here, a lot of
10 critical discussions that will move us on this journey.
11 But the summary notes definitely, in terms of the
12 moderators and the speakers, the presentations from
13 this morning, the summaries from the breakout sessions,
14 definitely they will need to be posted on the website.
15 My information here is that has to be finalized by
16 January 5th. I do not know when they will post, but
17 January 5th is the deadline for speakers and moderators
18 to get summary breakout sessions to JIFSAN.

19 Another next steps is to make sure that all
20 slides that were presented in the morning session and
21 also as part of the breakouts that they will be
22 provided on the website.

1 And then third is kind of an open question.
2 You know, what does the audience think should be a next
3 step? You know, what have you learned from today that
4 could help us move to the next step. So I'm going to
5 leave that as kind of an open question to the audience
6 in terms of next steps because I think it's important
7 to hear it from all stakeholders.

8 Any thoughts? I think I see one -- one show
9 of hands in the back row. Yes.

10 STEVE: About PLM. Just a thought and moving
11 into (inaudible). Just a thought that be aware that
12 there are standard development processes currently
13 taking place concurrently and that my belief is that
14 everybody that's involved, and certainly all the folks
15 in this room, ought to provide comment when those --
16 whenever those standards publish to make sure that we
17 get the best -- ultimately the best standard. So
18 that's just a reminder to be on the lookout when things
19 publish to read them and comment on them.

20 So that -- thank you, Steve (ph).

21 And I don't know if anyone's familiar here
22 with the USP Standards that are in process, just to

1 follow up on that comment. We have a public comment
2 period through proposing -- our standards are official,
3 so if we make any changes to these official standards,
4 we have to go public and we have to solicit input
5 comment feedback.

6 Given the number of stakeholders that are
7 involved and the impact of us revising the USP
8 Standard, my thoughts are that USP could probably
9 convene all stakeholders prior to the publication of
10 this standard so that we could get input before we
11 actually propose it, because it pretty much -- once it
12 goes into the PF, the formal PO forum, you have a 90-
13 day comment period. The expectation is that that will
14 go before the counsel of experts for approval and
15 ballot to become official. It's very difficult when it
16 gets on that track, so I think it's important that we
17 get some feedback as Jeff (ph) said, that we do this
18 publicly and we invite all stakeholders in to give us
19 input on where this revision is going. So --

20 AUDIENCE MEMBER 11: Kind of getting back to
21 the question about, you know, what to test for and the
22 definition for asbestos. Based on some of the -- what

1 I've heard here is that there are others compounds that
2 don't presently fall under the asbestos umbrella that
3 have similar toxic and carcinogenic effects and should
4 those compounds be now pitch or clustered underneath
5 the umbrella of asbestos, or do we need to come up with
6 a different term than "asbestos" than what we're using
7 right now? Can it be better descriptive?

8 CATHERINE SHEEHAN: Martin here? Martin?

9 MARTIN RUTSTEIN: This is artificial, and I'm
10 speaking for myself, but to avoid this dangerous debate
11 upon what EMP might be out there, I believe that my
12 colleagues are moving in the direction of using
13 regulatory asbestos as the group of materials for which
14 we will have analytical method and that will end that.
15 If we were to invent -- if we were to develop methods
16 for these other materials, which may or may not be
17 hazardous to human health, we would be going into major
18 uncharted territory, and we collectively didn't think
19 it would be prudent at this time.

20 CATHERINE SHEEHAN: Thank you, Martin.

21 So any other thoughts? Next steps.

22 AUDIENCE MEMBER 12: Yeah. I was gonna add to

1 what Martin just said that there was -- that we have
2 been considering that the methodology must develop for
3 the determination of asbestos as currently defined may
4 be applicable to other mineral vipers in mineral
5 counters.

6 MARTIN RUTSTEIN: I left out one thing. I'm
7 pretty sure in STEM Article 1 we said minerals -- other
8 minerals that have known hazard.

9 AUDIENCE MEMBER 12: Right.

10 MARTIN RUTSTEIN: I think we included that
11 one. So that's our ruling. That would be in there if
12 the evidence is pretty good for it. Like winchite
13 (inaudible).

14 CATHERINE SHEEHAN: I think that's in the STEM
15 article, Martin, right?

16 MARTIN RUTSTEIN: In the previous STEM
17 articles.

18 CATHERINE SHEEHAN: I think -- I would advise
19 to -- yeah, to -- that goes into the details.

20 MARTIN RUTSTEIN: That's posted. They really
21 should read it.

22 ANN WYLIE: As was pointed out in our session,

1 the tolerable level is a policy decision, not a
2 scientific decision. And we need a tolerable level
3 because an analyst can never prove the absence of
4 something, and a tolerable level gives an analyst a
5 target, designs techniques designed to meet that level;
6 and since that's a policy decision, without that, I
7 think we really have a problem. So that's an -- FDA
8 needs to provide that policy decision on what level the
9 analysts should aim their methodologies.

10 CATHERINE SHEEHAN: Thank you. Okay.

11 MARTIN HARPER: If I might just add --

12 CATHERINE SHEEHAN: Okay.

13 MARTIN HARPER: -- to that. If I may just add
14 to that that the tolerable level may be different
15 depending on whether we're talking about, you know,
16 bulk talc that's feeding into a product line or a final
17 commercial product. Just a thought kind of.

18 AUDIENCE MEMBER 12: And then, again, we have
19 to come back to, well, what's detectable and what's
20 tolerable. If we look at the high court of history,
21 when we developed standards in the past, the regulatory
22 agencies have often said, "Anything that's detectable

1 is unacceptable." So if you have a zero-tolerance
2 policy, then you have to define what your detectability
3 is, and that becomes your edge point.

4 GREGORY MEEKER: I assume we're talking about
5 a tolerable level with respect to health?

6 AUDIENCE MEMBER 12: Well, that's why we're
7 really here.

8 GREGORY MEEKER: Is there a tolerable level
9 with respect to impact on industry? Should we consider
10 that also? Because it always seems to fall on the
11 health side, and I don't know.

12 MARTIN HARPER: That would be more like an
13 OSHA regulatory process where the socioeconomic impact
14 has to be dealt with --

15 (Crosstalk)

16 GREGORY MEEKER: No, not worker health. I
17 mean, the impact on the industry.

18 MARTIN HARPER: Yeah. Well, you know, OSHA's
19 standards are set taking into account what's achievable
20 by industry. So for example, the methylene chloride
21 standard allows a risk above what they would like to
22 have, simply because the furniture refinishing industry

1 wouldn't exist without methylene chloride and it can't
2 really be controlled to the level they'd like to
3 control it. So yeah, I mean, there's definitely
4 precedent for not setting everything entirely on the
5 panel.

6 AUDIENCE MEMBER 13: From an FDA perspective,
7 we want to thank you for all the thoughts and all of
8 the hard work that went through this morning as well.
9 And there's a lot of food for thought for all of us,
10 not just at the FDA but all through regulatory agencies
11 that are here and a variety of governmental agencies
12 that are present today as well to go back and think
13 about what all of our discussions mean for the products
14 that we all regulate and have some jurisdiction over.
15 That you.

16 CATHERINE SHEEHAN: Any other comments,
17 suggestions on next steps? No? Okay.

18 So I believe the meeting is over, but I would
19 like to give a special thanks to -- I'm gonna call out
20 everybody because I think everybody did a really great
21 job. Presenters: Brad, Greg, Martin, Martin, Brooke,
22 and Ann; and then the afternoon session, the co-

1 moderators: Robyn, Frank, Ann, Art, Brooke, and Matt.

2 Thank you so much.

3 (Applause)

4 And a final thank you to JIFSAN staff, and a

5 special call-out to Veronica -- sorry -- Nora Petty

6 for the assistance in getting the moderators and

7 speakers together and trying to get this altogether.

8 (Applause)

9 Thank you.

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December 9, 2018



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| | | | |
|---|--|--|---|
| & | 145:4,4,4,16,21 | 15 3:3 18:13 30:3 | 20005 1:22 |
| & 49:17 76:22 105:14,15 | 148:3,9 150:18 | 30:3,5 31:7 107:3 | 2006 40:1 |
| 0 | 153:16 154:22 | 114:8 150:20 | 2007 50:1 |
| 0.0012. 157:8 | 159:17 162:15,18 | 181:16 182:3 | 2008 16:12 47:22 |
| 0.028. 157:7 | 164:2 168:7 171:6 | 150 88:21 | 2009 29:6 |
| 0.05 173:16 | 175:6 189:13 | 16 18:13 150:20 | 2010 81:22 93:5 129:10 |
| 0.09. 157:5 | 191:4 192:10 | 17 67:22 114:8 | 2016 53:5 |
| 0.1 161:6 167:22 | 206:6 210:4 221:7 | 159:5 | 2017 11:21 12:2 145:17 |
| 0.1. 161:10 | 1,000 86:3 | 17004 226:16 | 2018 1:6 227:12 |
| 0.15 159:21 161:4 | 1.2 146:3 | 175 146:10 | 202 1:12 |
| 0.15. 158:1 159:12 164:5 | 1.5. 146:4 | 18 92:16 159:5 | 20740 1:11 |
| 0.2 161:3,16 | 1.578. 140:7 | 162:5 | 210,000 12:6 |
| 0.25 158:1 164:7 | 10 2:3 55:2 97:9 | 19 57:1 141:5 | 23 29:4 |
| 0.25. 159:13 177:8 | 97:17 132:21 | 1948 16:10 | 25 65:7 152:12 172:22 |
| 0.3 160:22 169:10 | 142:18 183:2 | 1960s 176:8 | 28 1:6 |
| 0.35 173:15 | 202:10,13 210:4 | 1970s 152:17 | 29 2:4 |
| 0.4 158:3,11 164:8 173:15 177:7 | 10.2. 62:20 | 1971 149:4,6 | 3 |
| 0.4. 158:21 | 100 60:8,10,12 | 1972 49:4 137:6 | 3 2:2 5:16 8:17 9:4 9:6,10 12:5 58:19 60:4 65:18 128:8 136:4,19 139:6 141:11 145:4,16 153:16 154:21 164:2 192:10,15 204:3,6,9,16,19 |
| 0.45 105:2 | 73:20 77:9 88:21 | 1974 16:12 | 30 34:10 50:2 55:2 69:8 97:22 110:1 115:1 117:3 122:14 159:4 182:1 212:11 |
| 0.451 157:2 | 90:7 111:1 160:3 | 1980 130:2 | 300 80:21 |
| 0.85 159:21 | 161:7 168:5 175:5 | 1981 30:7 36:19 | 33 150:14 |
| 000 106:17 | 100-150 100:15 | 1982 23:17 | 34 151:17 |
| 001 13:5 | 108 12:1 | 1985 147:7 | 35 144:2 |
| 003 80:15 | 11 90:1 98:4,10,14 | 1988 19:2 | 350 1:21 60:4 |
| 01 167:22 | 98:18 99:1,7,9,14 | 1990s 122:7 | 380,000 12:7 |
| 02 152:9 | 99:20 100:2,9,13 | 1997 127:12 | 39 42:9,13 |
| 025 111:20 | 126:18 142:4 | 1:14:55.1 165:14 | 3d 124:4,13 |
| 03 144:2 147:11 | 219:20 | 2 | |
| 045 80:15 104:11 104:15,20 | 110 19:12 | 2 7:14,16 8:3,6,13 17:22 62:15,16 135:19 145:20 150:20 153:16 154:2,4,7 171:6 175:5 191:11 | |
| 05 111:20 147:12 148:20 | 115 2:7 | 2.4. 107:14 | |
| 1 | 11:00 114:9 | 20 55:2 65:20 122:14 175:6 189:6 212:11 | |
| 1 7:2 55:1 58:20 65:18,20 88:15,17 90:21 91:8,11 92:1,4,4 106:17 111:19,19 126:5 134:18 135:8 139:6 141:11 | 12 100:20 101:3,6 101:10 220:22 221:9 222:18 223:6 | 20,000 80:13 104:9,18 105:5 111:3 167:15 | |
| | 1250 1:21 | 200 73:19 | |
| | 12:30 180:18 | 2000 10:2 | |
| | 13 102:16,21 224:6 | | |
| | 137 2:8 | | |
| | 14 104:17,21 105:2,4,7 | | |
| | 14841 227:12 | | |

| | | | |
|---|--|---|---|
| 4 | 174:16 175:9,18 209:19 | 90s 152:18 | abundant 144:11 145:3 150:4 170:9 177:15 |
| 4 41:12,14,19 144:2 145:4 146:2 146:12 148:7 159:11 169:4,18 170:12 205:19 | 60 94:13 153:12 153:16 | 95 157:3 160:17 | abuse 167:16 |
| 40 119:15 130:19 153:1 172:21 | 600 31:22 | 96 90:11 | academia 4:5 216:1 |
| 400 60:2 73:19 108:10 111:2 | 62 92:3 | 97 33:1 | academics 214:8 |
| 40s 162:21 | 7 | 98 160:1 | academy 29:7 |
| 43 18:18 19:20 | 7 68:17 75:6 | a | accept 140:15,21 193:5 |
| 44 2:5 | 150:19 158:3,8,21 159:11 164:8 | a.m. 1:7 114:9 | acceptability 112:6,7 |
| 45 104:22 181:14 | 175:19 176:11,20 212:19 | aaronfeld 181:4 182:5,10,14,18,21 183:3,17 190:8 191:6,16 203:15 | acceptable 65:13 104:12 112:9 |
| 450 60:3 | 70 94:14 163:10 172:15 | abatement 64:5 | accepted 103:18 |
| 5 | 70s 63:9 | abc 68:17,19,20 68:21 | access 8:13 143:20 166:7,14 |
| 5 42:21 70:10 126:6 145:4 152:13 153:13,14 154:6,21 159:17 164:2 171:20 177:10,15 192:10 193:4,11 206:16 207:1,17 208:5,7 208:14 | 75 152:13 | ability 8:7 94:20 110:18,21 130:17 131:2 226:7 227:4 | accessing 16:20 |
| 5.27 68:6,6 | 77 2:6 38:20 40:2 142:5 | able 4:1 24:19 47:6 68:10 69:21 73:1 88:20 100:19 101:21 102:14 110:10 117:14 122:2 129:19 134:5 135:6 136:7 149:18 156:1 164:14 178:15,16 185:8 199:3 202:16 203:13 | accomplish 20:14 |
| 5.27. 69:4 | 7777 1:10 | abnormal 126:13 | accomplishments 115:4 |
| 5.28 68:6,9 | 79 58:5 | abounding 14:13 | account 53:17 131:8 223:19 |
| 5.3 68:9 | 8 | absence 69:17 78:16 104:5 222:3 | accreditations 107:20 |
| 5.3. 68:11 166:12 | 8 73:9,13 158:1 159:12 164:6 176:22 177:10 178:2,11,15 180:3 213:15 | absents 195:8 | accredited 90:2 |
| 5.38 200:7,11 | 80 55:14 | absolute 138:10 | accumulated 77:10 |
| 50 20:9 48:11 86:1 88:22 153:12,16 | 80s 125:12 | absolutely 81:14 82:4 169:16 180:2 180:5 206:20 | accumulation 124:14 |
| 506 42:18 | 83 141:5 | absorbency 30:14 | accurate 32:17 79:5 81:3 95:16 109:9 202:19 226:6 |
| 540,000 11:22 12:8 | 85 90:21 91:8 94:18 205:11 | abundance 143:1 146:19,21 148:8 149:16 | accurately 64:11 |
| 58 159:2 | 85-90 109:21 | abundances 142:16 | achievable 223:19 |
| 59 126:18 | 857-3376 1:12 | | achieve 4:1 |
| 5th 6:19 217:16,17 | 8:04 1:7 | | achievement 115:3 |
| 6 | 9 | | acicular 35:9 |
| 6 50:6,11 53:10 126:5 142:18 150:19 174:1,14 | 9 74:7,11,14,20 75:14 93:13,18 179:1,7 180:12 214:18 215:14 227:12 | | acircular 51:16 |
| | 90 26:15 55:14 219:12 | | acknowledge 96:9 |
| | | | act 124:15 |

| | | | |
|---|---|---|---|
| <p>actinolite 14:1,9 24:6,17,22 25:1 32:8,15 33:2,13 38:22 39:2 51:4 82:11 87:19 88:1 89:3 176:13 198:5 198:10 212:8,10</p> <p>actinolites 14:10 198:14</p> <p>action 78:3 226:9 226:13 227:7,9</p> <p>activation 121:8</p> <p>active 155:14</p> <p>activity 23:4</p> <p>actors 103:21</p> <p>actual 108:1</p> <p>add 129:12 204:2 220:22 222:11,13</p> <p>added 19:15 155:12 158:15 183:8 211:6</p> <p>adding 134:12</p> <p>addison 83:4 100:6 101:2</p> <p>addition 5:22 126:15</p> <p>additional 129:9 155:21 189:16 190:2</p> <p>address 56:3 169:12</p> <p>addresses 127:13</p> <p>adds 113:22</p> <p>adequate 31:12 57:3</p> <p>adequately 4:13</p> <p>adhered 83:2</p> <p>adjust 134:13</p> <p>adjusting 61:18</p> <p>administration 129:4</p> <p>admit 114:4</p> <p>adopted 55:1</p> | <p>advance 124:11</p> <p>advantage 21:9 194:3</p> <p>advantages 56:20 59:6 61:7 69:16 191:12</p> <p>advil 56:12</p> <p>advise 221:18</p> <p>aerodynamic 143:18</p> <p>aerosolizing 209:14</p> <p>affect 109:3 121:20</p> <p>africa 84:5,10 149:15</p> <p>afternoon 5:9 217:4 224:22</p> <p>age 98:14 132:8</p> <p>agencies 222:22 224:10,11</p> <p>agency 36:13 129:10 211:20 214:2</p> <p>agenda 82:5</p> <p>agents 131:8</p> <p>aggravating 161:22</p> <p>aggravation 58:13 61:21 71:5</p> <p>aggravations 63:4</p> <p>ago 16:15 18:13 27:15 30:5 39:8 45:15 64:15 66:6 72:17 80:12 83:20 84:4 141:21 151:10,14 155:7 172:22 176:8 196:2</p> <p>agree 36:20 41:10 50:20 55:22 65:9 65:9 69:22 70:12 70:15,19 173:2 175:18 192:9</p> | <p>194:11 203:7</p> <p>agreed 191:13 192:21 193:3,22</p> <p>agreement 3:20</p> <p>ahead 102:3 190:2</p> <p>ahold 85:4</p> <p>aids 5:22</p> <p>aiha's 91:18</p> <p>aim 222:9</p> <p>aims 91:20</p> <p>air 33:12 55:10 64:8 95:20 96:5 118:1 119:20 151:13 193:16</p> <p>airborne 185:1 209:8</p> <p>airways 118:4,5 120:7</p> <p>al 56:7 158:10</p> <p>alexadre 95:12</p> <p>algori 75:2</p> <p>align 118:3</p> <p>aligned 119:9</p> <p>alignment 37:21</p> <p>alike 165:14</p> <p>allamore 11:6</p> <p>allen 137:15 146:9</p> <p>allow 5:11 62:11 203:13</p> <p>allowing 108:7</p> <p>allows 223:21</p> <p>alphabet 56:18</p> <p>alter 23:11</p> <p>alteration 23:9</p> <p>altered 25:5</p> <p>altering 185:22</p> <p>altogether 225:7</p> <p>aluminum 13:14</p> <p>alveolar 118:12</p> <p>alveoli 118:5 119:2</p> <p>amazing 98:16 106:19</p> | <p>ambiguity 69:14</p> <p>ambiguous 70:21</p> <p>american 11:5 23:18 77:2 90:2 115:5 211:7,16</p> <p>amosite 66:13 78:21 80:14,15 82:15 92:5 100:3 117:5 122:13 123:2 124:22 145:4 147:20 149:11 150:18,21 151:5,19 153:17 155:12 157:4 159:4</p> <p>amount 12:12,13 12:21 21:13 47:8 110:22 133:14</p> <p>amounts 24:10 25:2 72:4 113:8</p> <p>amp 203:17</p> <p>ampha 109:7</p> <p>amphibole 10:12 13:17,18 14:14 18:11 22:18,20,22 23:10 32:6,7 38:6 62:15,19,21 66:10 76:5 88:10 117:18 118:3 138:1 139:22 140:11 142:16,19 151:2 151:13 163:2,6,17 164:13 165:1 173:18 197:16 200:8 201:13,16 202:3 206:22 207:13,14 208:18</p> <p>amphiboles 10:16 13:21 14:17,22 15:3 17:1 25:9 26:1 28:1,4 32:12 33:17 50:1 58:14 63:4 64:3 69:18 70:11 87:10 104:9</p> |
|---|---|---|---|

| | | | |
|--|--|---|---|
| 117:5 138:19 139:12 169:5 200:12 206:12 208:3,4 213:16 analyses 205:15 214:14 215:2 analysis 3:22 5:13 22:3 25:4 28:10 31:14,22 32:18 33:4,9,10 58:7 61:6 81:5 86:21 87:1 90:3 95:7 102:5 111:5,14 113:16 144:16 162:3,22 167:4 179:2 180:4 183:9 185:12 186:10 187:12,13,17 190:3 192:12 193:3,11,14,17 194:5,7 195:4,6 199:14,18 200:8 210:3,8 214:13 215:6 analyst 195:7 222:3,4 analysts 112:17,20 222:9 analyte 69:22 analytical 31:11 32:11 46:21 50:2 56:5 63:12 69:20 70:7 71:3,8 79:6,9 81:8 94:2 184:15 184:16 185:4,5,7 190:15,17 195:10 196:17 197:2 220:14 analytics 104:22 analyze 78:8 104:18 186:13 187:13 189:5,6 201:7 203:18 210:8 | analyzed 110:22 177:2 186:15 analyzing 4:14 103:5 111:1,2 187:1 anderson 99:9 andrew 129:16 137:18,18 angerous 220:10 angle 69:11 198:1 198:3 199:9 angular 61:12 animal 123:18 128:14 134:4 animals 129:6 132:5 animated 117:17 ann 2:8 35:22 115:15 127:12 134:10 135:5 137:9 162:17,20 169:1,15,19 170:19 172:6,17 172:20 173:2 174:10,15,18 175:13 176:3,12 177:9,12 178:6,14 179:6,17 180:5,14 181:6 187:7 197:18 209:9,11 209:16 221:22 224:22 225:1 ann's 91:3 132:11 answer 56:1,15 62:7 63:19 70:11 70:17 78:12 79:3 102:14 106:6 138:4,5 176:4,19 190:18 192:21 answered 6:15 191:7 answers 52:21 anthophyllite 13:22 14:7,16 | 17:12,13,22 18:2 18:9 23:15 24:7 24:16 38:22 39:1 51:1,10 54:19 57:18,19 58:2 64:20 66:14 67:6 67:9,12,16,19 69:6 82:16 86:9 86:12,14 87:16,20 87:21 128:9 153:3 163:4 165:8,13 166:3,8,13,16 179:17,20 180:1 197:19,22 201:9 207:4,10,18,20 antigorite 125:3 antioxidants 123:13 136:16 anybody 8:4 46:2 107:1,17 161:15 176:2 195:12 204:1 anymore 33:15 84:6 93:6 155:16 205:4 anyone's 218:21 anyway 159:2 apart 38:3 39:7 142:13 151:5 161:18 165:22 197:20 198:2,6 apologize 40:8 116:9 apologizing 131:11 apophyllite 24:12 apparently 105:17 176:13 appear 30:17 67:16 88:5 129:5 144:12 146:17 appears 165:12 applause 28:19 43:17 73:8 76:17 | 96:17 114:5 132:13 168:21 192:2 195:14 208:21 225:3,8 apples 175:7,7,17 175:17 applicable 91:10 221:4 applied 38:2 120:17 126:16 155:4 apply 107:22 193:15 195:11 appreciate 133:8 172:7 appreciated 10:6 approach 34:2,4 141:12,13 168:10 210:9 216:18 approaches 4:13 203:8 appropriate 78:12 79:21 81:21 184:15,17 208:12 approval 219:14 april 93:16 area 16:17 27:6 40:15 49:15 107:7 109:10,12,13 130:13 133:12 134:9,16 179:20 179:21 180:1 areas 5:4 109:15 134:14 214:5,7 arenite 109:17 179:5 argue 48:4 63:16 158:13 168:16 arguing 58:5 argument 180:11 arguments 30:6 arizona 134:19 135:12 |
|--|--|---|---|

| | | | |
|---|--|---|--|
| <p>arm 57:6 68:1 arranged 116:1 arrow 152:9 art 141:20 142:2 192:4 225:1 article 23:17 46:16 47:7 149:4 149:6 221:7,15 articles 196:11 221:17 artificial 89:10 91:1 220:9 asbestiform 13:19 29:3 31:8 35:9,15 37:9 40:20,22 42:12 43:5 52:1,7 52:8,9 57:18,20 58:3 66:8 80:2,6 84:17 95:1 109:12 120:1 124:21 125:2 128:7 131:16 132:20 163:6 198:1 asbestos 1:3 4:1 4:15 10:1 14:19 29:8 30:10,17 31:4,5,12,15,15 31:16,22 34:8,22 35:1,15 36:9,12 36:14,17 37:3,5,7 39:1,2,2 40:6,7,13 41:21,22 42:21 43:7 44:3,4 45:22 48:6,18,19 49:1,3 49:11,14,18 50:3 50:15,16 55:2,13 55:14 56:2,18 57:15 59:9 64:5,8 64:10 65:15,17 68:11 71:17 72:1 72:9,11,19 75:17 76:1,2 77:5,18 78:3,8,17 79:22 80:1 84:16,18</p> | <p>85:5,17,20 89:12 89:16 90:3,6,7,8 90:12,12,15 91:13 91:18,20,21 92:8 92:9,11,13,16,18 92:21 93:3 96:19 104:14 107:4,14 112:8,12 117:5,14 120:22 121:3,22 122:6,9,15,18 124:22,22,22 125:7,8,10 126:3 126:11,15 127:4 127:17 128:2 129:2,2 130:6,16 131:7 132:8 138:3 140:17,17,20,21 141:1,4,9,11,16 141:20 142:3,6,11 143:8,11 146:7,22 147:1,5 148:12,16 149:11,21 150:10 150:11 151:7 152:16 153:10,12 154:2,5,14,15 155:20 156:14 157:6,13 159:5 162:2,8,13 163:2 163:18 164:9,12 164:13,14 165:8 165:13 166:4 167:4,8 170:4 171:5 173:11,12 174:4,5,5,8,14 176:9 179:9 183:10,16 187:18 188:2,12,14 192:14 193:1,2,17 194:16 196:13 200:12 201:3,7,13 205:20 207:15 208:15 211:8 216:10 219:22 220:2,5,6,13</p> | <p>221:3 asbestosis 134:2,2 177:21 179:18,22 aside 62:5 asked 66:22 70:15 90:3 139:21 160:13 166:2 167:1 186:22 192:19 asking 178:3 183:20 aspect 3:5 40:3,5,9 42:1,2 65:17 169:13,15,16 174:2,3,7,9,11,20 174:21,22 175:2,8 175:10,13 192:10 aspm 87:5 assembled 214:8 assess 131:20 140:16 assessing 193:1 assessment 112:13 158:11 193:9 assessments 94:7 103:16 189:20 195:2 assets 99:16 assign 37:1 assistance 183:14 225:6 associate 162:11 associated 10:14 10:17 14:12 102:13 117:4 145:2 association 77:3 90:3 177:1 211:8 211:16 assume 139:2 223:4 assuming 198:9 206:14</p> | <p>assumptions 107:11 156:15 assurance 79:13 82:9 191:15 assurances 164:18 astm 82:4 93:8 211:2 astmd2207 183:19 astn 209:21 attempt 87:6 attend 8:5 attendee 5:11 attendees 6:9,12 attention 36:9 65:3,5 72:18 91:21 attorney 226:11 attraction 83:3 attribute 81:6 attributed 37:1 41:21 aubrey 178:22 audience 4:4,7 5:21 6:6 7:2,14,16 8:3,6,13,17 9:4,6 9:10 19:12 39:19 41:12,14,19 42:5 42:14,21 44:7,16 45:9,16 50:6,11 50:13 53:10 56:13 66:20 68:13,17,18 71:18 73:9,13 74:7,11,13,14,20 75:14 86:4,20 93:13,18 96:20 97:9,17 98:4,10 98:14,18 99:1,7,9 99:14,20 100:2,9 100:13,20 101:3,6 101:10 102:16,21 104:17,21 105:2,4 105:7 107:3 112:3 134:18 135:8,19 136:4,19 160:3</p> |
|---|--|---|--|

| | | | |
|--|---|---|---|
| 162:15,18 169:4 169:18 170:12 171:20 174:1,2,14 174:16 175:9,18 175:19 176:11,20 176:22 177:10 178:2,3,11,15 179:1,7 180:3,12 183:2,21 189:13 191:4,11 195:22 201:10 204:3,6,9 204:16,19 205:19 206:16 207:1,17 208:5,7,14 209:4 209:19 212:19 213:15 214:18 215:14 218:2,5 219:20 220:22 221:9 222:18 223:6 224:6 audio 5:22 227:3 audrey 43:2 australia 148:19 149:22 author 77:6 authors 35:22 122:3 automotive 205:15 availability 136:18 210:21 available 6:1,16 15:13 84:13 85:20 93:21 94:2 155:9 155:22 213:20 avenue 1:10 average 119:16 157:2 160:21 averaged 157:1,1 158:22 avoid 78:22 220:10 award 115:4,5 | awarded 66:18 aware 135:13 218:11 awful 165:14 axes 200:21 axis 200:15,19,19 b b 5:10,14 99:12 181:5,21 182:8 ba 137:1 baby 140:2 162:7 back 14:17 17:2 18:16 29:13 30:7 30:19 36:18 42:6 44:13 56:11 61:1 62:2,6 67:5 68:13 68:15 70:8 72:6 73:2 75:5 82:18 96:2 98:2 105:20 114:8,14,22 123:3 139:10 146:5 180:22 181:12 182:22 185:13 186:14,18 205:4 211:18 218:9 219:20 222:19 224:12 background 11:2 11:18 19:11 44:22 79:9 182:20 183:4 184:6 backward 160:13 backwards 98:3 bad 34:14,15 49:14,18 52:10 66:20 bag 22:6 bailey 36:1 94:17 bake 59:12 baker 85:19 ball 57:14 75:7,8 173:8 217:7 ballot 219:15 | baltimore 1:10 bam 190:1 bannon 205:22 barbecue 57:10 bare 190:9 barns 33:12 barrett 27:1 barretts 11:9 bart 181:6 base 213:7,10 based 15:3 32:12 44:5 48:11 67:1 81:5 93:7 95:12 99:2 112:16 144:18 153:4 171:13 173:20 189:19 193:10 196:8 197:16 219:22 basic 10:20 20:2 53:8 138:9 140:14 197:4 basically 13:6 23:18 107:8 155:17 170:13 182:2 basics 13:1 basis 47:19 65:17 138:7 178:10 180:1 batch 100:5 103:7 103:7 bathroom 44:7 140:1 bear 3:4 80:20 beat 46:8 beating 39:19 beats 62:10 97:15 98:21 beautiful 204:11 beautifully 63:11 becke 199:7 beekeepers 86:13 | beg 72:19 212:13 began 10:1 125:12 167:9 beginning 30:21 36:3 47:8 151:18 179:4 behalf 47:2 77:22 behave 193:10 behavior 143:19 belief 218:13 believe 8:9 36:15 36:16 39:20 43:8 43:9 57:19,20 88:3 91:3 92:3 139:11 193:13 213:17 217:6 220:11 224:18 believes 144:9 bell 49:18 125:14 belongo 150:7 bend 143:12 beneath 16:19 beneficial 130:4 benefit 25:3 92:20 187:12 194:7 benefited 137:17 best 16:4,6 22:19 33:10 47:1 56:17 90:22 112:20,20 186:12 196:6 201:16 202:5,20 203:5 204:18 218:17,17 226:6 227:3 bet 214:3 better 53:19 62:12 71:9,10 102:13 154:5 171:21,22 188:3 190:16 202:7 206:4 220:7 beyond 28:14 60:4 113:3,15 133:1 208:12 |
|--|---|---|---|

| | | | |
|--|---|---|--|
| bi 151:18 153:5,21 | blah 70:3,3,3 | boxing 53:16 | bright 46:17 |
| bias 52:13 67:3 72:12 | blasting 21:10 | boy 58:1 59:17 167:2 | bring 61:1 91:21 97:6 190:13 |
| big 33:19 41:16 50:21 51:13 59:7 60:1,11,19 85:18 150:5 168:4,8 206:12 216:14 | blend 99:1,13 | bozeman 27:4 | broad 192:4 |
| bigger 109:14 | blends 98:19,19 99:15 102:18 | brad 9:21 10:2 28:20 33:21 37:15 46:1,7 48:9 49:22 56:2 85:11 86:11 102:2 156:14 180:7 224:21 | broadcast 9:3 |
| biggest 174:3 212:22 | blindly 112:18 | bradley 2:3 10:3 102:3 104:1,6 | broke 176:10 |
| billion 16:15 60:9 215:4 | blm 167:22 | bra 141:6 | broken 35:2,3,4 38:12 51:12,16 152:1 |
| billions 172:22 | block 55:7 136:15 | braids 146:12 | bronchial 118:5 |
| bin 34:12 147:19 148:3 | blood 134:1 135:10 | brainstorming 216:3 | bronchiales 117:21,22 |
| binders 203:17 | blowing 54:13 55:9,10 60:2 | branch 83:22 117:21 | brooke 2:7 115:12 133:3,21 134:21 135:13,21 136:10 138:22 143:7 144:6 157:9 176:3 176:6 181:7 195:18,20 224:21 225:1 |
| bins 147:15 | blown 121:12 | break 5:5 6:4,8 38:3 44:7 50:5 51:13,14 114:8,13 142:10,21 151:5 163:19 180:16 181:10 | brookite 87:20 |
| bio 139:3 200:9 | blows 96:13 | breakdown 176:7 | brought 134:9 140:3 210:17 |
| biologic 131:20 | blue 27:7 55:9 122:13 | breaking 38:12 41:5,6 101:15 163:21 176:18 | bruny 152:7 |
| biological 98:7 99:16 147:21 191:21 | bob 136:11 176:8 | breakout 4:17 5:9 5:20 6:4,8 7:2,3 114:10 180:20 217:13,18 | brush 39:11 |
| biologists 47:17 57:7 130:5 131:12 | bodanic 99:14 | breakouts 7:12 115:9,9 217:21 | bs 76:21 |
| bioreactivity 49:2 | bodies 19:16 54:18 | breaks 53:1 120:5 | buffalo 87:22 |
| birefringence 165:3 | body 26:15,15 27:8 31:10 43:11 49:7 76:14 85:1 141:7 143:22 161:19 | breathing 40:17 96:7 159:16 | buffet 180:19 |
| birthday 213:13 | bold 214:3 | breeze 54:13 | build 119:13 |
| bit 7:17 17:3 20:15 21:12 29:21 41:4 48:22 67:13 72:8 77:11 79:8 84:8 102:4 108:19 133:16 143:6 144:15 146:5,13 149:12 150:4,5 152:14 153:19 166:21 194:20 | bolivia 149:1 | brian 205:1,22 | building 32:1 49:11 54:21 55:12 56:15 57:12 58:7 58:21 59:18 71:22 91:22 107:14 108:7 175:9 188:16 |
| bite 105:20 108:12 | book 47:22 58:6 | brian's 205:21 | buildings 140:19 |
| bla 48:17,17 | boots 64:22 | briefly 5:3 9:21 133:4 136:20 | bulk 32:16,17 82:8 91:18 103:6 111:2,6,9 122:14 193:14,17,20,20 194:7 211:8 213:11 214:11 222:16 |
| black 26:8 27:10 76:4 | born 49:5 | | |
| | bottle 56:12 140:1 140:2 162:7,16,19 163:14 164:20 | | |
| | bottom 17:4 23:20 76:10 84:7 | | |
| | bought 87:16 96:1 101:16 | | |
| | bound 136:6 184:21 | | |
| | boundaries 19:4 | | |
| | bounded 24:22 | | |
| | boxcar 187:14,18 | | |
| | boxes 116:15 | | |

| | | | |
|--|---|--|---|
| bulks 215:7 bullet 115:15 bump 146:3 150:5 bunch 35:16 65:22 159:16 bundle 162:8 165:4 169:9,9,11 170:2,7,13,19 171:1,2,17,17 172:3 175:21,22 bundles 22:1,9,21 141:4 163:16 167:6 169:7 176:7 176:18 burden 98:5 202:19 bureau 38:21 147:7 burlington 27:14 burn 57:10 business 66:20 105:14 buy 85:18 104:16 106:7 buys 87:14 | calculating 33:8 95:11 173:5 calculation 33:6 calibrate 61:22 212:6,7 calibration 79:7 185:3 212:11,21 calibrations 212:9 california 40:12 79:16 85:9 86:10 88:2 94:9,17 150:2 call 34:13 38:17 40:21 41:2 44:14 52:14 65:3,4 93:4 96:6 144:19 148:11 154:5 180:9 198:10 213:6 224:19 225:5 called 23:11 50:22 92:13 97:11 117:3 119:22 121:18 123:8 124:16 125:10,21 126:21 129:20 166:3 207:6 calling 68:2,3 76:2 calls 82:4 camalital 135:5 camera 40:2 141:19 canada 12:21 74:9 98:21 134:22 canadian 134:19 135:2 cancer 116:21 121:11,13 123:15 129:11 130:19 132:9 179:11,19 180:5,9 214:2 cancerous 120:20 124:17 | cancers 129:6 capabilities 212:1 212:2 capability 63:13 capacity 117:19 cape 147:12 148:18 149:12,16 156:19,21 capital 1:20 car 75:8 carbide 101:20 carbo 103:6 carbon 17:9 26:4 53:15 carbonate 15:10 16:6 20:6 24:9,10 carcinogen 147:1 carcinogenic 37:2 115:18 120:14 133:18 144:10 162:4 220:3 carcinogenicity 30:18 131:15 144:17 carcinologist 37:2 card 35:14 care 96:6 111:18 career 115:3 careful 75:12 82:11 86:7 185:18 185:22 carefully 119:8 147:8 carlisa 61:8 carried 106:2 carry 26:3 carrying 15:14 carryover 100:5 cartoon 70:21 cartoonish 23:16 26:5 cascade 121:7 cascades 121:8,20 | case 9:16 16:5 28:4 54:10 62:7 88:13 125:2 126:22 149:17 176:1 210:19 cases 66:18 130:20 145:10 castillo 155:3 180:7 catch 195:21 categories 51:11 53:7 category 23:6 62:16 159:3 catherine 1:5 2:2 3:2,9 7:4,10,14,15 7:19 8:4,7,11,16 9:1,11,15,20 28:20 29:10 43:18 44:11 76:18 96:21 102:2 105:12 114:6,14 115:13 129:17 132:14 136:20 168:22 169:2 176:21 178:20 180:16 181:11 182:7,12 182:15,19 208:22 210:18 212:15 213:13 215:15 220:8,20 221:14 221:18 222:10,12 224:16 caught 114:7 causally 125:22 cause 49:8 118:8 121:4,20 131:4,8 143:8 150:10 161:1 caused 128:2 131:3 causes 121:5 causing 123:16 |
| c | | | |
| c 2:1 3:1 5:10 181:21 182:8 calaveras 94:10 94:12 calcic 22:21 201:15 calcite 17:9,12 20:17 21:13 24:11 24:14 26:4,14 calcium 13:14 15:10 16:6 17:17 22:18 50:1 66:15 67:8,8,10,10,14 201:14 calculate 33:4 107:17 109:21 172:11 | | | |

| | | | |
|--|--|--|---|
| <p>caution 91:15 201:1</p> <p>cautionary 86:22 201:2</p> <p>cavity 117:12</p> <p>cc 154:22 156:5</p> <p>ceiling 31:15 49:12 71:21</p> <p>cell 121:10,12,13 123:7,11 124:3,16 126:9,10,12 128:1 128:3,4 129:14 130:10 136:7,14</p> <p>cells 117:9,9 118:21 119:2,5,21 120:6,6,15,19 121:6,17 123:4,5 123:9 124:7,10 127:1,2,6,7,7,8,10 127:20,21,21 129:21</p> <p>cenogenics 176:1</p> <p>center 11:20 12:19</p> <p>ceramic 19:6</p> <p>ceramics 12:3,16 19:6 20:20 103:14</p> <p>certain 7:12 35:4 47:8 61:12 93:13 107:11 130:16 158:19 161:20 179:20 185:11 186:22 194:13 201:18</p> <p>certainly 17:20 24:5 57:14 120:10 122:20 130:13 139:1 150:17 155:8 162:3 218:14</p> <p>certainty 194:17</p> <p>certificate 226:1 227:1</p> <p>certificates 210:1</p> | <p>certify 226:3 227:2</p> <p>chains 121:21</p> <p>chair 183:18</p> <p>chairs 44:2 209:2</p> <p>challenges 75:15 185:12</p> <p>chance 5:11</p> <p>change 33:3 52:14 52:15 64:18 75:2</p> <p>changed 30:3 85:7</p> <p>changes 127:19 130:18 133:19 136:16 219:3</p> <p>changing 53:13</p> <p>channel 119:10</p> <p>chaos 181:2</p> <p>chapter 57:1</p> <p>character 53:14</p> <p>characteristic 21:22 37:9,10 49:10 68:1 141:15 151:7 152:3 159:9</p> <p>characteristics 139:14,17 142:11 145:8 153:7 156:8</p> <p>characterization 4:17 29:2 78:5 79:5 95:3 135:4</p> <p>characterize 46:6 47:19 55:21 79:15 93:22</p> <p>characterized 121:1 122:4 133:7 135:5 150:11</p> <p>characterizing 31:12 214:11</p> <p>charge 103:4 122:19 130:13 183:7 184:18 194:21 209:17</p> <p>charged 136:17 183:8</p> | <p>charles 98:16</p> <p>chart 161:5</p> <p>charts 5:21 152:8</p> <p>chase 71:8</p> <p>chasing 171:22</p> <p>chatfield 81:11</p> <p>chatter 182:20 183:4</p> <p>check 114:11 212:9</p> <p>cheerleaders 101:22</p> <p>chemical 15:4 30:15 32:17 61:6 71:13 103:1 130:12 197:8 201:18 213:15 215:2,11</p> <p>chemically 33:18 131:5</p> <p>chemicals 44:1</p> <p>chemistry 14:22 15:1 17:2 32:13 33:15,19 42:1 48:10,16 57:4 64:2 67:4,17 77:2 79:9 81:3,8 130:13 136:17 137:19 165:12,21 185:15 186:16</p> <p>child's 197:20</p> <p>children 139:19 162:20</p> <p>children's 162:7</p> <p>childs 27:3</p> <p>china 12:21</p> <p>chloride 223:20 224:1</p> <p>chocolate 101:4</p> <p>choice 182:17</p> <p>chose 30:3</p> <p>chris 99:14 185:18</p> <p>chrisantha 137:14</p> | <p>chronic 123:17</p> <p>chrysler 80:12 98:20 99:5</p> <p>chrysolite 82:12 109:6 117:5</p> <p>chrysotile 10:14 14:12,14,16 23:14 24:6 51:1 69:18 75:5 92:4 120:5 124:21 127:17 132:7 134:19,20 134:22 135:12,20 136:12 157:7 163:3 164:10,11 164:12,16 202:21</p> <p>cindy 227:2,13</p> <p>circular 21:21</p> <p>circulation 15:21 25:17</p> <p>circumstances 171:11</p> <p>citizen 53:20</p> <p>citizens 214:4</p> <p>city 71:7 75:20,21</p> <p>claimed 87:16</p> <p>claims 19:5</p> <p>clamps 124:4</p> <p>clarify 69:13 95:18</p> <p>class 39:8 55:8 81:8</p> <p>classic 25:8</p> <p>classical 65:16</p> <p>classification 48:12 122:5</p> <p>classified 40:4</p> <p>clay 22:2 24:14 93:22</p> <p>clean 82:12 83:6 100:8 135:9</p> <p>cleanup 64:11</p> <p>clear 27:20 36:9 79:19 89:15,16 91:13 138:6</p> |
|--|--|--|---|

| | | | |
|--|--|--|---|
| <p>140:20 156:4 179:22 201:20 clearance 31:18 119:1 139:16 cleared 119:9 clearly 17:20 22:18 25:12 28:13 42:3 59:1 61:3 71:17 95:1 144:6 150:16 151:19 cleavage 13:5 34:10,13,18,20 35:1,8,12,16 38:17 40:4,21,22 41:6 48:20 51:12 51:14 52:6 66:7 86:17 87:3 88:7 88:12 89:5,13,17 89:18 90:8,13,15 91:13 142:21 close 165:2 215:17 closed 16:12 55:10 153:1 closely 178:18 closer 38:9 closet 140:1 closing 3:11 182:3 215:19,20,21 217:2 clouds 72:1 clue 58:22 cluster 38:1 214:14 clustered 220:4 cm 73:14 coal 193:5 coatings 206:15 coded 59:8 codified 64:10 codify 87:6 coding 100:22 coefficient 107:21 coffen 176:13</p> | <p>cold 16:5 coldest 98:16 cole 98:16 collapse 207:19 colleague 95:12 206:1 colleagues 58:18 73:4 125:1 220:12 collect 191:20 207:22 collected 86:11 94:16 109:17 132:19 151:14 197:3 200:14 collection 214:9 collectively 220:18 college 1:11 114:22 136:22 137:1 colonies 128:1 color 102:22 colorado 30:1 88:4 colors 141:2 142:8 199:8 columbia 137:4 combination 19:13 30:12 189:14 come 4:12 8:15 10:2 16:1 30:19 40:16 49:2 50:19 56:14 66:5 70:8 79:2 80:3 82:17 86:8 95:14,16 118:20 119:14 139:10,21 146:5 147:6 155:21 156:16,17 161:18 162:6 176:1 180:22 181:12,18 189:9,20 215:22 220:5 222:19</p> | <p>comes 46:21 92:12 119:10 121:6 141:22 147:1 coming 12:22 25:19 49:16 52:21 58:10 62:6 76:5 76:10 78:12 85:12 135:15 150:7 155:5 158:7 188:18 196:19 200:13 commence 3:7 comment 81:20 128:10 132:17 168:13 171:20 187:22 218:15,19 219:1,1,5,13 comments 163:5 166:21 187:6 191:8 201:10 210:21 224:16 commerce 189:19 commercial 10:11 10:17 13:22 31:5 31:14,20 34:8 36:12 37:7 41:22 43:7 71:12 133:11 179:9 222:17 commercially 12:9 79:22 committee 3:17 10:4 29:7 93:8,16 93:17 130:2 commodities 12:10 common 13:13,16 14:7,8 21:20 69:22 76:4 84:12 139:18 156:10 216:16 communicated 7:20 communicating 50:17</p> | <p>community 36:15 47:16 48:2 59:13 122:8 134:12 184:9 188:4 195:10 companies 11:4 103:12,13,18 company 1:20 11:6 22:10 85:5,7 85:17 103:10,19 comparable 122:19 134:14 comparably 125:4 comparative 134:16 175:15 comparatively 129:2 compare 81:12 109:6 130:22 147:4 157:11,18 175:1,13 compared 12:8 65:14 94:16 111:2 127:9 174:14 194:16 comparing 84:18 149:20 175:7,10 175:17 comparison 174:16 compiled 177:5 complaints 84:12 complement 203:10 complete 18:8 completely 18:1 57:3 91:13 119:22 completing 77:4 complex 18:9 24:1 25:13 206:17 complicated 55:16 168:9 173:7 200:1 200:3</p> |
|--|--|--|---|

| | | | |
|---|---|--|---|
| <p>complicating 102:17</p> <p>complimentary 185:7</p> <p>component 3:13 79:22 168:6</p> <p>components 15:4 190:10 202:17</p> <p>composed 80:5,8 139:5 141:4 142:9 161:15</p> <p>composition 13:16 22:16 47:20 54:1 136:8 156:9 166:6 166:11 197:8,12 197:15 212:12 213:16,19 214:11 216:4</p> <p>compositional 205:9</p> <p>compositionally 207:3</p> <p>compositions 130:12 214:3 215:11</p> <p>compounds 220:1 220:4</p> <p>computer 195:16</p> <p>computers 5:22</p> <p>concentrate 88:20 167:19 202:3</p> <p>concentrating 61:17 106:16</p> <p>concentration 104:10 105:19 167:16 202:8</p> <p>concentrations 123:12,14 125:7 131:22 137:2</p> <p>concern 53:2 60:13 65:7 72:16 86:20</p> <p>concerned 72:12 188:11</p> | <p>concerning 62:8</p> <p>concluded 105:14 174:12</p> <p>conclusions 185:5</p> <p>concur 194:6</p> <p>concurrence 192:6</p> <p>concurrent 4:16</p> <p>concurrently 218:13</p> <p>conditions 10:19 10:21 16:14 28:2</p> <p>conducted 1:5</p> <p>conductivity 30:14</p> <p>conference 80:11 80:16 93:12 155:6</p> <p>confidence 157:3 160:17 190:6,11 190:13</p> <p>confident 190:20</p> <p>confidential 47:4</p> <p>confirm 95:15 185:8 200:8</p> <p>confirmatory 190:2,19</p> <p>confirmed 64:17 87:8 111:15</p> <p>conflict 63:21</p> <p>confuse 165:20</p> <p>confusing 138:6</p> <p>confusion 36:10 138:6 162:12</p> <p>congo 1:18 226:2 226:17</p> <p>connect 68:5 69:2</p> <p>connotates 52:9</p> <p>cons 202:5</p> <p>consensus 4:13 188:13 196:2 216:19</p> <p>consider 18:10 97:20 122:1 130:9 130:10 184:11</p> | <p>223:9</p> <p>considerable 12:12 26:13</p> <p>considerations 184:12</p> <p>considered 20:18 22:17 23:4 80:2 187:19</p> <p>considering 221:2</p> <p>considers 130:8</p> <p>consistency 166:8 167:12</p> <p>consistent 166:16 166:17 197:9</p> <p>consists 118:14</p> <p>constantly 166:6</p> <p>construction 96:19</p> <p>consulted 27:4</p> <p>consulting 29:21</p> <p>contact 8:22 15:18 16:1 21:4 23:2 25:19 118:20 119:14 121:6</p> <p>contain 23:14 24:6 24:10 122:19 126:18 163:3 193:17 199:2</p> <p>contained 87:21 126:4 128:6</p> <p>containing 4:14 88:22 92:7,16 117:4,13 120:5 122:12 125:9 192:8 196:4</p> <p>containment 45:22 46:2</p> <p>contaminate 101:18</p> <p>contaminated 31:13 188:18 211:12</p> <p>contamination 100:4</p> | <p>contend 163:17</p> <p>content 92:14 132:20 136:15 156:7 165:17,17 187:18 201:13,13</p> <p>context 10:8</p> <p>contiguous 117:10</p> <p>continue 70:19</p> <p>continuity 151:4</p> <p>contradictions 203:11,12</p> <p>contrary 54:19</p> <p>contrast 194:3</p> <p>contrasted 125:10</p> <p>contribute 77:16</p> <p>contributions 115:7</p> <p>control 103:17 104:3 123:15 143:18 224:3</p> <p>controlled 143:22 224:2</p> <p>controls 143:19</p> <p>controversy 45:6 65:8</p> <p>conundrum 144:21 177:13,17</p> <p>conundrums 55:20</p> <p>convene 180:20 219:9</p> <p>conveners 70:16</p> <p>convenient 57:11</p> <p>conventional 194:1</p> <p>conversation 192:5</p> <p>conversations 137:18 188:1</p> <p>conversion 107:10</p> <p>converted 19:1 107:9</p> <p>convince 50:18 61:8</p> |
|---|---|--|---|

| | | | |
|---------------------------|---------------------------|----------------------------|---------------------------|
| convinced 49:12 | counters 221:5 | creations 91:2 | crux 140:22 |
| cook 133:13 | counting 5:16 | creatively 193:19 | 141:14 163:1 |
| cooked 53:22 | 73:17 87:4 108:10 | credit 27:3 | crystal 33:19 35:2 |
| cooperative 3:20 | 109:4,20 140:16 | creep 67:3 | 35:5,9 37:19 52:2 |
| copied 152:8 | 167:9 189:4 194:1 | crisapa 206:9 | 69:4 166:10 197:7 |
| 161:6 | country 14:13 | crystalite 55:7 | 197:7,13 201:4,6 |
| copy 101:2 137:16 | 25:5,6,11 103:6 | criteria 5:15 51:22 | 207:8 |
| 152:9 | counts 108:12,16 | 55:1 67:12 90:6 | crystalline 130:11 |
| core 15:14 26:7 | 109:1,3 193:2 | 91:11 140:16 | crystallite 123:1 |
| 57:5 185:5 | county 94:17 | 158:19 161:1 | crystallographic |
| corechefska | couple 18:20 19:2 | 181:5 192:7 | 35:3 |
| 137:18 | 52:11 150:17 | 193:20 195:11 | crystallography |
| corner 161:5 | 185:11 186:21 | critical 14:18 15:1 | 131:6 |
| corollate 124:4 | 187:6 210:20 | 54:5 62:14 81:14 | crystals 13:13 |
| correct 35:18 69:3 | 211:2 | 121:9,21 198:17 | 37:22 38:1 51:13 |
| 69:11 93:12 94:6 | course 4:12 14:1 | 217:10 | 86:17 206:12 |
| corrective 56:20 | 22:4 23:13 59:14 | criticisms 60:1 | cult 47:14 |
| correctly 61:1 | 84:11 107:12 | criticized 84:16 | cumingtonite |
| 90:11,14 207:11 | 114:1 116:2,4,6 | crocidolite 38:15 | 14:3 198:5,13 |
| correlate 42:3 | 135:11 144:13 | 82:16 89:14 | 206:17,21 207:6 |
| correlation 180:8 | 161:2 192:3 | 120:22 121:3,16 | 207:18 208:15,17 |
| correlations | 212:22 | 122:13 124:6,22 | curious 18:14 |
| 214:14 | courser 24:14 | 125:7 126:3 127:4 | 104:3 |
| corridors 7:7 | 151:21 210:12 | 127:9,16 132:8 | curiously 127:5 |
| corroborates | courses 59:10 | 135:3 145:3 147:9 | 130:1 |
| 212:4 | 137:6 | 147:11 148:12,16 | current 11:3 |
| cosmetic 102:4 | court 145:10 | 149:2,10 153:11 | currently 91:11 |
| 138:15 162:22 | 222:20 | 153:18 155:11 | 136:21 218:12 |
| 184:18 190:22 | courts 44:4 | 156:19 158:22,22 | 221:3 |
| 210:10 213:2,7 | cousins 48:11 | 159:3 171:7,9 | curvature 37:14 |
| cosmetics 5:14 | 66:12 | 173:18 176:10 | 42:1 |
| 12:5,14,17 103:14 | cover 54:15 | cross 141:2 142:8 | curve 40:2,7,13 |
| 183:10,11 192:8 | cow 47:11 | 151:15 | 146:5 160:5 |
| 196:4 203:15 | cowboys 47:11 | crosstalk 101:12 | curved 123:12,15 |
| cost 96:12 187:12 | crack 39:7,15 | 108:14,17 110:11 | curves 160:19,21 |
| 211:14,15 | crazy 67:5 75:19 | 112:15 204:5 | custor 156:14 |
| counsel 219:14 | create 111:19 | 208:19 223:15 | cutting 178:20 |
| 226:8,11 227:6 | 185:19 188:20 | crossword 69:20 | d |
| count 74:1,1 91:13 | created 10:22 23:5 | crumbly 21:8 | d 3:1 99:9 |
| 107:7,9 108:10 | 25:15 26:1 27:22 | crush 81:15 | d.c. 1:22 |
| 109:8,8,14 110:6 | creates 109:13 | 109:18 174:19 | d7200 87:6 |
| 164:2 168:14 | creating 189:3 | crushed 92:7 | da 71:10,10,10,10 |
| counterintuitive | creation 89:10 | crust 16:16 26:6 | dabbed 22:5 |
| 190:12 | 211:17 | 142:17 | |

| | | | |
|---|--|--|---|
| <p>dakota 155:13 157:13</p> <p>damages 45:7</p> <p>dan 58:17</p> <p>dancing 60:21</p> <p>dangerous 72:10 142:12 171:10</p> <p>dariets 98:6</p> <p>dark 19:11</p> <p>darn 46:21</p> <p>darnton 155:1 180:8</p> <p>data 4:18 5:7,17 11:21 57:3 72:14 91:4 98:5 113:12 113:12,16 114:19 137:16 139:5,9 145:17,21 146:9 147:6,17,17,19 149:22 150:1,16 151:9 152:6,7 155:3 156:3,13,16 157:16 158:4 160:10 161:5,8 164:3,4 171:15,17 174:12 176:4 177:4 178:7,8,13 178:16 180:6 181:7 189:7 191:20 194:4,13 197:2,2,4 198:6,8 198:17 199:1,15 200:14,14 203:11 207:22 215:11</p> <p>date 6:17,20 227:13</p> <p>davis 83:5 100:6 101:2 145:11</p> <p>dawned 82:19</p> <p>day 10:8 19:12 28:11 103:7,7 111:14,19 219:13</p> <p>days 12:10 45:15 75:19 185:13</p> | <p>196:2</p> <p>de 210:1,14</p> <p>deadline 217:17</p> <p>deal 36:5 65:13 86:16 113:6 138:7 164:3 166:20 168:12 177:18 186:7 201:16</p> <p>dealers 87:12</p> <p>dealing 31:19,20 43:12 108:5 138:14 197:2 198:1,4</p> <p>dealt 171:18 202:1 223:14</p> <p>dear 46:1</p> <p>death 18:12,19,20 18:21 19:18 21:18 23:1 37:15 49:19 50:1 53:11,12</p> <p>deaths 154:19 159:9</p> <p>debate 24:18 49:14 70:20 220:10</p> <p>decades 39:8 47:12 49:2 72:17 115:22 120:15 129:22</p> <p>december 227:12</p> <p>decide 63:5 71:4</p> <p>decided 87:9 101:15 171:7 209:8</p> <p>deciding 71:2</p> <p>decision 222:1,2,6 222:8</p> <p>decks 111:1,2</p> <p>decomposition 59:1</p> <p>decreased 17:6,13</p> <p>decreases 127:22</p> <p>decreasing 12:12 153:22</p> | <p>deep 19:14 72:9 143:20 155:16</p> <p>defaults 65:6</p> <p>defect 59:2,2</p> <p>defer 205:21</p> <p>define 49:1 71:17 71:19 73:2 188:7 216:9,9 223:2</p> <p>defined 48:6 150:17 170:13 221:3</p> <p>defines 83:13 208:5,7</p> <p>definitely 65:15 86:22 95:1 99:12 136:13 209:21 217:11,14 224:3</p> <p>definition 32:3 34:22 50:8,20 55:20 69:22 70:13 70:16 108:9 113:21 140:21 166:13 188:2,20 194:17 197:5 216:8,10,11 219:22</p> <p>definitional 141:15 158:19</p> <p>definitions 5:4 32:3 34:17 35:1 52:4 170:5 188:3 188:12,14 216:4 216:12</p> <p>degrees 62:15,16 70:10</p> <p>deliberately 55:17</p> <p>deliver 6:11</p> <p>dem 70:11</p> <p>demolish 185:20</p> <p>demonstrate 179:21</p> <p>demonstrated 126:2</p> | <p>demonstrating 42:3</p> <p>density 143:18 165:18,18</p> <p>department 98:13 136:22</p> <p>depend 103:10,21 144:17</p> <p>dependent 10:18 103:5 127:4 204:14</p> <p>depending 52:4 197:9 222:15</p> <p>depends 52:12 73:22 138:4 167:20</p> <p>depiction 26:5</p> <p>deposit 10:13,20 14:6,12 15:3 16:7 18:10 25:16 26:13 27:7,15,18 28:3,8 40:14 54:2,3,4 162:6 164:16 184:14 187:15 190:22</p> <p>deposition 68:8</p> <p>deposits 10:11,17 10:22 11:16 13:22 14:4,10 16:14 17:18 18:12,15,18 19:3,19,20 23:2,5 24:3 25:21 26:17 26:18 27:20,22 53:6</p> <p>depression 16:16</p> <p>depth 15:22 25:19 26:22 54:17</p> <p>derive 94:7</p> <p>derived 113:12</p> <p>derrick 126:21</p> <p>describe 10:9,20 18:4 21:19 59:22 89:2 107:5 139:9</p> |
|---|--|--|---|

| | | | |
|---|--|--|---|
| <p>described 17:19 24:13 85:2 106:10 144:6 145:7</p> <p>describing 82:19</p> <p>description 19:19 85:8</p> <p>descriptive 19:18 220:7</p> <p>designed 64:5,6 108:6 113:10 222:5</p> <p>designs 222:5</p> <p>desirable 30:17</p> <p>desk 6:22</p> <p>despite 36:8 128:5</p> <p>detail 79:17 126:17 185:4</p> <p>detailed 103:19</p> <p>details 21:7 221:19</p> <p>detect 125:20 189:3</p> <p>detectability 223:2</p> <p>detectable 132:21 222:19,22</p> <p>detected 64:16 92:5 113:7</p> <p>detection 60:8 62:10 195:7</p> <p>determinant 70:21</p> <p>determination 66:4 208:12 221:3</p> <p>determinations 134:16</p> <p>determine 79:21 94:5 169:8 170:16</p> <p>determined 23:20 175:20</p> <p>develop 3:21 134:4 193:20 220:15 221:2</p> | <p>developed 13:12 31:14,21 140:18 222:21</p> <p>developing 129:6 216:15</p> <p>development 87:5 124:18 130:19 218:12</p> <p>deviation 160:16</p> <p>devices 6:2</p> <p>diagram 19:17 23:16 37:18 151:15</p> <p>diameter 174:5</p> <p>diamond 32:22</p> <p>died 85:6</p> <p>diers's 47:22</p> <p>differ 48:3</p> <p>difference 33:7 42:11,15 84:21 136:8,11 147:17 154:9 156:6 157:19 198:2 207:5 208:1</p> <p>differences 36:16 37:1 123:20 134:15 207:11 208:2,2</p> <p>different 11:5 14:6 32:12 46:3 49:21 50:2,17 52:4,21 53:6 54:1 54:8,18 59:4 68:5 78:7,10,10,11,18 79:1,10,12,12,20 81:18 89:11,12 98:20 99:2 102:19 122:9,9 123:2 125:16 128:21 129:3 130:11 131:5,14 132:3 135:17 136:9,12 141:15 146:19 147:9 148:15</p> | <p>149:3 151:22 154:10,14 156:11 157:10 159:18 160:21 165:5,15 167:2 170:16 175:7 179:13,14 186:21 191:5 196:12 199:6,12 199:19 200:21 205:20 207:7,8,9 211:12,12 214:4,6 214:10 220:6 222:14</p> <p>differentiate 201:8</p> <p>differentiates 208:8</p> <p>differently 53:22 145:9</p> <p>differing 179:3</p> <p>difficult 41:9 79:14 97:4 166:19 169:7 199:20,20 203:20 219:15</p> <p>difficulties 5:1 8:18 205:16</p> <p>difficulty 134:3 168:12</p> <p>diffraction 61:4 205:5,10 206:19 207:9,11 208:11 210:15</p> <p>digested 120:4</p> <p>dilute 185:21</p> <p>diluted 105:16</p> <p>dilution 105:19</p> <p>dimension 68:7 69:10,10 116:14 116:20 156:9</p> <p>dimensional 159:9 180:11</p> <p>dimensionless 169:17</p> | <p>dimensions 68:20 69:11 81:12 118:3 120:11 130:9 131:2 132:12 139:2,4,5,12,14 139:18 143:5 153:17 172:9 180:9 186:16</p> <p>diminish 185:20</p> <p>dioxide 17:9 26:4 53:15</p> <p>direct 16:1 25:19 85:21 194:20</p> <p>directed 137:6</p> <p>direction 196:17 220:12 226:5</p> <p>directions 199:6</p> <p>directly 6:22 15:20 23:3 28:3 197:15</p> <p>director 183:18</p> <p>dirty 70:9 106:5</p> <p>disadvantage 59:7 60:20</p> <p>disadvantages 59:21,22 61:20 64:12,13 186:4 191:13</p> <p>disaggregate 162:9 171:10</p> <p>disaggregates 170:4,5</p> <p>disagree 48:3 73:6 173:3</p> <p>disagreement 57:6 140:14 141:10</p> <p>disagreements 95:9</p> <p>disclaimer 77:22</p> <p>disclosure 29:20 78:2</p> <p>disconnect 75:11</p> <p>discovered 123:1 126:2 183:21</p> |
|---|--|--|---|

| | | | |
|---------------------------|----------------------------|--------------------------|---------------------------|
| discriminates 56:1 | distinction 140:13 | 202:5,8,21 203:7 | driven 15:17 94:4 |
| discrimination | 166:18 198:2 | 204:7,17 205:6,11 | driving 66:16 |
| 87:6,7 89:20 | distinctions | 207:10 209:12 | dropped 81:7 |
| 90:20,22 | 207:12 | 215:1,2,8 | drops 157:5,5,7 |
| discriminatory | distinguish 64:2 | doke 213:14 | drove 16:17 20:9 |
| 87:4 | 67:19 163:3 | dolomite 15:10 | duane 137:19 |
| discuss 28:1,5 | distinguishable | 16:21,22 17:7,11 | ducts 76:5 |
| 95:10 189:13 | 67:7 | 17:16 20:5,11,17 | due 35:14 |
| 202:5 | distinguished | 21:1,5 24:11 | dumped 34:12 |
| discussed 13:20 | 114:20 | 26:14 27:13 | dunn 86:10 |
| 28:11 184:12 | distribution 80:20 | dolomitic 26:21 | duplet 210:7 |
| 191:8,11,17 194:6 | 81:18 146:8 149:3 | dolostone 15:9 | durability 30:15 |
| 196:15 209:11,12 | 150:3 151:18 | 25:21 | 139:4 156:9 |
| 209:21 217:3 | 153:6 169:22 | domestic 11:19 | durable 30:10 |
| discussion 4:6 | 175:10 | 12:15 102:19 | 130:18 157:17 |
| 19:21 28:17 30:22 | distributions | donated 85:6 | dust 22:5,7,8 23:5 |
| 116:19 167:14 | 90:20 148:2 | dorado 39:13 40:1 | 40:17 |
| 181:21 188:6,12 | 153:21 169:21 | 40:11,18 | dynamics 117:12 |
| 189:1 194:20 | 171:5 | dose 119:11 | |
| 202:1 203:14 | district 11:7 26:20 | 125:19 131:18,21 | e |
| 209:5 | 28:7 | 131:22 132:4,7 | e 2:1 3:1,1 9:6,16 |
| discussions 89:8 | divided 5:3 145:20 | 135:7 173:22 | eagle 68:15 |
| 196:14 201:14 | 180:21 | dosed 89:12 | ear 118:18 |
| 209:1 217:10 | division 45:14 | doses 131:21 | earlier 38:19 |
| 224:13 | 84:1 121:10 | dosone 214:5 | 143:17 160:18 |
| disease 94:5 115:3 | 124:16 | dots 68:5 69:2 | 167:14 172:15 |
| 116:13 118:8 | divisions 66:10 | doubting 205:16 | 194:6 199:21 |
| 145:2 150:11 | dna 121:20 | dough 53:20,21 | 203:7 |
| 154:11 157:14 | doctor 43:9 | dozen 18:20 19:3 | early 125:22 134:6 |
| 173:12 177:22 | doctor's 53:3 | dozens 52:3 | earth 142:17 |
| 178:9 179:12,13 | document 74:9 | dr 76:20 114:20 | easels 115:11 |
| diseases 142:1 | documented 14:4 | 116:1,11,12,15 | easier 134:15 |
| 143:9 155:20 | 186:17 | 126:19 128:9 | easiest 68:19 |
| disillusioned | documents 200:16 | 130:3,4 132:15 | easily 13:10 17:9 |
| 135:14 | dod 120:18 | 136:21 177:1,18 | 21:10 22:7 38:2 |
| dispersed 164:15 | dodson 50:2 177:1 | draft 6:6 | 51:2 55:14 60:5 |
| dispersion 199:7 | 177:18 | drain 120:9 126:7 | 67:7 73:17,20 |
| dispersive 22:3,16 | dodwu 9:13 | draining 54:12 | 74:2 142:10 |
| 101:10 | doing 3:10 55:5 | drawing 37:12,12 | 165:22 170:4,5 |
| dissent 193:5 | 59:9 70:2,5 73:17 | dream 48:7 | east 22:9 |
| distance 19:10 | 76:18 103:20,20 | dreamed 158:2 | easy 19:9 32:13 |
| distant 11:13 | 108:9 109:15 | drew 56:8 | 33:18 68:17 75:13 |
| 12:17 | 115:16 187:12 | drill 47:3 | 88:9 138:4,5 |
| | 199:8,14 201:21 | | 140:13 168:1 |

| | | | |
|--|--|---|---|
| <p>eat 48:8 economic 137:2 ecorp 88:14 ed 107:2,3 edge 38:8 223:3 edges 26:13 eds 81:5 95:7 185:12 212:6 educating 130:5 effect 60:11 82:21 97:12 101:7 139:12 effectively 119:21 120:3 124:9 126:3 140:7 effects 37:2 53:14 110:7 120:21 121:18 127:2 135:22 162:2 220:3 effort 43:13 eight 158:22 eirong 212:17,17 either 15:9 18:18 23:9 34:5,8,14,15 42:19 84:15 97:4 107:5 108:7 109:12 125:20 127:19 185:7 189:2 204:12 213:8,10 el 39:13 40:1,11 40:17 elap 46:4 electric 30:14 electro 191:14 214:13 electron 21:16 22:3,16 32:14,16 52:18 61:5 75:9 92:10 142:7 164:1 166:20 184:4 194:4,12 207:10 212:5</p> | <p>electronic 201:8 electrostatic 83:2 element 215:3 elemental 213:19 215:6 elements 14:18 15:2,16 151:16 191:8 215:13 elevators 7:8 eliciting 120:20 eliminate 209:8 ella 50:4,5 elm 73:16 elongate 10:9 17:20 35:7 46:9 50:22 63:20 64:16 78:8 80:5 94:21 105:17 elongated 36:13 46:7,8 52:22 109:11 139:6,7 145:15 em 169:14 emerald 71:7 emerge 131:1 emp 35:6,6,7,17 48:21 64:9 139:8 220:11 emphasize 28:7 115:19 117:6,8 121:14 122:16 125:8 127:11 128:15 129:14 130:8 131:18 132:4 emphasized 123:20 124:5,20 emphasizes 118:2 126:8 emphasizing 115:17 116:3 118:13 employed 110:18 226:8,11 227:7</p> | <p>employee 226:10 emps 50:22 72:13 72:14 76:11 empty 49:11 enable 141:16 211:21 encompassed 116:15 120:1 encounter 207:5 ended 83:9 87:18 138:22 endorse 27:20 endpoint 126:11 130:15 endpoints 123:22 136:1 ends 52:20 endurability 130:16 endurance 64:13 energy 101:10 engineering 137:4 engulfed 124:7,10 enhance 194:17 enhanced 194:1 enjoying 29:14,22 enshrined 204:6 ensl 183:16 enstatite 87:17 ensuring 91:12 enter 118:2 entered 145:11 entering 117:19 enterologists 34:3 enticed 176:10 entire 173:8 entirely 10:18 224:4 entry 192:18 envelope 63:6 environment 10:19 environmental 43:22 52:14 75:2</p> | <p>115:2 environments 23:7 71:22 140:17 193:16 epa 31:22 87:4 120:16 200:16 epidemiological 184:5 epigenetic 121:18 epithelia 152:5 epithelial 124:3 127:2,7,8,21 epma 214:13 equal 25:16 27:22 equipment 21:10 equipped 4:5 203:6 equivalent 89:13 eric 81:11 err 91:15 error 160:12,18 173:16 errors 160:15,15 especially 19:6 44:1 51:6 53:4 59:17 70:9 81:1 111:9 122:17 203:2 essential 36:16 essentially 20:3 74:15 134:20 establish 78:16 192:6 194:12,15 195:4,6 196:2 210:5 established 83:16 194:14 estimate 77:9 109:9 estimated 11:22 12:7 168:11 estimates 154:16 estimation 108:8</p> |
|--|--|---|---|

| | | | |
|--|---|--|--|
| et 56:7 158:10 evaluate 98:5 166:9 168:18 evaluated 12:1 166:12 evaluating 198:17 evaluation 89:21 evenly 150:3 event 53:12 124:3 events 53:13 121:5 121:7 123:16 eventually 85:11 118:7,19 189:9 everybody 3:2,4,6 3:9 7:12 40:21 114:15,15,16 181:8,12 184:7 200:10 215:22 218:14 224:20,20 evidence 24:11 25:1 67:1 72:15 145:11 167:6 221:12 evident 164:11 evil 49:13,19 evolving 49:6 exactly 98:2 110:13 145:13 147:16 150:6 151:12,16 159:21 174:10 177:17 178:11 195:3 exaggerate 193:1 193:2 examine 79:10 80:10 132:22 examined 80:13 87:21 102:11 122:21 133:7 examining 113:18 example 13:4 15:5 16:4,6 19:8 22:1 37:4,6,11 38:6 78:15 80:4 93:5 | 98:20 120:4 136:18 202:10 223:20 examples 14:6 16:2 90:1 excavating 22:12 exceed 171:3 excel 160:12 excellent 100:1 exception 14:2 excess 13:15 124:8 157:14 excuse 37:2,20 195:16,18 executive 85:1 exist 26:7 28:4 118:16,21 224:1 existing 82:7,10 exists 135:16 expect 161:3 expectation 154:22 219:13 expected 154:19 159:8 expecting 163:12 expense 202:20 experience 111:22 170:11 174:10 187:1,3 201:3 experimental 122:17 experimented 99:15 experiments 83:5 123:18 124:19 135:2,6 expert 44:2,4 196:12,16 198:22 expertise 111:22 112:21 experts 4:3 192:20 219:14 explain 7:16 42:11 56:19 131:2,15 | 149:15 179:22 201:19 exploitable 30:12 exploited 80:1 exploration 179:4 export 12:6 exposed 31:18 60:12 72:1 155:18 exposure 37:3 76:9 117:4 119:11 122:11 128:18 140:17 144:16 147:1 154:15,21 156:5 158:18 178:7,10,12 193:1 exposures 128:14 144:18 154:13 156:1 expression 89:1 127:3 extend 93:20 184:20 extender 19:7 extent 80:13 81:20 186:9,11 187:11 187:20 extinction 198:1 199:9 extra 61:7 extracted 151:10 extraordinarily 147:8 165:2 extrapolate 113:3 173:8 extrapolations 111:8 extremely 13:13 132:6 166:19 eye 1:21 | 128:5,20 131:3 132:7 135:16 136:15 188:14 209:11 211:7 212:22 factor 107:10 factors 65:17 180:10 factory 22:13 facts 115:18 faculty 137:5 fail 36:22 62:16 75:10 fair 21:13 133:14 fairly 33:18 141:3 145:20 fall 33:9 137:17 159:3,21 220:2 223:10 fallen 41:17 falling 49:11 71:21 falls 40:12 false 190:1 192:11 192:13 193:22 familiar 7:12 34:3 128:17 184:5 218:21 far 11:7 63:5 91:4 157:4 170:9 171:3 198:8 205:17 215:10 farther 30:7 fashion 4:3 fashioned 59:16 fast 61:7,15 70:9 fat 51:19,19 fatter 174:9 fault 16:20 26:8 27:10 favorite 86:13 fda 3:20 141:13 161:12 193:13,18 203:2 222:7 224:6 |
| | | f | |
| | | face 144:22 194:3 fact 87:7 91:7 97:21 102:17 106:21 127:15 | |

| | | | |
|--|--|--|---|
| <p>224:10 fdas 106:22 feature 123:18 136:14 features 37:13 116:14 federal 19:5 29:5 36:12 44:4 58:19 78:1 88:22 fedra 75:5 feedback 117:7 219:5,17 feeding 222:16 feel 13:11 36:7 131:12 169:19 194:13 feeling 77:12 feels 177:18 feet 20:9 fellow 77:1 fellows 196:5 felt 216:6 ferric 33:5 ferrous 33:5 fi 8:13 9:14 fiber 5:15 22:1,9 52:3 65:11 68:2 81:12 83:6 88:15 88:20 89:16 90:7 101:17,19 107:4 131:2,7 134:15 141:4 144:1 145:3 145:19,21 148:7 149:7 150:21,21 151:21,22 152:12 153:5 154:19,19 154:20,22 156:5 158:18,18 159:3 159:14,15 160:17 161:20,22 162:8 163:16 164:16,16 167:6 168:9,15 170:15 172:16 173:6 176:7</p> | <p>177:15 178:10 187:18 188:8 193:2,8 194:22 213:12 fiberglass 136:13 fibers 4:15 5:5,14 10:9 17:20 18:7 19:22 22:8,20 24:17 29:2 37:13 48:18,19 52:1 54:13,19 55:9 57:8 63:2,20 65:11,12,12,13 66:1,3 67:22 75:6 80:9,14 83:1,3 88:6 89:12 90:12 91:1 97:10,14 100:22 101:14 106:15 109:19,21 109:22 116:2,12 117:14,18 118:9 118:17 119:8,9,12 119:19 121:3 123:6 124:6,9,12 124:15,15 126:5 126:19 128:7,8 131:4 136:9 143:10,19,20 144:3,7,8,9,11,12 144:13,18,18,20 145:1,2,6,8,18,21 146:12 147:22 149:14 151:3,4,6 153:13,22 157:18 161:16 169:10,10 170:14,15 172:14 172:19 173:1 174:4,5,5,8,12 176:2,5,9,17 177:7 183:9 192:8 192:16 196:4 206:5 fibril 172:1,2</p> | <p>fibrils 142:9 172:1 fibrogenic 179:11 179:12 fibrogenics 133:20 fibrosities 79:20 fibrosity 81:10 82:1 fibrous 13:7 17:21 18:2,3 22:21 30:13 37:10 51:8 52:8 57:16,20 79:18 87:21 88:5 94:9,15,18 109:5 109:9 127:18 128:5,20 139:10 151:16 163:4 164:21,22 165:7 165:13 166:3 field 49:5 57:11,12 66:1 73:18 79:15 81:2,3 96:4,14 98:9 115:2 figure 84:9 112:19 figures 81:5 99:2 filers 119:1 fill 54:11 filler 55:7 filter 135:10 187:6 188:6 205:1 filtered 187:22 filters 186:20 188:21 final 191:14 222:16 225:4 finalized 217:15 finally 45:16 104:11 152:15 financially 226:12 227:8 find 7:11 13:21 14:7,9 15:2 20:15 21:12,20 22:1,4,8 22:20 31:17 33:17</p> | <p>33:20 38:5 46:22 52:21 54:2,3 58:14 70:5 85:10 90:19 104:18 114:9 127:7 143:2 143:3 144:11 149:9 154:3 177:7 178:16,18 196:22 finding 52:3 133:22 140:5 178:19 198:12 findings 86:21 128:13 finds 51:7 fine 9:3 19:18,22 74:5 86:17 150:18 206:5 210:10 finer 56:5,5 finger 21:6 fingerprint 61:4 fingers 57:9 finish 182:3 finished 191:1 finland 152:15 161:8 fires 88:22 first 9:20 10:3 16:8 17:7 23:19 36:18 42:9,10 46:13,15,15 47:10 49:3 56:9 61:9 63:9 77:10 93:5 96:1 111:2 148:16 158:20 182:9 190:14 214:10 215:21 216:3 fit 22:19,21 66:12 83:16 fitree 83:20 fits 67:12 69:16 five 8:9 46:16 48:17 58:19 87:18 110:12 141:12 144:20 145:16</p> |
|--|--|--|---|

| | | | |
|---|--|--|--|
| 177:6 178:7,7,12 182:2 fix 44:19 flag 72:4 flakes 39:21 flame 57:13 flat 38:11 174:9 flex 143:14 flexibility 30:13 118:10 143:15 flexible 143:11 flip 5:21 floor 20:13 31:16 florida 30:1 flows 203:17 fluid 117:12 143:21 fluidized 106:10 106:11 fluids 15:14,21,22 16:18,21 17:8 25:18 26:3,7,7 27:12 fluoride 24:22 focus 145:6 193:4 193:11 focused 120:16,18 121:15,17 122:10 fodders 150:18 folks 4:7 92:3 183:5 218:14 follow 40:8 198:20 216:19 219:1 followed 5:6 11:17 12:4 following 77:8 food 224:9 foregoing 226:3 foreign 102:19 forgive 21:6 form 4:2 10:19,21 14:19 15:2,6,16 16:14 17:8,11 21:20 23:11 25:20 | 26:21 28:3 37:21 38:3 115:16 142:20 151:2 191:14 formal 219:12 formation 14:22 53:15 formed 17:22 20:7 20:16 22:1 23:2,8 25:17 52:2 138:10 former 22:12 forming 23:6 26:4 forms 17:14 53:16 142:13 143:1 162:3 formula 14:16,21 81:7 207:2 formulae 81:4 formulated 116:16 188:15 213:1 formulation 99:3 213:10 forrister 227:2,13 forth 56:12 85:19 145:5 forthcoming 196:19 fortunate 46:22 122:1 forum 4:3 219:12 forward 43:13 158:16 found 22:15 42:10 75:15,15 80:14 85:11 87:15 91:6 104:9,11 105:4 140:1,2,5 164:11 164:20 174:3 196:22 foundation 120:17 213:7 four 10:20 44:17 56:18 73:19 | 106:17 142:2 148:15 154:14 fourths 12:13 fraction 186:17 200:15 201:8 214:21 fracture 16:20 26:9 88:20 99:19 fractured 62:13 fragment 34:20 35:16 51:14,16 58:11 66:7 89:17 89:18 126:15 fragmented 83:1 157:12 fragments 34:11 34:13,18 35:12 38:18 40:4,21 41:1,6 48:20 51:12 75:10 86:14 86:17 87:3 88:7 88:12 89:5,13 90:9,13,16,22 91:14 120:1 124:10 125:11 129:2 131:16 142:21 152:1 192:14 fragrance 102:22 frames 30:21 110:1 france 129:18 frank 82:5 181:4 181:18 182:5,10 182:14,18,21 183:3,17 190:8 191:6,16 203:15 225:1 frankly 86:12 fred 125:15 158:5 free 35:14 71:6 123:7 frequency 40:3 147:16 151:15 | friday 50:14 friend 160:14 friends 29:15 front 114:3 145:10 frustrated 123:8 full 69:19 78:2 95:2 103:15 107:10 121:12 179:18 187:17 fundamental 216:7,14 fundamentally 56:21 funding 3:19 funny 55:5 furniture 223:22 further 17:13 46:19 89:2 133:1 150:5 151:20 152:14 215:18 226:10 future 4:13 93:19 fuzziness 67:5 |
| | | | g |
| | | | g 3:1 gabbro 20:3,22 53:11 gabby 47:21 gain 159:1 garden 142:20 garret 180:7 garret's 68:1 garrett 155:3 156:13 gary 74:3,4,4 209:6 gates 126:13 gathered 16:19 40:15 151:9 gathering 93:9 gazetteer 85:10 gem 13:12 39:5 gems 82:13 |

| | | | |
|---------------------------|-------------------------|-------------------------|--------------------------|
| gene 127:3 | 74:21 77:12 102:3 | 47:18 50:11 52:17 | 137:8 138:2,18,19 |
| general 19:21 24:1 | 116:8 117:7 | 52:18 54:1,2 | 139:4,7 141:6,16 |
| 35:7 51:21 78:5 | 120:11 166:14 | 56:13,17 59:3,14 | 143:4,7 144:14 |
| 122:5 213:18 | 172:12 202:6 | 59:15 60:4 68:22 | 146:13 148:5 |
| 217:2 | 205:8 219:20 | 69:9 70:6,9 71:11 | 157:8 163:16,18 |
| generalization | 225:6 | 72:7 74:3 78:18 | 168:13,14 169:8 |
| 51:18 | gibberish 83:18 | 103:15 106:20 | 172:16 173:5,17 |
| generalize 23:22 | gigantic 163:11 | 109:4,10 110:6 | 177:19 180:20 |
| generalized 27:5 | give 6:11 10:22 | 113:15 120:8 | 181:13 186:9 |
| generally 20:8 | 29:13 59:18 60:21 | 123:3,21 134:5 | 187:20 189:4 |
| 21:9 91:22 138:2 | 61:5,18 80:17 | 150:17 155:15 | 196:17,18 197:6 |
| 153:18 | 84:10 85:22 87:1 | 158:15 164:1,17 | 197:11,14 198:5 |
| generate 88:11 | 87:12 96:14 108:1 | 165:19 181:8,21 | 204:9,11 214:22 |
| 123:6,8 | 108:11 112:2,18 | 182:7,9,18 183:5 | 215:16,16 218:4 |
| generated 65:8 | 112:21 121:9 | 186:18 190:2,17 | 219:19 220:17 |
| generating 125:9 | 168:20 189:20 | 195:19 211:5 | gold 63:15 64:4 |
| generation 122:11 | 190:5 192:10,13 | 213:2 215:18 | 106:4 135:9 |
| 123:4,9,19 125:21 | 196:5 210:18 | 216:14 219:4,14 | 155:14 157:13 |
| 205:5 | 216:2 219:18 | 224:12 | golden 68:15 |
| genes 125:21,22 | 224:19 | goal 4:2 58:13 | 98:14 |
| genotoxicity | given 3:10 70:4 | 69:19 83:11 192:6 | gonna 14:5,6 |
| 129:20 | 182:15 196:1 | 196:1 | 30:19 33:15 42:11 |
| gentleman 214:7 | 219:6 | goals 4:20 50:19 | 44:19 66:19 84:9 |
| geologic 10:18,19 | gives 13:10 18:2 | god's 140:2 | 88:11 91:3 93:8 |
| 10:21 27:6 28:2 | 56:1 61:15 62:1,6 | goes 40:9 49:18 | 104:16 108:22 |
| geological 10:1 | 143:15 192:10 | 50:14 56:11 98:2 | 114:9 141:9 145:6 |
| 29:4 48:2 76:21 | 194:4 196:15 | 113:19 174:9 | 146:5 149:20 |
| 125:15 | 222:4 | 200:5 219:12 | 154:2,3,5 156:16 |
| geologist 9:22 | giving 81:18 | 221:19 | 158:4 160:6 170:6 |
| 21:7 29:4 59:12 | 116:17 156:18 | going 4:11 5:19 | 172:14,19 173:4 |
| 130:4 | 157:2 | 7:18,21 10:10,11 | 178:8 181:11 |
| geologists 57:7 | gladly 60:12 | 13:21 30:4,7 36:4 | 189:5 197:7 |
| 115:21 122:2 | glass 101:17,19 | 44:12,17 45:13 | 198:20 220:22 |
| 183:22 188:1 | 109:22 200:9 | 47:1,5 55:9 57:14 | 224:19 |
| geology 11:1 14:2 | 212:17,17 | 57:18,19 58:11,13 | good 3:2 7:4,5,19 |
| 19:21 20:2 43:22 | glaucophane 94:9 | 60:16 64:11 65:19 | 9:11 16:6 20:1,21 |
| 56:22 136:22 | 94:13,14,19 | 66:21 67:11 70:19 | 25:15 29:10,13,15 |
| 137:1,2,7 | globe 134:19 | 71:6,15 73:5 | 36:2,4 37:6,6 38:6 |
| geometry 66:4 | glue 151:3 | 78:19,21 82:1 | 48:4 49:13 52:19 |
| 205:2 | gneiss 25:7,9 | 86:8,22 93:10,11 | 59:17,20 60:10,21 |
| geoscience 27:4 | 84:12,16 | 103:8,18 104:2 | 61:18 64:12 67:3 |
| getting 8:18 19:11 | go 7:3,8,11 17:4 | 114:22 115:14 | 71:3 72:22 76:19 |
| 25:10 36:18 52:2 | 18:16 31:17 35:21 | 117:2 119:8 | 84:14 87:19 90:20 |
| 59:13 61:8 70:11 | 42:6,18 44:6,13 | 131:20 135:18 | 91:7,8,16 116:8 |

| | | | |
|---|--|---|---|
| 117:7 134:8 139:11 152:10 167:16 174:1 178:6 182:19 195:1 200:17 221:12 gordon 56:7 gosen 2:3 9:22 10:3 85:11 102:3 104:1,6 gosh 141:21 214:16 gotten 125:1 gouverneur 18:4 54:5 126:18 government 32:9 56:16 58:19 78:1 211:20 governmental 224:11 grab 142:14 183:2 grad 51:7 grade 31:5,20 34:8 36:12 37:7 41:22 43:7 59:19 61:19 85:17 102:18 graduate 185:14 grain 119:5 grains 165:13 gram 86:3 grams 86:1 grant 211:20 granted 210:11 gray 19:10 158:20 greasy 13:11 great 42:11 60:19 63:10 64:1 81:20 85:11 86:20 98:15 98:17 133:12 134:1 143:16 155:15 156:6 163:15 168:12 186:7 224:20 | greater 65:20 92:1 126:5 133:15 144:20 158:21 159:10,12 177:6 greatest 148:9 greece 141:22 142:2 146:7 160:7 160:20 green 59:19 greg 28:21 29:1,3 29:6,9 48:9 56:3 97:1 185:13 187:7 187:9 188:5 224:21 greg's 28:6 gregory 2:4 29:10 32:21 41:13,16,20 43:1 97:2 100:1 102:9 132:17 172:7,18,21 209:7 209:10,15,18 212:16 223:4,8,16 grifferson 149:5 grind 81:15 88:16 gritty 24:15 gross 61:15 ground 125:13 188:19 groundwaters 26:7 group 6:7 10:13 10:15 13:17 14:15 115:6 119:12 139:16 191:13 195:12 204:1 206:1 209:8 220:13 groups 203:2 207:12 208:3 grow 37:20,20 38:1 growing 126:11 growth 37:19,21 52:2 151:22 | grunerite 87:19 88:3 89:4 155:18 157:12 gualtieri 116:1,11 116:16 guard 71:6 guess 29:20 37:22 44:6 51:19 74:16 83:9 103:10 172:12 176:22 guesswork 212:3 guide 20:1 gun 68:14 guy 38:10 56:9,9 56:10,10 guys 69:1 96:4,7 100:18 h ha 45:8,8,8 habit 13:19 37:9 142:15 162:2 hair 86:19 half 27:9 47:6 104:19,21 169:11 181:22 hallmarks 121:11 hallway 187:8 hamersley 149:13 149:22 156:22 hammer 39:6,15 80:7 88:11 hammered 68:8 hand 52:16 55:13 55:15,19 57:1 58:6 65:15 75:4 119:18 170:4 handed 72:22 handle 5:20 45:16 handlets 79:14 hands 85:7 178:22 183:20 187:2 218:9 happen 162:10 174:7 | happened 82:22 happening 132:2 happens 52:22 117:16 118:1 119:6,12 120:4 124:2,2,12 175:21 happy 133:11 159:1 213:13 hard 21:12 23:22 29:17 31:2 39:6 39:15,18,20 40:8 49:16 62:16 77:14 137:11 180:6 224:8 hardness 13:4,12 harm 49:8 harper 2:6 76:20 77:8 93:15,19 97:15,21 98:8,12 98:15,22 99:4,8 99:11,17 100:3,10 100:15 101:1,4,9 101:13 102:8,10 102:20 103:3 104:4,7,20 105:1 105:3,6,9 106:8 106:13,21 107:8 108:3,15,20 109:16 110:4,8,12 111:4,13 112:5,11 112:16 113:5,14 113:17 187:8 210:20 222:11,13 223:12,18 harvard 23:19 hate 89:1 180:16 hatton 85:16 hazard 31:5,6 76:6 221:8 hazardous 41:10 138:9,11,14 141:17 220:17 hazards 162:11 |
|---|--|---|---|

| | | | |
|---------------------------|----------------------------|---------------------------|----------------------------|
| head 178:3 | hereto 226:11 | hold 65:14 86:3 | 76:9 120:19 121:4 |
| headed 46:4 | hero 62:2 | holds 85:22 137:1 | 127:6,9 131:1 |
| healing 123:15 | hey 50:14 74:10 | 199:18 | 143:9 147:1,2 |
| health 31:3,5,6 | 105:12 190:10 | home 122:22 | 178:19 220:17 |
| 36:4,14,22 60:11 | 213:9 | 128:17 130:6 | humans 130:22 |
| 72:5,14 76:6,9,22 | hi 76:16 | 160:11 | 132:12 |
| 84:19,22 91:16,19 | hide 122:12 | homestake 155:13 | hundreds 152:16 |
| 92:13 162:2,10 | high 16:18 18:15 | 155:13 157:12 | hunthro 176:21 |
| 179:11,15 187:10 | 20:19 23:21,21 | 159:6 | hurt 34:16 |
| 187:20 220:17 | 24:13 25:13 30:13 | homogeneo | hydrothermal |
| 223:5,11,16 | 30:14,15 40:10 | 167:13 | 15:21 |
| hear 8:19 23:4 | 42:20 59:19 61:2 | homogeneous | hydroxyl 14:21 |
| 28:16 49:17 75:20 | 63:12 117:4 | 83:14 | hydroxyls 14:18 |
| 127:14 178:2 | 119:11 123:13 | homogenous | hygiene 76:22 |
| 218:7 | 125:8 128:6 | 111:21 | 77:2 90:3 137:19 |
| heard 13:2 15:10 | 140:10 141:22 | honest 45:10 | 211:8,16 |
| 56:2 78:6 115:20 | 146:20 147:8 | honor 3:10 46:14 | hypothesis 94:4 |
| 216:9 220:1 | 165:3 179:20 | hope 28:16 42:5 | 99:22 133:1 |
| hearing 42:18 | 180:1 185:14 | 50:18 60:3 77:15 | i |
| heart 57:21 | 190:5,6,11,13 | 86:9 89:7 144:22 | i4 79:14 |
| 133:22 | 222:20 | 158:15 201:19 | iarc 129:10,10 |
| heat 15:18 16:18 | higher 110:5 | hopefully 4:1,6 | iatl 183:18 |
| 17:4,5,6,12 20:9 | 174:11 202:18 | hoping 10:7 | ibdsd 206:11 |
| 25:14 42:20 | highest 17:4 146:1 | 141:18 | icp 185:14 |
| heated 15:14,22 | highly 70:1 111:10 | host 15:8,13,15,20 | idea 45:15 47:10 |
| 15:22 25:18 26:3 | 121:3 130:4 162:4 | 16:1 20:6 21:2 | 89:19 111:12 |
| 26:3,9 27:12 | hill 54:16 63:22 | 23:3 25:20 | 186:12 195:1 |
| heating 26:6 53:12 | 64:5 | hot 16:13 19:11 | 196:16 200:7 |
| 53:13 | hills 39:13 40:1,11 | 25:17 | 202:6,18 203:1,2 |
| heavily 84:17 | 40:18 | hour 182:1 | 203:16 |
| heavy 21:10 46:17 | historic 115:7 | housekeeping | ideal 13:16 148:14 |
| 194:8 202:11 | historical 198:11 | 5:19 | ideas 182:6 |
| held 72:4 114:10 | 198:15 | hsa 85:1 | identical 138:21 |
| 155:6 | historically | hse 85:1,6 | identifiable 51:2 |
| help 4:22 7:6 8:22 | 116:12 126:8 | hse's 210:22 | 62:20 |
| 9:10 26:9 85:11 | 128:16 198:13 | hsl 92:21 | identification 5:15 |
| 96:15 161:12 | history 63:9 | hudson 75:22 | 28:18 69:12 92:1 |
| 195:5 218:4 | 222:20 | huge 66:18 75:15 | 94:3 111:11 |
| helped 27:11 | hit 39:6,15 57:12 | 111:8 149:15 | 141:16 192:7 |
| 131:13 | 80:7 88:10 95:3 | 163:9,10 172:18 | 194:18 198:19 |
| helpful 135:18 | 189:21 | 214:9 | 203:21 |
| 168:10 | hitting 101:14 | hum 176:20 | identified 85:12 |
| helps 210:11 | hodgson 155:1 | human 31:3,9,9 | 90:11,14 92:9,10 |
| | 180:7 | 52:12 60:11 72:5 | 201:1 202:8 |

| | | | |
|--|---|---|--|
| <p>215:10 identify 32:7,11 33:1,18 47:18 48:4 52:17 55:13 56:22 68:11 138:12,17 197:4 206:19 214:22 identifying 189:17 189:17 200:20 igneous 15:19 25:18 ihhe 189:19 ii 135:10 illuminated 133:6 illuminating 116:19 illustrate 36:6 117:15 illustrates 56:13 image 37:16,16 imagine 211:4 imagines 39:4 57:22 199:9,10 imerys 11:10 27:2 immediately 6:3 45:6 52:9 63:5 96:3 140:10 impact 28:3 139:3 139:16 219:7 223:9,13,17 implied 199:22 import 12:7,11,12 12:20 importance 131:18 136:17 important 5:18 30:8 31:8 36:7 37:8 50:19 51:22 52:13 63:17 97:7 104:2 110:15 113:1 116:4,7,21 118:7,17 120:11 120:13,20 121:15 123:3,5,11,19</p> | <p>126:13 127:12 128:19 129:8 130:14 131:19 133:17 136:14 144:10,15 148:10 177:19,20,20,21 177:22 179:15 188:5 192:16 198:7 204:2 208:2 210:3 217:1,8 218:6 219:16 importantly 4:16 6:13 64:20 180:19 imported 12:13,15 improvable 60:6 improve 61:17 108:21 158:16 improves 108:18 impurities 13:14 impurity 13:16 inadept 55:11 inadvertently 55:18 inaudible 51:22 53:10 62:14 63:3 70:20 106:12,18 111:16 137:14 155:14,15 159:2 160:9 165:14 171:9 209:10 218:11 221:13 incidence 142:1 include 4:15 11:5 12:15 13:14 15:9 23:7 80:1 91:11 93:21 201:5 included 92:4 192:17 221:10 includes 26:22 including 18:20 77:5 95:11 129:16 184:11 185:12 inclusive 213:22</p> | <p>incombustibility 30:16 inconsistency 166:9 incorrect 198:9 incorrectly 34:10 92:17 increase 121:10 129:20 174:22 increased 121:10 127:20 176:17 increases 127:20 128:3 increasing 63:18 172:1 incredibly 109:5 independent 150:15 independently 63:1 103:15 199:3 index 140:6,8,10 140:12 157:17,18 193:7 197:21 indexing 208:1 indicate 90:4 136:6 indicated 136:16 indication 167:7 193:7 indicators 134:6 indices 164:22 165:3,18 197:16 individual 22:8 47:2 53:21 56:20 75:10 115:11 148:17 167:9 170:8,15 171:3 172:2,5,8,14 176:1 201:21 205:7 206:5 individuals 36:15 116:5,13 171:14 induction 94:5 119:15 120:12</p> | <p>industrial 30:11 30:17 55:21 58:16 60:14 77:2 90:2 129:18 137:19 147:2 211:8,16 industry 4:4 70:6 102:12,13 213:8 216:1 223:9,17,20 223:22 inesite 87:18 inevitable 114:1 inferences 197:17 infinitive 67:9 inflammation 123:17,17 124:14 133:17,18 177:21 inflation 132:5 176:14 influences 179:11 179:15 information 5:18 7:11 11:19,20 12:19 36:2,4 62:2 63:12 112:17 115:8 161:11 191:21 195:4 196:18 199:2,14 205:9,10 217:9,15 inhalation 100:14 100:16 117:19 119:19 121:16 124:5 134:2 135:6 136:2 inhale 141:6 161:22 inhaled 141:5 162:9 inheriting 71:15 inhomogeneity 167:18 initial 188:14 190:4 initially 124:20</p> |
|--|---|---|--|

| | | | |
|---------------------------|----------------------------|---------------------------|---------------------------|
| initiated 93:5 | 198:7 | invasion 17:8 | issues 32:3,5,6 |
| initiative 94:8 | interested 4:11 | invent 220:15 | 50:21 59:22 62:9 |
| initiatives 211:3 | 47:20 87:2 93:9 | inventions 115:16 | 67:4 78:5 79:6,11 |
| injected 44:18,20 | 93:10 96:13 | invest 211:17 | 139:15 162:22 |
| 45:6 | 192:12 226:12 | investigated 148:1 | 165:10 199:19 |
| input 5:21 6:5,12 | 227:8 | invisible 140:7 | 200:13 201:17,18 |
| 219:4,10,19 | interesting 94:19 | invitation 10:5 | 206:2,3 |
| insensitive 110:16 | 99:22 150:22 | invite 116:18 | italy 129:19 152:4 |
| 110:18 165:19 | 179:2 194:19 | 219:18 | 153:20 160:10 |
| insert 101:20 | 197:1 | invited 8:4 | 161:3 |
| inside 22:5 55:6 | interests 43:21 | inviting 29:12 | j |
| 63:3 98:3 | interference 59:1 | 77:14 137:10 | jail 35:13 |
| insoluble 139:17 | 59:2 | involved 14:22 | january 6:19 |
| inspection 49:4 | internal 87:8,9 | 17:11 89:20 184:9 | 217:16,17 |
| instance 24:3 33:4 | 103:11 | 191:2 211:14,15 | japan 12:22 |
| instances 23:14 | international | 218:14 219:7 | jars 85:18 |
| instant 166:13 | 115:6 129:10 | inward 24:8 | jaw 81:15 |
| institute 29:7 | 214:2 | ion 204:19 | jeff 219:17 |
| 134:1 214:6 215:5 | interpret 75:12 | iron 13:14,15 | jersey 183:18 |
| institutions | interpretation | 15:12 23:8 33:5,5 | jet 81:16 82:22 |
| 135:17 | 4:18 5:7,16 64:14 | 54:9 76:5 117:4 | 83:7,9 97:10 |
| instructions | 68:5 114:19 181:7 | 117:13 122:12,19 | 99:18,20 100:7,21 |
| 182:16 | 196:3 197:1 | 125:9 130:14 | 101:13,16,19,21 |
| instrument 33:6 | interpreted 67:1 | 132:20 135:9 | jetting 86:6 |
| 42:4 | interstitial 179:12 | 136:15,17,17 | jifsan 1:2 3:17,20 |
| instrumentation | interval 160:17 | 201:17 207:19,20 | 6:15 7:6 8:5 10:4 |
| 47:1 61:2 194:2 | intervals 157:3 | ironically 30:16 | 29:12 77:14 |
| instruments | introduce 3:3 9:21 | ironness 51:5 | 137:10 189:10 |
| 198:18 | 43:19 102:17 | irrelevant 70:13 | 217:18 225:4 |
| insurance 93:10 | 114:18 132:15 | 172:13 | jim 65:5 |
| intake 76:1 | 136:21 | irrespirable 55:4 | jimmies 97:11 |
| intended 83:16 | introduced 77:17 | iso 83:13 166:4 | job 91:12 97:5 |
| intense 46:17 | introducing 29:1 | 200:18 | 224:21 |
| intentionally | introduction 3:15 | isolate 139:18 | john 66:20 |
| 188:15 | 29:11 36:8 57:1 | isolating 205:7 | johnson 49:17,17 |
| inter 211:3 | 99:21 115:13 | issue 33:16,20 | 80:11,16 105:14 |
| interact 122:2 | intruded 15:19 | 56:3 65:1 66:4 | 105:14,15,16 |
| interacted 131:13 | 20:4,14 21:1 | 68:6 76:7 86:16 | join 8:8 92:19 |
| interaction 121:17 | intrusion 15:19 | 102:5 104:5 | joined 137:5 |
| interest 3:6 9:17 | 21:4 25:18 | 110:14 111:11 | joke 71:17 |
| 61:13 79:8 88:17 | intrusions 26:22 | 138:20 139:10 | journal 23:18 |
| 92:2,14 93:21 | invaded 27:12 | 144:9 165:10 | 155:4 |
| 103:2 115:6 | invariably 120:21 | 204:13 208:9 | journey 217:10 |
| 122:10 177:3 | | | |

| | | | |
|--------------------------|-------------------|---------------------------|---------------------------|
| judge 114:2 | 15:6 23:13 31:2 | 180:14,22 187:11 | laboratory 46:3,5 |
| judgment 66:5,7 | 31:10 33:12 36:1 | 188:7 189:19,19 | 64:19 84:19 85:2 |
| jumps 46:7 174:7 | 38:15 43:10,11 | 190:5 193:9 195:3 | 87:8,9 91:20 |
| jurisdiction | 44:10 45:12 46:4 | 195:21 197:18 | 92:13 129:16 |
| 224:14 | 48:7,8 50:7 57:8 | 199:11,20 200:7 | 183:17 186:1,1 |
| jury 49:15 105:15 | 63:4 65:15 66:19 | 201:14,17 202:9 | 199:17 207:15 |
| 114:2,3 | 66:21 68:11,12 | 202:10,12,21 | 211:3 |
| k | 70:22 73:14 77:8 | 203:3,16 204:1 | labs 89:11 90:14 |
| keep 3:14 43:14 | 78:17 80:8 81:3 | 206:11,12,18,21 | 91:6 92:8,17 |
| 84:6 143:3 162:19 | 81:13 83:4,7 | 207:15 208:16 | 107:16 201:4 |
| 171:22 210:1 | 84:11 85:4,13 | 209:2 211:9,10,14 | 211:22 212:14 |
| kelly 36:1 | 86:19 87:13,16 | 211:19,20 212:1,5 | 216:19 |
| kept 22:14 86:3 | 89:17,18 90:13,14 | 212:7,10,13 213:4 | lack 27:22 131:15 |
| kevon 1:18 226:2 | 90:16 91:1,2,8,14 | 214:1,16,20 217:3 | 149:16 185:2 |
| 226:17 | 91:14,16 94:10,21 | 217:16 218:2,3,21 | lanberg 130:4 |
| key 5:4 | 95:5,7,18,18,21 | 219:21 222:15 | lance 158:10 |
| kidding 81:6 | 95:22 96:11,12 | 223:11,18 | landfill 84:7 |
| kids 75:20 | 97:22 98:1,2,3,10 | knowing 54:10 | landfilled 84:4 |
| killed 176:15 | 99:5,11,13 100:5 | 186:5 211:18 | lands 19:5 |
| killer 72:11 | 100:10,15 101:2,7 | knowledge 4:12 | langer 181:6 |
| kind 4:19 30:21 | 101:11,22 102:12 | 226:7 | 192:4 |
| 34:12 38:11 39:11 | 102:15 103:12 | known 27:18 30:8 | language 47:12 |
| 40:19 43:2,13 | 104:4,12,16 105:9 | 31:19 35:19 86:2 | large 11:9 16:17 |
| 54:6 60:22 70:16 | 105:10,10 106:17 | 118:11,18 119:2,8 | 25:20 26:18 27:15 |
| 80:3,22 82:16 | 106:18 107:1,13 | 119:20 120:4 | 27:18 57:4 65:20 |
| 112:18 126:19 | 108:18 109:20 | 121:4 128:16 | 66:16 140:9 150:3 |
| 149:3 151:20 | 110:9 111:21 | 140:18 143:8 | 163:14,19 168:2 |
| 152:11 163:15 | 112:16,18 113:20 | 151:8 163:21 | 194:14 215:12 |
| 173:17 180:4 | 117:8 122:5 | 193:16 194:16 | largely 45:20 |
| 196:5,7 197:10 | 123:14 131:1 | 221:8 | 54:18 69:14 |
| 199:18 202:20 | 133:4 134:3 138:3 | knows 181:8 | 117:11 |
| 212:7 218:1,5 | 138:16 139:1,19 | krishi 88:14 | larger 6:7 16:8,11 |
| 219:20 222:17 | 144:6 146:7,22 | I | 35:2 50:3 153:19 |
| kinds 79:6,12 | 147:5,13,13 148:5 | 15 144:19,19,20 | largest 11:14,16 |
| 154:14 | 150:10 152:16,22 | 145:15 | 26:20 27:18 |
| kinks 67:22 | 153:1 154:10,13 | lab 46:4 49:6 59:9 | 155:14 |
| kinky 64:21,21 | 155:19 156:22 | 85:17 90:11 92:19 | larry 42:17 |
| 65:2 | 160:7,12,22 161:2 | 96:2 101:18 150:1 | lastly 131:10 |
| kneaded 53:21 | 162:10 163:11,22 | 150:12 183:22 | 132:4 |
| knew 85:8 127:13 | 164:18,22 166:18 | 201:6 | latency 119:16 |
| 139:19 140:20 | 167:4,8 173:19 | lab's 213:3 | laughs 19:12 |
| knock 68:21 | 175:2,11 176:2 | laboratories 79:1 | 39:20 42:5,14 |
| know 3:16,19 4:8 | 177:12,17,18 | 90:1 92:6 125:18 | 44:7,16 45:9 |
| 4:9 8:1,21 13:7,18 | 178:16 180:9,12 | 129:16 133:8 | 50:13 56:13 66:21 |

| | | | |
|---|---|--|--|
| 68:13,18 71:18 74:13 86:4 96:20 112:3 160:3 174:2 178:3 195:22 law 66:17 lawsonite 94:15 lawyer 68:9 layer 117:10,11 136:5 layered 21:8 layers 13:9 lead 28:6 44:5 157:13 leads 72:12 leak 193:17 leake 32:19 33:1 48:12 leaky 66:10 learn 129:22 187:4 learned 31:7 73:10 121:22 130:21 143:3 196:1 218:3 leave 17:9 168:13 195:21 201:3,9 218:5 leaving 133:1 led 28:2,17 lee 50:9,10,10 56:7 69:12 185:14 left 24:3 34:16 40:2 57:13 64:7 83:21 84:8 85:15 93:1 96:10 147:10 221:6 legal 55:22 78:3 188:4 length 27:9 60:19 143:6 144:5,5,19 158:21 159:10,12 168:16 170:18 175:3,14,16 177:5 177:11,13 186:6 | lengths 145:3 175:11 lesser 24:10 lessons 187:5 lethargy 58:17 letting 54:7 level 53:1 54:6 90:16 112:6 161:9 194:21 195:5,8 222:1,2,4,5,8,14 223:5,8 224:2 levels 62:10 79:10 89:12 167:11,18 211:13 215:3,4 libby 39:18 40:19 41:3 145:4 151:8 151:9,13 153:20 155:12 157:7 159:5 195:3,3 library 213:5 lidia 161:2 lie 19:4 lies 25:19 life 45:20 72:8 lifespan 134:4 lift 102:22 light 58:10,21 59:5,7,11,14 60:9 75:5 163:14 164:12 165:6 184:3 186:8 190:21 191:19 194:2,9,9 199:6 200:2 lighter 57:10 liked 97:9 135:12 196:5 likes 109:12 limit 60:2 186:10 186:11 192:15,17 195:6,7,9 limitation 60:20 limitations 45:7 59:21 69:15 | 191:19 200:4 limited 195:16 limits 60:14 216:15 line 33:2 76:10 159:7,22 222:16 liner 22:9 141:20 lines 13:9 26:8 27:10 33:9 175:20 199:7 lineup 4:19 lipstick 184:21 liquid 194:8 202:11 list 46:15 50:8,14 96:11 listed 32:7,9 127:18 129:1 listened 45:9 listening 8:2 9:2 55:8 listing 125:5 literally 139:22 literature 54:17 128:14 144:4 litigation 66:16 litman 157:21 little 7:16 11:1,18 17:2 18:17 20:15 21:14 22:8 24:14 29:21 30:7 38:9 39:9 41:4 48:22 49:14 67:13 72:8 77:11 79:17 82:14 83:1 84:8 92:20 102:4 107:4 108:19 122:17 132:12 141:8 142:9 143:6 144:15 146:5,12 149:12 150:4,5 152:13 161:9 163:22 166:21 167:13 168:3,7 | 189:12,22 194:20 live 48:16 49:8 llc 211:17 loan 213:2 locally 24:5 location 148:14 156:7,7,12,12,15 locations 148:15 149:15 156:20 214:16 logical 72:12 logically 67:16 lollipop 82:13 lollipops 101:22 london 76:22 long 19:10 23:17 28:11 30:12 41:4 42:9,10 48:17,18 49:2 68:14 75:6 109:13 117:13,18 119:12,15 124:6 124:12 130:19 142:5 143:10,12 144:8,9,11,12,18 145:1,6,8,18 146:18 151:10,14 158:8 159:17 164:2 175:13 176:8,9,15 178:4 190:8 193:5 longation 199:11 longer 46:10 76:3 77:22 81:2 83:1,3 84:13 135:16 141:12 144:20 145:16 153:13,14 154:6,21 158:2 164:6,8 174:6,8 174:11,21 192:9 193:4,11 longo 145:17 look 19:22 24:19 31:21 32:19,21 34:7 37:5 38:9,11 |
|---|---|--|--|

| | | | |
|--|--|--|---|
| 38:16 39:9,10,12 39:16,21 41:6 49:6 52:15,15 53:3 56:4,6 57:21 57:22 58:7 60:13 60:17 61:10,13 64:6,9,10 65:10 65:16,21 67:6,20 68:4 69:21 71:9 72:20 75:4,5,9 78:19 79:17 82:11 83:4 90:12,16 100:8 104:8 105:21,22 106:19 109:14,18 111:6,7 119:7 128:19 129:1 134:6 135:19 139:11 141:2 142:8 144:5 146:14 147:3,4 149:20 150:2,9 153:10 154:3,11 155:8 157:4 158:14 164:3 165:13,15 166:7 169:20 174:4,19 179:2,10 184:13 185:15 193:3 202:12 214:14 222:20 looked 18:15 38:5 38:18 41:1 42:8 49:3,5 68:14 82:15 90:19 96:3 104:9 108:3 109:17 116:12 123:18,22 124:19 125:4 126:9,10,12 126:21,22 127:1 127:16,17,19,22 128:4,13,21 129:17 133:15,20 134:1,10,18,22 140:4 163:7 | 167:14 176:16 177:14 199:11 213:18 looking 19:11 22:11 33:13 38:14 39:14 46:9,16 52:12 57:16 61:10 63:9 65:14 66:2 70:1 71:11,12,20 71:20,22 72:6,14 73:3,7,17,19 74:18 76:8 78:9 78:13 79:4,14 83:10 97:18 98:6 106:4 113:11 127:22 131:8 133:17 136:1 149:8 154:2 165:21 167:3,6 169:5 189:21 190:4 193:7 197:10,12,14 202:13 210:12 213:11 216:13,18 lookout 218:18 looks 38:9,15 39:2 39:2 41:2,17 75:16 82:16 86:5 86:6 109:19 116:13 151:12 159:16 195:3 206:10 losing 191:3 lost 62:5 lot 16:9 28:16 29:15 34:17,22 35:19 36:2,3,20 36:21 38:16 39:19 40:21 41:1,9 43:8 44:7 46:11 51:6 61:20 62:5 65:8 68:2 73:10 79:1 81:1 84:12 86:1 102:5 103:21 | 110:15 119:18 133:10 134:15 139:13,17 141:7 141:10 146:19 147:9,20 150:20 150:21 152:12 153:6 155:9 156:15 157:20 161:20,21 162:1 164:7 165:14 170:6 174:12 176:6 180:10 183:14 187:3 189:8 191:2 196:5 197:18 200:21 201:3,10,11 202:7 203:1,8,9,12 214:8 215:3,6 216:3,6 217:6,9,9 224:9 lots 75:18 142:9,9 145:5,5,5 164:6 louis 49:16 loutel 137:20 love 13:18 44:15 loved 54:5 63:10 low 13:11 40:5 92:13 106:20 123:12 132:8 140:12 146:19 165:1 167:11,18 167:20 lower 17:5 105:19 161:5 165:18 202:18 lowers 165:17 lows 132:8 ludlow 11:12 lumber 144:11 lump 151:20 lunch 180:17 181:9,10 lunchtime 178:21 | lung 31:9 43:10 76:13 115:2 117:12 118:1,6,11 119:20 124:3 127:21 130:10 133:22 138:11 139:14 142:1 143:20 158:5,9 162:1 172:15,16 175:22 177:2,22 178:19 179:11,12 179:12,19 180:5,9 188:7,8 lungs 116:12 144:13 176:17 lying 56:11 lymphatic 119:10 120:9 lymphatics 119:3 m macaroy 85:13 machine 61:21,22 63:10 macrophages 119:3,22 120:2 124:14 mag 15:7 38:15 magma 15:6,19,22 20:4,22 23:2 26:6 magna 20:14 magnesiobornbl... 32:10 33:3,14 magnesite 24:9 magnesium 13:2 14:17,21 15:7,8 15:10,11,12 16:5 17:17 20:6,7 21:1 23:8 24:4,10 25:12,22 26:12 33:3,13 55:6 67:14 120:5 206:22 magnetic 15:21 |
|--|--|--|---|

| | | | |
|---|--|---|---|
| magnification 18:16 60:1 63:19 75:3 79:11 84:20 110:6 147:9 171:21 | marker 129:20 markers 125:20 128:3 markey 7:4 76:18 martin 2:5,6 43:19 44:6,12 45:2,5 50:7,12 53:11 68:19 69:9 73:12 73:15 74:10,12,19 75:1,19 76:20 77:8 93:15,19 97:15,21 98:8,12 98:15,22 99:4,8 99:11,17 100:3,10 100:15 101:1,4,9 101:13 102:8,10 102:20 103:3 104:4,7,20 105:1 105:3,6,9,12,13 106:8,12,13,21 107:8 108:3,15,20 109:16 110:4,8,12 111:4,13 112:5,11 112:16 113:5,14 113:17 183:8 187:8 195:1 200:6 210:20 212:19 220:8,8,9,20 221:1,6,10,15,16 221:20 222:11,13 223:12,18 224:21 224:21 | masses 53:21 172:1 massive 25:21 38:21,22 39:5,14 88:10 massively 16:21 26:11 match 213:1 matches 178:18 material 31:17,20 40:11,20 41:1 43:4,5 57:12 63:6 73:1 80:1,5,13 81:19 82:3,14,19 83:8,12,13,14 84:3,19 85:6 86:8 88:16,17 91:20 94:16,20 95:6 107:13,14 109:10 109:17 125:13,13 127:13 130:8 138:11 140:10 141:3 142:20 146:11,18,19,20 161:17 165:5 167:12,21 184:11 185:22 187:13,17 187:19 193:15 211:1 213:7,12 materially 184:22 materials 31:13 32:1 49:21 51:11 52:7 54:21 55:12 58:7,21 59:18 79:8,10 81:12 82:7,9,10 83:19 83:22 84:2,13,22 88:22 91:22 93:20 100:6,11 102:18 107:12 108:7 111:21 112:1 120:7,11,20 121:2 122:12 123:11 124:20 125:19 | 126:20 127:10 128:5,6,10 131:20 132:3,18 133:2,6 134:13 135:22 136:12 187:1 188:15,16 193:21 194:7 203:4 210:2 211:12 212:7 220:13,16 math 181:15 matrices 124:16 185:9,16 matrix 184:11,12 184:21 213:11 matt 69:12 103:8 103:9 107:19 108:5,18,21 110:3 110:5,9,14 111:5 112:4,10,14 113:1 113:6,15 133:10 134:17 181:8 195:15 204:4,8,10 204:17,21 205:21 206:20 207:2,21 208:6,9,16 213:17 213:22 214:20 225:1 matter 24:18 130:6 141:14 143:13 154:8,10 163:1 195:10 md 1:11 mean 14:14 34:18 42:19 53:19 78:6 84:15 88:15 103:3 104:16 105:7 107:12 112:17 138:13 139:6 141:2 146:17 155:22 161:17 163:9 164:8 170:20 173:5,15 197:21 204:19 207:21 211:11,13 |
|---|--|---|---|

| | | | |
|--|---|---|---|
| <p>223:17 224:3,13 meaning 13:4,6 24:13 70:14 108:12 127:20 129:10 means 21:13 34:5 100:4 112:5 117:10 144:20 152:22 199:4,15 meant 35:10,17 133:3 measure 46:6 63:3 71:9,14 80:19,21 110:20 133:12 154:17 155:1 168:6,15,15,17 169:15 170:8,19 171:11 172:4 173:4,7,10 178:10 194:14 197:8 201:12 203:20 measured 147:7 154:21 156:5 170:18 171:1 173:15 186:16 measurement 5:15 108:1 109:2 181:5 216:4 measurements 5:8 52:20 70:1 82:2,4 114:20 147:14,15 170:22 196:3 199:12 207:22 measuring 62:13 73:3 76:6 169:13 172:8 173:9 191:17 measurment 83:17 mechanical 30:15 mechanisms 119:1 123:2,7 144:7 167:8</p> | <p>media 78:9 medical 160:9 184:5 medically 49:1 medicine 29:7 77:1 114:22 meeker 2:4 29:10 32:21 41:13,16,20 43:1 97:2 100:1 102:9 132:17 172:7,18,21 187:7 209:7,10,15,18 212:16 223:4,8,16 meet 34:21 145:16 222:5 meeting 3:5,6,8,18 6:16,17 8:5 32:4 36:5 47:3 93:17 133:5 135:15 184:8 196:9 215:22 224:18 meetings 47:3 93:8 meets 141:11 158:19 megapee 88:14 melt 106:2 member 7:2,14,16 8:3,6,13,17 9:4,6 9:10 29:6 34:2,3,4 41:12,14,19 42:21 50:6,11 53:10 68:17 73:9,13 74:7,11,14,20 75:14 93:13,18 97:9,17 98:4,10 98:14,18 99:1,7,9 99:14,20 100:2,9 100:13 102:16,21 107:3 134:18 135:8,19 136:4,19 162:15,18 169:4 169:18 170:12 171:20 174:1,14</p> | <p>174:16 175:9,18 175:19 176:11,20 176:22 177:10 178:2,11,15 179:1 179:7 180:3,12 183:2 189:13 191:4,11 204:3,6 204:9,16,19 205:19 206:16 207:1,17 208:5,7 208:14 209:19 212:19 213:15 214:18 215:14 219:20 220:22 221:9 222:18 223:6 224:6 membrane 118:14 mental 70:2 mentioned 24:16 55:4 66:6 98:18 138:12 143:17 186:20 189:15 200:6 203:16 204:10 206:16 209:13 210:22 211:2 213:17 217:7 merge 205:17 merit 202:7 merlet 65:5 67:18 mesothelial 117:9 119:5 120:15,19 127:1,6,9,21 128:4 129:21 134:6 136:5 mesothelioma 115:6,7 117:3 118:20 120:17 121:5,6 126:1 127:6 130:21 131:3,4,9 142:1 149:7,8,16 151:8 152:5 153:2 154:12,16 156:6</p> | <p>157:22 159:20 160:5,8 161:1 178:1 179:3,16 mesotheliomas 128:22 134:3 152:19,21 message 8:18 122:22 128:18 messy 48:13 met 90:5 111:15 173:10 metal 99:21 140:8 metamorphic 15:12 16:7 17:16 25:6,7 26:10 43:21 53:8,9,13 metamorphism 15:17,19 16:5,16 23:2,9 metaplasia 124:17 meters 75:6 method 22:18 32:22 52:5 56:1 56:17 57:11 71:8 110:21 183:9 185:6 190:17,21 192:18,22 193:14 193:15,20 216:15 216:20 220:14 methodologies 222:9 methodologists 166:4 methodology 3:22 47:7 140:18 221:2 methods 4:17 5:5 5:13 31:11,13,21 32:11 50:2,17 58:6,15 59:4 73:11 93:7 108:6 123:14 129:4 181:4 184:15,16 185:7 196:17 200:18 209:12</p> |
|--|---|---|---|

| | | | |
|--|---|--|--|
| 214:19 220:15 methylene 223:20 224:1 metric 11:22 12:6 12:7,8 metrics 74:5 metsova 161:13 metsovo 141:22 146:7 153:11 160:7,20 mg7si8o22oh2 207:3 mic 44:10 michelle 99:9 mickey 45:7,8 57:1 mickey's 51:7 micky's 47:21 micro 172:15 microanalysis 32:14 microbeam 19:22 25:3 28:10 micrometer 146:3 158:8 159:17 168:7 193:11 micrometers 141:5 142:4,5 145:4 148:4,8 153:13,14 158:1 158:12 159:17 161:6,17 162:5 163:10 168:5 171:7 177:15 192:15 193:4 micron 32:18,18 90:21,21 91:8,8 91:11 126:6 169:12 microns 48:17 206:6 microprobe 32:16 37:17 214:13 215:8 | micrnas 121:19 microscope 21:17 28:14 39:22 52:18 57:22 58:4 109:19 140:4 163:7 164:1 186:8 212:6 microscopist 186:13 microscopists 166:2 184:3,4 microscopy 5:7 52:19 58:15,21 59:5,7,11,14 60:9 61:5 73:21 75:9 82:21 92:10 114:19 142:7 163:15 164:12 165:6,16 166:21 190:21 191:14,19 194:3,4,9,10,12 196:3 197:2 200:3 201:21 miehs 127:16 migration 143:21 mile 27:9 117:10 mill 26:20 54:8 81:16 83:7 95:20 96:1 101:13,16,19 milled 82:22 97:10 97:13 99:18 100:7 125:13 miller 43:2 milligram 88:21 210:4 milligrams 100:16 202:11,14 210:4 milling 64:17 83:9 99:20 100:21,21 101:6,21 million 12:1 215:3 millions 172:2,19 mimic 51:9,9 mind 3:4,14 22:14 43:15 61:11 89:10 | 96:13 142:11 145:13 179:19 mine 11:11,12,14 27:2,6,17 72:19 78:16,17,20 85:9 85:13 90:2 103:4 103:10 126:18,21 147:2 149:8,10,11 153:1 155:14,16 157:13 160:14 206:1 210:18 mineable 10:17 mined 16:7 18:19 19:5 27:15 148:16 152:16 miner 56:16 mineral 5:5,14 10:9,13,15 12:10 13:2,5 14:15 15:5 15:8 23:12 28:9 33:1 35:5,7 42:22 53:16 63:20 76:4 77:5 78:3,8 80:5 87:12 94:7,21 95:3 115:16 116:2 131:14 139:6,8 144:18 145:15 148:13 155:2 156:1 157:10,17 157:19 163:21 183:9 187:18 192:8 194:22 196:3,22 197:5 198:7 200:20 201:1 213:12 214:22 216:9 221:4,4 mineralogical 35:18 48:2,11 55:21 116:14 150:22 mineralogist 29:3 51:12 116:1 131:12 143:16 | mineralogists 30:8 47:11,14 55:13 115:21 mineralogy 20:15 39:8 43:20,21,22 56:22 57:5 128:10 130:5 137:3,3 minerals 10:12 11:9,20 12:19 13:18,21 14:20 15:7 27:1 29:3 30:11 31:8 33:20 36:17 37:3 47:13 47:18 48:5 51:6 52:1 61:16 62:8 66:13 71:12 78:18 83:12,22 87:19 93:21,22 94:15 115:20 116:16 151:2 156:7 157:21 166:5,10 185:8,15 188:16 188:18 191:18 193:10 197:3 200:1,21 213:5 221:7,8 miners 155:16 mines 11:9 16:12 19:8,14,14 27:1,1 38:21 51:9 54:7 86:10 98:20 99:2 99:12 102:19 103:15 147:7 155:17 214:10 minimis 210:1,15 minimize 110:6 minimum 79:5 80:21 mining 16:9 21:9 23:5 54:14,20 84:1 103:12,16 137:4 149:2 154:11 155:12 214:7 |
|--|---|--|--|

| | | | |
|--|--|--|---|
| minnesota 30:9 | modernization 186:3 | motion 49:10 | 130:1 133:22 |
| minor 25:2 137:2 189:8 215:12 | modes 150:16 | mounds 140:3 | native 159:19 |
| minute 61:9 114:8 117:15 181:16 | modification 103:1 | mount 140:6 | natural 31:12 123:13 197:6 |
| minutes 3:3 69:8 93:7,16 124:1 181:14 182:1,3,5 | modo 148:21 | move 4:6 5:1 8:12 9:17 24:8,12 25:5 28:21 43:13 58:11 132:10,15 148:20 153:20 158:9 180:17 197:21 208:22 215:17 217:10 218:4 | naturally 119:4 130:22 |
| misinterpretation 199:16 | molds 147:10 | moved 27:12 134:11 | nature 66:12 78:6 124:21 149:5 |
| misinterpreted 173:4 | molly 98:10 | moving 4:21,22 16:20 60:22 182:16 198:16 218:10 220:12 | navigate 9:18 |
| misleading 175:8 | moments 64:15 65:5 66:6 | mri 151:9 | nbs 42:18 |
| missed 212:12 | money 66:18 211:17 213:3 | muck 72:19 | near 90:15 |
| mistakenly 36:16 | monoclinic 207:6 207:7,13 208:3 | multidirectional 37:21 | neat 51:8 |
| misunderstanding 35:15 | montana 11:10,11 11:16 26:18 27:21 51:8 157:7 | multiple 53:13 66:10 99:12 111:18 189:1 190:19 203:8 | necessarily 31:6 74:18,21 80:8 97:18 166:15 169:6 192:13 193:18 213:6 |
| misuse 35:14 | monten 125:15 | murmur 188:13 | necessary 120:14 121:12 166:18 199:3 203:8 210:1 |
| misused 35:20 | months 124:11 134:5 | myriad 116:22 | need 3:13 10:10 23:3 28:11 29:20 36:5 42:15 57:3 61:22 65:20,20 69:11,19,21 78:13 78:15 79:5 80:2 80:10,19,21 82:2 95:5,13 112:22 118:7 138:16 141:14 157:17 160:2 187:17 188:19 190:18 191:18 194:11,12 195:9,9 197:3 200:18 203:11 211:22 216:11 217:14 220:5 222:2 |
| mix 29:14 | monument 19:1 | n | |
| mixed 22:2 53:20 105:18 154:13 | morning 3:2 5:3,4 9:21 29:10 115:14 127:15 187:5 191:9 196:21 216:17 217:4,13 217:20 224:8 | n 2:1,1 3:1 | |
| mixing 54:4,10 | morphological 37:9 90:5 192:7 | name 3:9 32:6 48:12,12,12,13 137:12,12 | |
| mixture 19:4 20:17 | morphologies 21:18 28:9 79:19 | narrow 117:18 118:9 143:10,11 144:1 146:14,20 147:19,22 148:22 150:21 151:6 152:12 153:5,22 174:6 | |
| mobile 145:3 146:10 151:18 153:6,21 | morphology 18:14 33:16 34:1 51:18 64:2 89:21 165:12 192:22 | narrowest 144:3 145:20 148:19 | |
| mode 145:22 146:1 150:14 194:13,15 205:4 206:3 | mortalism 156:6 | national 11:20 18:20,22,22 19:1 19:2,4,8 29:6 | |
| model 95:12,15 124:13 | mortality 154:12 | | |
| models 120:18 122:21 124:12 125:4 126:22 128:22 134:2,13 | mortar 81:16 | | |
| moderator 6:18 195:19 | moscow's 122:13 | | |
| moderators 5:20 6:5,11 181:3,5,14 181:22 209:2,3 217:12,17 225:1,6 | mossman 2:7 114:20 115:12 133:3,21 134:21 135:13,21 136:10 176:6 195:18,20 | | |

| | | | |
|--|--|---|---|
| <p>negative 62:12 63:21 129:9</p> <p>neither 226:7 227:6</p> <p>never 29:19 46:8 78:2 97:5 114:2,3 139:20 169:15 171:13,14 172:16 186:13 198:5 208:16 222:3</p> <p>new 14:3 17:13 73:9 75:21 88:3 93:3,4,6 126:17 127:18 130:7 141:19 183:18 200:10</p> <p>newhouse 98:11</p> <p>news 25:15</p> <p>nice 82:12 85:20 86:12 100:8 142:7</p> <p>nicely 85:21 94:18</p> <p>nickel 13:14</p> <p>nidhs 133:22 135:4</p> <p>niehs 88:2</p> <p>nights 70:22</p> <p>nih 120:16 135:15</p> <p>nine 99:2,15,16</p> <p>nioh 84:5</p> <p>niosh 29:8 77:3,6 77:19,20 78:1 83:11,19 85:20 86:9 87:4 89:6 94:1 100:13,18 132:19 133:2 135:17</p> <p>nitration 60:7</p> <p>nivhs 121:1</p> <p>noise 44:22</p> <p>nomenclature 32:2 35:18 66:9 66:11 216:5</p> <p>non 120:1 125:2 125:10 126:15</p> | <p>128:7 129:2 131:15 132:21 174:4,8</p> <p>nonamphibole 202:17</p> <p>nonasbestiform 36:13,17 37:3,18 37:19 42:12 57:19 87:10,22 88:6</p> <p>nonasbestos 56:2 109:7,8</p> <p>nonempty 108:11</p> <p>nonhomogeneous 112:1</p> <p>nontoxic 120:2</p> <p>nora 29:16,17 77:13 137:11 225:5</p> <p>normal 121:12</p> <p>normally 167:11</p> <p>north 27:9,14</p> <p>northern 27:14</p> <p>notary 226:1,18</p> <p>notation 53:5</p> <p>note 201:2</p> <p>noted 79:10 123:20 128:1 192:15</p> <p>notes 60:18 182:10,12 183:14 195:17 198:20 203:22 217:11</p> <p>notetakers 6:1</p> <p>notice 14:16,20</p> <p>noticed 82:17 196:21</p> <p>notion 81:10</p> <p>november 1:6</p> <p>nuances 203:9</p> <p>number 13:3 21:14,14 73:18 74:1 79:5 93:20 100:20 101:3,6,10 104:17,21 105:2,4</p> | <p>105:7 116:3,16 121:5,7,8,21 123:2 124:20 125:18 129:9,12 130:3 140:9 146:21 150:3 161:21 166:1 167:2 168:9,16 171:2 172:1,14 173:6 183:22,22 184:3,10 187:2 189:21 194:13 207:2 219:6</p> <p>number's 50:3</p> <p>numbers 91:9 134:1 151:16 176:17</p> <p>numerous 42:7</p> <p>nvlap 46:4 91:18 201:5 211:10</p> <p>nw 1:21</p> | <p>occupational 76:22 115:2 144:15 154:21 156:4 178:12</p> <p>occur 13:18,19 20:2 117:10 130:18 140:18</p> <p>occurred 23:21 25:13 109:16</p> <p>occurrence 17:15 24:16 164:19</p> <p>occurring 31:12 197:6</p> <p>occurs 164:13</p> <p>ocean 20:13</p> <p>office 140:3</p> <p>officer 226:2</p> <p>official 219:2,3,15</p> <p>offs 211:4</p> <p>oh 23:4 29:16 42:10 44:15 74:14 78:20,21 87:12 94:22 98:12,15 105:2 109:20 110:8 122:7 179:17 204:21</p> <p>ohara 63:14,15 64:4</p> <p>oil 140:6</p> <p>okay 3:16 7:10,13 8:6,11,16 9:4,16 9:19,20 44:11,13 45:2,5 47:10 74:14 76:16,18 78:22 91:2,17 93:15,19 101:5 107:15 108:4 132:16 136:20 137:9 141:19 151:8 161:11 162:22 163:6 176:11 178:20,22 180:16 182:7,18 183:5 186:7</p> |
| | | | o |
| | | <p>o 2:1 3:1</p> <p>o'clock 182:2</p> <p>objection 177:6</p> <p>observations 132:11</p> <p>observe 110:19</p> <p>observed 132:9 199:10</p> <p>obstacle 212:22</p> <p>obtained 5:7 114:19 186:17</p> <p>obtaining 205:9</p> <p>obvious 28:9</p> <p>obviously 93:20 124:21 133:10 179:4,7 184:17 191:1,18 211:13</p> <p>occasionally 14:8 18:1 23:14 92:2 211:1</p> <p>occluded 119:13</p> | |

| | | | |
|--|---|---|--|
| <p>187:15 190:8 191:22 195:13 209:15,16 210:11 215:16 222:10,12 224:17 okay 213:14 old 29:15 59:16 135:12 160:13 200:16 older 72:7 oldest 155:14 olivine 23:9 omitted 62:3 once 68:8 183:1 186:7 202:8 219:11 one's 38:21 82:17 ones 28:7 84:8 88:15 117:1 145:6 153:7 154:20 157:20 216:21 ongoing 103:16 online 155:10 open 11:9 16:9,11 16:11 19:13 64:8 96:1 103:11 218:1 218:5 opening 3:11 operates 11:6,9,10 operational 42:5 operations 16:11 opinion 35:13 90:18 137:13 173:12,19 opportunity 10:4 24:20 177:1 193:14 opposite 25:10 174:11 optical 43:22 58:15 73:21 82:21 165:15,16 198:6,8 options 185:17 186:3</p> | <p>oral 6:11 orden 56:8 order 101:20 157:21 185:8 190:15 191:20 194:15 210:8 ordinary 142:20 174:19 ore 19:15 21:3 24:8,20 38:15 49:21 102:6,11 105:17,22 106:1 151:11 187:14 190:22 orebodies 20:8 organization 77:14 organized 3:17 original 58:6 82:18 106:9 176:7 orthorhombic 207:13,18 208:4 osha 87:3 185:12 223:13 osha's 223:18 otomicroscopy 66:2 ought 218:15 outcome 52:14 133:20 160:6 226:12 227:8 outcomes 133:19 outcrop 79:16 outs 181:20 outside 19:3,8 81:2 180:19 190:21 194:20 outward 25:5,9 ovals 16:13 ovarian 127:1,7,7 overactive 62:10 overall 156:18,20 157:7</p> | <p>overarching 69:19 overcome 185:11 overview 184:13 overwhelm 172:19 owner 56:15 owns 216:10 oxidant 124:8 125:9,21 oxidants 121:14 122:10,11 123:5,7 123:9,19 oxidation 123:10 oz 71:7</p> <p style="text-align: center;">p</p> <p>p 3:1 pacific 135:11 pack 116:11 211:16 packages 122:9 pads 166:7 page 42:9 47:21 65:6 67:22 pages 42:10,13 paid 22:13 72:18 paint 12:3,14,16 20:20 paints 11:8 19:7 44:5 pair 6:10 pakistan 12:21 panel 44:2 46:14 46:18 196:9,16 198:22 224:5 panels 196:12 paoletti 152:7 paper 12:3,16 30:9 42:6,9,13,14 42:16 95:10 135:5 143:16 155:7 156:17 214:15 paper's 158:7 papers 53:3,4 56:7 56:8 82:18 155:9</p> | <p>paragraph 67:21 parallel 37:20 165:4 170:14 parallels 37:14 parameter 169:17 parameters 113:2 113:4 131:22 pardon 41:13 162:17 parent 85:1 parents 49:4 parietal 118:15,15 park 1:11 18:21 18:22 19:1,2,4,9 22:10 40:17 137:1 part 3:15 14:5,8 18:21 20:12 21:19 22:4 39:5 57:4,5 66:16 69:4 70:5 72:18 74:16 76:7 78:1 89:19 94:8 109:13 145:11 147:14 201:22 207:6,7 217:21 partial 18:7 partially 18:1 38:12 80:1 participants 6:1 196:6 211:19 participate 5:12 participated 78:2 participation 211:15 particle 32:15 34:21 35:4,8,8,10 38:7,18 41:3,14 88:8 107:6,8 110:21 113:18,18 113:19 138:4,6,7 142:4 150:4 154:9 162:5,7,12 167:2 168:17 169:13 170:1,10,17,17 171:16 175:3</p> |
|--|---|---|--|

| | | | |
|--|--|---|---|
| 186:15 188:8 192:22 215:9 particles 10:9 21:21 22:15 35:1 35:2 36:13 37:19 38:3,16 39:10,10 39:16,16 40:3,6 40:15 41:11 42:12 46:9 50:22 56:2 63:20 64:7 73:18 77:5 78:9 79:4 80:5,10,19,22 81:1 82:14 88:13 90:5,15 94:21 99:21 104:7,9,18 106:2 109:11,12 109:14 110:22,22 111:6,7 119:19 120:8 136:4 139:6 139:7,8 140:9 141:8,17 143:8 148:8 150:6 153:15 154:1,6 155:19 158:6,8,11 159:17 161:6,22 163:9,11,19,22 164:5,6,7,9 167:10 168:2,3,4 168:5,7 169:11 170:8 171:3 173:4 173:11,14,22 174:20 175:5,6 193:4,6,12 199:5 201:21 203:21 205:7 particular 150:19 153:3 particularly 37:7 77:13 94:1 167:19 177:19 particulates 44:1 parties 199:3 226:9,11 227:7 | partitioned 115:10 parts 26:12 60:8 145:15 215:3,4 party 130:1 pass 126:13 passthrough 214:10 patch 192:11 pathogenic 121:4 122:12 131:7 pathology 114:21 pathway 133:17 133:18 pathways 121:9 126:1 patriots 71:6 pattern 151:11,12 151:12 186:17 205:5 214:21 patterns 37:21 38:8 154:11 166:14 208:11 pay 85:22 pc 67:6 pcm 58:16,16 86:19 89:4,19 95:19 peak 62:17,19,19 152:13 peel 39:7 penetrate 118:4 118:12,18 119:4 136:7 penetration 143:19 people 8:10 35:6 36:20,21 38:17 40:17 41:10 42:8 43:8 45:14 46:13 46:17,21 49:12 58:5 59:10 62:4 63:10 65:8,9 66:19,20 72:20,21 | 73:6 81:4 88:10 92:15 93:1 96:10 96:11,13 98:9 102:12 107:13 108:15 110:16 113:7,11 114:11 138:12 143:15 152:5 165:11,20 168:13 182:22,22 perceive 72:10 perceived 63:15 63:21 64:4 percent 12:5 26:16 55:1,2,14 80:15,16 88:16,17 88:22 90:7,8,11 90:13 92:2,4,5,17 94:14,14,18 104:11,15,19,22 104:22 105:18 106:5,17 107:4,6 107:7,7,9,14 109:21 110:2 111:19,20,20,20 122:14 126:5,18 128:8 132:21 142:18 150:19 153:12,16 154:18 157:3 159:2,4,8 160:1,3,17 161:7 167:1,22 172:22 205:11 212:11,12 percentage 107:17 percentages 109:11 153:15 168:11 percental 160:17 percival 86:10 perfect 13:5 71:8 perfectly 211:5 period 219:2,13 periodine 106:19 periods 119:15 124:11 130:19 | 151:22 perpendicular 165:4 perplexed 157:9 persist 119:14 144:8 persistent 123:4 person 8:5 50:15 50:16 85:5 personally 24:18 76:11 perspective 198:15 202:16 204:22 210:9 224:6 pertinent 191:20 203:20 perturb 124:7 pestle 81:16 petrology 43:21 137:3 petty 225:5 pf 219:12 ph 7:5 20:4 22:2 29:16 33:12 34:2 41:12 42:17 43:2 45:7 47:21,22 50:4,9 51:7 53:3 55:21 58:17 61:8 65:5 69:12 75:2,6 81:11,21 82:5 83:20 85:13,17 94:17,22 95:13 97:11 98:2,6,11 98:16,17,20 99:10 99:14 107:2 109:6 109:7 125:15 126:19 129:16 130:4 132:8 133:13 135:5,10 137:15,15,18,20 141:20 145:17 146:9 148:21 149:5 150:7 152:7 |
|--|--|---|---|

| | | | |
|---|---|---|--|
| 155:3 156:14,14 156:14 157:21 158:5,10 161:2 167:13 172:21 176:8,13,21 178:22 180:7,7 181:4,4,6,8 185:18 191:10 200:10 204:3 205:1,22 206:9 209:6 210:6,7,16 214:5 218:20 219:17 225:6 phagocytosis 123:8 pharmaceutical 102:18 138:15 210:10 pharmaceuticals 44:3 55:15 pharmacology 155:4 pharmacopeia 4:8 4:10 44:2 phase 17:22 104:19 198:4 phases 197:13 202:3 214:22 phd 23:19 76:21 137:2 205:1,22 philip 133:13 philosophical 72:13 phone 69:7 96:4 photo 11:13 photograph 89:14 95:20 photographs 199:5 photomicrograph 84:15 physical 71:13 physically 131:5 | physics 200:2 physiologic 133:19 pick 95:16 picked 45:11 149:21 picture 57:17 pictures 49:20 68:2 82:20 88:4 97:10 100:7 101:7 142:7 piece 137:13 141:1 pieces 83:1 199:13 pile 106:3 piles 19:10 106:1 pine 213:2 pink 16:13 pipe 55:6 piping 34:7 pit 11:9 16:11,11 27:14,16 54:9,12 pitch 220:4 pitching 195:19 195:22 pits 11:6 16:9 19:13 pittsburgh 84:1 place 35:17 63:17 90:10 139:11 155:15 218:13 plan 28:1 plane 13:6 195:21 199:6 planned 5:12 plastic 22:6 plastics 12:4,14,16 103:14 plate 51:15 72:22 95:14 platelets 140:11 platy 13:6 26:16 126:21 127:2 150:7 | play 103:1 197:20 played 116:5 please 3:4,7,12 82:5 95:16,16 96:7 114:16 212:6 212:6,8 pleasure 137:10 plenty 22:8 96:21 pleura 117:12,14 118:8,13,13,15,15 118:15,19 143:21 158:6,10,12 pleural 118:19,20 119:4 130:17 179:12 pliable 118:20 plm 58:16,20 59:4 59:8,9 60:1,18 61:10 63:1 65:22 70:4 74:15,19,20 75:13,17 86:21 92:8 110:16,18 161:13 162:5,13 162:13 165:7 167:7,17,18 191:11 197:14,19 199:5,21 202:14 203:5 205:8 210:16 218:10 plm's 197:14 plot 147:15 160:12 161:9 plots 160:20,21 plotted 145:12 147:18 158:17 plugged 67:20 plum 26:9 plumb 27:11 plumbing 27:11 plus 164:17 po 219:12 pockets 26:14 podium 10:2 | point 23:1 27:21 33:2,7,8,10 35:3 62:14 73:17 78:19 96:22 98:2 104:20 105:1 108:10 109:3,4,20 110:6 110:14 116:8,10 117:6,17 120:10 123:5 125:17 134:8 148:6 156:3 161:8 188:13 212:19 223:3 pointed 122:7 197:19 221:22 pointer 32:21 38:7 40:9 pointing 129:5 points 36:7 73:19 73:20,20 74:1 108:11 115:15 160:2,16 187:6,7 188:22 189:8 209:5 pokela 152:15,20 153:20 160:8 161:8 179:18 polarized 58:21 59:5,11 60:9 163:14 165:6 194:2,9 199:6 200:2 policy 222:1,6,8 223:2 polished 32:16 pollution 105:20 polyfilamentous 37:10 pond 76:3 pongee 135:10 pool 191:3 pooley 149:5 158:5 pools 191:12 |
|---|---|---|--|

| | | | |
|--|---|--|--|
| <p>poor 62:1</p> <p>poorly 147:22</p> <p>popularized 81:11</p> <p>population 64:16 65:21 147:2,2 152:20 154:12 155:20 159:10 168:18 177:14 178:17 179:18 194:15</p> <p>populations 138:7 143:10 149:8,21 154:9 155:13 159:1 170:20 173:14 174:4 175:1,1,3,11 176:16 179:5,5,8 194:16</p> <p>portion 61:12</p> <p>portions 16:22 17:5</p> <p>portugal 88:3</p> <p>pose 5:20</p> <p>positives 190:1 192:11,13 193:22</p> <p>possesses 30:11</p> <p>possibility 167:13</p> <p>possible 31:3 187:9 189:13 211:5 214:17</p> <p>post 217:16</p> <p>postal 177:2</p> <p>posted 6:15 47:22 60:18 217:14 221:20</p> <p>postulated 149:14</p> <p>potencies 147:21</p> <p>potency 154:16</p> <p>potential 95:11 98:7 143:20 150:10 153:3 159:20 178:9</p> <p>potentially 207:4</p> | <p>powder 49:21 113:19 140:2 141:7 162:7 164:20</p> <p>powders 198:11</p> <p>power 66:4 80:12 85:2,16 99:5</p> <p>powered 96:5</p> <p>powerplay 27:5</p> <p>ppm 60:10,12</p> <p>practically 77:19</p> <p>practice 91:16</p> <p>practices 87:3</p> <p>practicing 114:4</p> <p>pre 53:5 62:2 104:10 124:17</p> <p>precedent 224:4</p> <p>precise 22:17 215:11</p> <p>precisely 200:17</p> <p>precursor 133:18</p> <p>predict 153:4 160:4,5,10,11</p> <p>predicted 162:3</p> <p>preexisting 15:7,8 18:8</p> <p>preferentially 144:12</p> <p>prep 149:19 185:17 186:2 189:2 191:2</p> <p>preparation 81:13</p> <p>preparations 125:2,11,12 126:4 136:13 205:2</p> <p>prepare 82:3</p> <p>prepared 83:20 125:6 133:2 180:22 227:3</p> <p>prepped 96:2</p> <p>prepping 185:19</p> <p>presence 4:14 17:7,10,14 92:17 153:21</p> | <p>present 6:18 61:16 114:18 153:18 163:18 164:9 166:6 167:8 184:4 192:14 193:8 197:14 202:22 224:12</p> <p>presentation 6:19 30:4 35:21 37:5 48:10 106:9 128:11 132:11 133:5,9 137:8 183:15</p> <p>presentations 4:16 5:6 8:2 27:5 217:12</p> <p>presented 150:7 214:4 217:20</p> <p>presenters 224:21</p> <p>presenting 93:11</p> <p>presently 44:2 220:2</p> <p>presents 171:16</p> <p>pressed 105:13</p> <p>pressure 15:18 16:18 17:4,5,12 25:14 38:2</p> <p>pressures 23:22 170:4</p> <p>pretty 40:20 48:4 52:19 56:3 59:20 60:10 67:11 70:17 76:19 79:19 88:15 89:15,16 91:12 93:8,10 114:7 139:17 148:22 152:10 168:1 174:6 176:14,19 198:8 206:11 207:17 219:11 221:7,12</p> <p>prevention 64:1</p> <p>previewing 127:14</p> | <p>previous 37:12 127:18 221:16</p> <p>prey 58:17</p> <p>pride 50:8 67:1</p> <p>primarily 19:6 117:19 143:22</p> <p>primary 12:16 35:22 70:4 74:16</p> <p>principally 13:20</p> <p>print 173:8</p> <p>prior 70:14 80:4 82:3 219:9</p> <p>prismatic 17:19 21:20 25:8 51:17 58:10,11 79:18 86:17</p> <p>probably 13:3,15 16:4,20 26:19 32:15,17 46:1 47:5,20 57:5 58:12 60:7,10 74:16 83:2 100:5 100:21 101:8 103:20 104:1 116:8 130:6 177:8 205:10 219:8</p> <p>probe 32:14</p> <p>problem 35:20 43:10 66:2 67:13 67:18 69:1 70:22 71:1 72:21 76:14 101:13 119:10 140:5,22 141:13 141:13 161:15 162:4 163:16 164:15 165:6,11 166:2 169:21 177:17 222:7</p> <p>problematic 111:10</p> <p>problems 82:10 209:20</p> <p>procedure 81:13 82:3 87:7 88:19</p> |
|--|---|--|--|

| | | | |
|--|--|---|---|
| 89:20 procedures 103:11 proceed 126:9 proceeding 226:3 proceedings 226:4 226:6 process 83:17 97:3 106:18 116:21 120:14 178:5 189:16 218:22 223:13 processed 12:22 processes 15:16 218:12 proclaim 187:17 produce 12:9 53:18 99:18 124:8 157:22 produced 12:2,11 88:14 152:1 214:5 producer 11:14 54:4 104:13 211:5 producing 11:4 product 10:7 11:8 63:7 64:18 71:2 102:6 103:6 184:17,18 190:6 191:1 213:2 222:16,17 production 11:3 11:16,19,22 12:15 31:19 99:2 123:13 152:17 products 4:14 49:22 58:9,14 65:16 78:4 184:19 188:17 191:1 224:13 professor 43:19 43:20 114:21 136:21 proficiency 79:7 91:17 210:21 | 211:9,11 profile 150:6,19 152:3 profound 56:14 72:13 76:13 program 29:8 211:9,15 programs 211:7 progress 47:4 71:12 progression 94:6 progressive 17:3 17:15 projected 107:7 projects 64:6 77:4 183:16 proliferation 126:14 134:7 136:1 prominent 130:3 promise 115:10 pronouncements 97:19 proof 96:18 properly 35:19 145:1 properties 30:12 30:17 41:21 42:2 42:16 71:13 78:18 83:15 102:21,22 103:16 115:20 116:3,20 120:13 120:19 131:14 133:11 203:20 207:9 property 18:22 56:15 85:13 117:11 proportion 128:6 143:14 158:18 proportions 153:22 propose 108:16 219:11 | proposed 185:11 187:5 proposing 219:2 proposition 166:20 pros 202:4 prospected 18:19 protect 31:3 72:5 187:9 protected 187:20 protecting 140:19 protein 121:9 126:1,13 proteins 126:10 protocol 80:3 189:22 190:5,11 protocols 61:22 prototype 121:3 protruded 23:3 prove 69:17 104:5 195:8 222:3 proverbial 35:13 provide 10:7 11:2 15:15 26:11 131:10 166:18 218:15 222:8 provided 145:17 201:5 217:22 provider 211:10 211:10 providing 4:3 20:6 prudent 220:19 prunes 53:19,19 53:22 pt 211:5,6 public 49:15 91:16 105:13 145:12 187:9,20 190:7 219:1,4 226:1,18 publication 38:20 40:1 42:18 85:3 95:11 152:21 219:9 | publications 77:4 106:22 129:11 205:22 publicly 219:18 publish 218:16,19 published 11:21 27:4 47:7 69:13 105:11 106:21 149:4 152:7 155:2 155:11 156:21,21 158:10 174:13 196:12 puddle 72:9 pull 72:20 187:15 pulling 55:9 pullman 215:6 punish 49:19 purchase 92:21 pure 24:15 67:2 94:12 134:20 purifying 96:5 purity 20:19 24:13 purpose 3:21 4:20 139:8 purposes 78:10 79:12 175:15 push 63:2,5 199:1 pushed 62:5 63:14 pushing 65:1 198:21 put 21:6 29:16,18 29:20 30:4,20 43:13 46:15 49:20 50:8 51:3,4 54:22 55:17,17 64:18,22 69:20 77:21 81:16 82:5 141:7 145:22 159:7 160:2 174:1 182:6 186:11,14 202:11 210:15 211:13,20 putting 146:16 182:10,12 183:14 205:8 |
|--|--|---|---|

| | | | |
|---------------------------|----------------------------|--------------------------|--------------------------|
| puzzle 69:21 | 169:2,3 181:22 | 169:13,16,16 | 48:1,13 50:18 |
| pyro 200:9 | 189:11 191:22 | 174:7,9,12,22,22 | 51:8 52:9,19 |
| pyroxene 23:10 | 196:8 201:11 | 175:2,8,14 192:10 | 53:17 54:14,21 |
| q | 209:1,3,5 215:16 | ratios 40:9 174:2 | 55:19 57:2,10,21 |
| q&a 28:22 | 215:18 216:6,7 | 174:3,20 175:10 | 58:2,20 59:17,19 |
| q&as 6:14 | 217:6 | rats 176:13 184:1 | 60:4,9 62:3,11 |
| qualification 92:1 | quick 11:2 62:6 | raw 24:20 102:6 | 64:12 65:20 67:7 |
| qualities 88:21 | 63:19 140:8 | 102:11 | 68:12 70:6 72:4 |
| quality 13:12 37:7 | 212:17 | ray 61:4,21 62:3 | 72:10,22 74:5 |
| 60:6 79:13 82:9 | quickly 63:1 139:1 | 76:12 95:8 181:4 | 75:16 78:22 80:21 |
| 103:17 104:3 | 202:15 | 183:15 | 81:19 82:2 87:7 |
| 161:7 191:15 | quiet 3:11 | rdag 206:1 | 88:6 89:7 94:18 |
| quantification | quite 18:6 19:9 | re's 58:6 | 94:19 95:5 97:9 |
| 60:5 110:17 111:9 | 31:2 127:10 151:5 | reach 9:7 117:22 | 98:1 103:21 |
| 111:12 202:2,19 | quote 59:6 | 119:20 172:15,16 | 108:21,21 109:1,1 |
| quantified 74:2 | quotes 93:15 | react 15:15 | 110:17 116:8 |
| quantify 108:7 | 159:8 | reaction 20:7,7,9 | 117:7 119:7 |
| quantitate 73:20 | r | 20:16 26:2 | 120:16,18 125:8 |
| quantitation 74:5 | r 3:1 159:22 | reactions 17:3 | 130:15 131:13 |
| 202:7,16,18 | r.j. 56:7 | 21:2 23:20 120:13 | 132:2,22 133:5,8 |
| quantitative 73:11 | radiation 61:21 | read 34:18 42:13 | 134:8 135:18 |
| 73:12,15,16,17 | rain 106:1 | 67:21 116:18 | 138:15,16,18,20 |
| quarries 91:10 | raise 62:11 | 156:17 218:19 | 160:13 163:18 |
| 152:6 | raised 100:2 | 221:21 | 167:2,21 169:19 |
| quarter 26:17 | 192:21 | readily 151:5 | 169:19 172:13 |
| quarts 21:13 | raisins 53:18,22 | 171:8 185:1 | 179:2 195:1 202:6 |
| 26:13 155:18 | range 28:8 40:16 | reading 48:1 | 209:20 210:14 |
| quartz 20:18 | 79:19 132:19 | ready 44:8 114:7 | 211:22,22 216:2 |
| question 7:4,5,19 | 144:1 145:19,22 | 183:5 | 216:13,18 221:20 |
| 30:2 31:9 43:12 | 146:18,20 175:2 | real 43:11 45:21 | 222:7 223:7 224:2 |
| 70:15 73:10 102:9 | 175:14,16 | 52:13 53:14 65:7 | 224:20 |
| 102:10 132:18 | ranges 107:21 | 67:18 91:3 108:12 | realm 19:3 71:5 |
| 138:1,3,10 142:5 | ranging 192:4 | 108:12 109:9 | reason 67:4 87:2 |
| 161:12 170:12 | ranks 32:8 | 110:20 156:2 | 114:2 138:8 145:9 |
| 172:6 175:19 | rapid 203:3,5 | 198:15 208:1,17 | 159:20 165:16 |
| 177:16 178:3,6,21 | rapidly 202:15 | 208:17 | 175:21 193:15 |
| 179:19 190:9 | rare 12:10 13:13 | realities 66:17 | reasonable 20:10 |
| 191:7 194:21 | 88:15 132:6 | realize 118:7,17 | 91:12 |
| 218:1,5 219:21 | 142:22 | 129:8 | reasonably 189:18 |
| questions 5:20 | rat 176:15 | realized 96:10 | reasons 49:15 |
| 6:14,21 9:16 31:1 | rate 205:11 | really 16:8 24:14 | 105:15 145:7 |
| 56:14 70:15 73:8 | rates 144:1 | 29:18 30:2 33:12 | recall 180:21 |
| 78:13 96:22,22 | ratio 40:3,5 42:1,2 | 34:9,19 42:2,11 | 215:2 |
| 114:12 132:14,16 | 65:18 67:13 | 46:9,13,16,17 | |

| | | | |
|---------------------------|---------------------------|---------------------------|---------------------------|
| receive 80:6 | 149:18 185:2 | regulator 56:16 | remarks 3:11 |
| received 114:12 | 210:2 212:8,8,12 | regulators 4:4 | 182:3 215:19,20 |
| 115:3 125:13,16 | 212:21 213:7 | 45:13 57:6 216:1 | 217:2 |
| 185:22 | 216:22 | regulatory 36:12 | remediation 64:6 |
| receiving 84:5 | referenced 42:7 | 36:14 47:16 48:7 | remember 40:7 |
| reception 67:2 | references 42:17 | 51:22 55:22 60:14 | 58:5 64:4 70:20 |
| receptors 121:8 | referred 136:11 | 184:9 220:13 | 71:11,18 78:19 |
| 126:12 | referring 154:17 | 222:21 223:13 | 96:18 100:18 |
| reciprocal 68:22 | refinishing 223:22 | 224:10 | 146:4 148:11 |
| reclaimed 27:16 | reflect 156:9,11 | reinvent 189:7 | 163:20 168:2 |
| recognition 115:4 | reflected 156:8 | rejecting 63:6 | 206:6 |
| recognize 53:7 | reflects 91:2 | relatable 86:21 | reminded 185:17 |
| 137:14 | refraction 140:6,8 | related 31:8 35:4 | reminder 218:18 |
| recognized 115:21 | 165:1,4,19 | 77:4 125:22 | removal 64:8 |
| 117:1 | refractive 197:16 | 130:15 143:9 | remove 202:16 |
| recognizes 123:12 | 197:20 | 150:11 155:20 | removed 119:21 |
| recollection 206:2 | refractors 12:4 | 173:12 179:3 | 144:7,13 |
| recommend | regal 27:1 | 191:9 226:8 227:6 | removing 189:3 |
| 196:10 | regard 122:20 | relative 97:20 | 203:16 205:8 |
| recommendation | regarding 77:18 | 116:17 142:16 | repeat 102:9 |
| 203:4 | 186:2 | 143:14 226:10 | repeated 5:11 |
| recommendations | regardless 128:18 | relatively 10:14 | repeatedly 186:22 |
| 168:19 | 188:7 213:15 | 24:15 26:2 54:22 | replaced 18:2 27:8 |
| reconvene 6:9 | region 16:17 | 75:13 190:6 | 27:13 |
| record 5:21 6:9 | 18:12,19 19:11,20 | relax 17:6 | replacement 15:5 |
| 85:7 145:12 | 61:13 | release 22:7 123:4 | 17:21 18:8 21:5 |
| 168:16 226:6 | regional 15:17,18 | 124:8 161:19 | 23:7 25:21 26:21 |
| recorded 145:21 | 16:4,7,15 53:7,13 | releasing 106:15 | replacing 15:7,11 |
| 186:16 226:4 | registration 6:22 | relevance 62:5 | 16:22 24:4,11 |
| recording 6:2 7:22 | regression 159:7 | relevant 69:18 | 25:1 26:12 |
| red 16:10 27:8 | regularly 146:2 | 87:1 196:14 | report 6:6 19:18 |
| 64:21 | regulatable 52:10 | reliable 167:9 | 82:1 107:13,15,16 |
| redone 102:7 | regulate 48:18 | 203:3 | 107:21 181:13,14 |
| reduced 226:5 | 224:14 | reliably 203:19 | 181:19,20 199:2 |
| reepa 109:6 | regulated 13:17 | religious 49:13 | reported 1:18 |
| refer 82:13 129:9 | 14:19 31:4 43:5,6 | remain 70:4 | 14:4 80:11 92:17 |
| 154:18 | 48:14 49:9 58:19 | remaining 17:10 | 108:2 122:14 |
| reference 46:15 | regulating 31:4 | 84:3 | 142:2 144:3 |
| 47:22 65:3,4 79:7 | 187:10,21 | remains 25:8 | 152:19,22 198:13 |
| 80:13,17 82:7,9 | regulation 35:11 | 36:10 | 199:1,13 |
| 83:8,11,13,19 | 73:7 | remark 215:21 | reporting 1:20 |
| 84:2,19,22 92:21 | regulations 32:9 | remarkably | 81:4 |
| 94:20 122:4 | 48:15 | 146:11 | repository 83:12 |
| 132:22 135:1 | | | |

| | | | |
|---|---|--|--|
| <p>represent 22:6 54:1 175:4,4,5</p> <p>representations 152:10</p> <p>representative 78:14</p> <p>represented 184:2 213:3</p> <p>representing 26:8 216:1</p> <p>represents 26:19</p> <p>reproduce 101:15</p> <p>reproducibility 168:12</p> <p>reproducible 80:20</p> <p>request 211:6</p> <p>requests 84:6</p> <p>require 21:10 28:13 199:12</p> <p>required 68:10</p> <p>requirements 78:10</p> <p>research 9:22 29:1 29:8 35:10 43:20 84:1 104:11 115:1 115:7,17 120:17 129:11 137:6 214:2 215:5</p> <p>researchers 36:22 214:7</p> <p>reserving 93:1</p> <p>residents 142:2</p> <p>residual 64:10</p> <p>residues 202:13</p> <p>resistant 127:8</p> <p>resolution 206:4 206:13</p> <p>resolve 79:3 203:11</p> <p>resources 96:15</p> <p>respect 78:3 83:15 179:14 223:5,9</p> | <p>respirable 43:4 49:7 88:8,8,12 99:18 106:15</p> <p>respiration 192:16,17</p> <p>respirators 96:5</p> <p>response 126:11 129:6 131:19,21 132:5 135:7 144:10 173:22</p> <p>responses 125:19 132:7</p> <p>responsible 30:18</p> <p>responsive 125:22</p> <p>respro 41:12,15</p> <p>rest 10:8 164:19</p> <p>restrooms 6:22</p> <p>result 81:14 95:7 113:2,2 121:16 122:11 208:11</p> <p>results 6:19 74:22 89:7 90:10 94:7 97:13 121:7 130:22 199:4 212:9,10</p> <p>retained 144:12</p> <p>retention 139:13</p> <p>retired 29:14,21 43:19 77:3,20</p> <p>retirement 29:5 86:4</p> <p>review 6:5 29:8</p> <p>revised 216:12</p> <p>revising 216:11 219:7</p> <p>revision 219:19</p> <p>revolved 201:11 201:14</p> <p>revolving 202:2</p> <p>rhodesia 99:7,8</p> <p>rhodesian 135:3</p> <p>rich 15:8,8,12 16:19 20:6 21:2 23:8,9,10,10,12</p> | <p>23:13 24:4,5,22 25:7,18,22 26:10 26:12 27:12 66:15</p> <p>richterite 22:22 32:10 39:5 157:6 159:5</p> <p>richterites 33:22</p> <p>rick 23:17 25:3</p> <p>rick's 98:2</p> <p>rid 59:13 190:3</p> <p>ridiculous 88:18</p> <p>riebeckite 87:13 88:4 89:4,5,14 125:3,11 126:4,6 150:2</p> <p>right 3:16 5:2 8:12 9:15 32:22 33:2 34:15 38:4,10 43:1 45:4 49:18 56:9,10,12 57:2 59:2 60:2 61:7 62:14,19,21 64:3 68:6,18 69:14 71:19 75:1 77:21 78:21 89:6 93:18 98:22,22 99:17 100:21 102:5 104:6 108:15 110:13 111:13 112:4,14 113:5 114:6,14 123:16 134:21 156:10,17 158:9,13 159:7 160:19 169:15 170:21 171:2,9 172:4,17,20 178:14 186:18 190:13 192:11 195:15 204:12 208:20,20 212:7 215:15 216:22 220:7 221:9,15</p> <p>rightly 197:18</p> | <p>rigidity 118:10</p> <p>ring 125:14</p> <p>ringing 69:7</p> <p>rise 121:9 128:22</p> <p>rising 26:6</p> <p>risk 94:7 112:13 144:16 189:17,20 193:8 195:2 223:21</p> <p>river 75:22</p> <p>rivets 68:3</p> <p>rj 69:12</p> <p>rmeso 154:18 155:2 156:18 157:14 160:22</p> <p>road 66:21 100:17</p> <p>roadmap 77:6 83:11</p> <p>robin 89:4 93:9,11 181:4,18 183:15 225:1</p> <p>robins 94:3</p> <p>robust 127:4 200:4,14</p> <p>rochester 137:20</p> <p>rock 14:13,13 15:8,10,11,12,13 15:15,20 16:1 17:17 20:6 21:2,3 21:5,11,12,14 23:3,10,10,10,11 23:13 24:4,9 25:1 25:6,6,7,11,12,20 39:14,18 53:14 72:11 80:7 94:11 94:12 111:16 141:2 142:19 143:12 155:17</p> <p>rocks 16:19 23:8,8 26:11 39:19 52:22 53:18 66:12</p> <p>rockwood 88:2</p> <p>rod 118:2</p> |
|---|---|--|--|

| | | | |
|---|--|--|--|
| roe 172:21 roggli 116:12 role 103:2 116:5 149:6 roll 57:9 rolling 217:7 rome 109:18 roofing 12:4,17 room 3:7 8:14 29:19 46:2 55:10 115:9 116:5 122:3 141:10 180:20 181:12 183:1 184:7,8 187:2 218:15 ross 204:3 rossiter 98:16 rotary 101:4 roughly 214:18 round 89:4 91:9 92:3,6,15 93:9,10 94:3 111:16 route 117:20 routes 128:18 routinely 207:14 row 200:7,11 218:9 royal 77:1 rti 85:21,22 88:19 88:20 rub 57:14 rubbed 161:18 rubber 12:4,17 rule 73:7 210:8 ruled 105:15 rules 49:9 59:8 62:2 64:9 ruling 221:11 run 214:20 runoff 106:1 rustein 69:9 rutstein 2:5 43:19 44:6,12 45:2,5 50:7,12 53:11 | 68:19 73:12,15 74:10,12,19 75:1 75:19 105:13 106:12 200:6 220:9 221:6,10,16 221:20 s s 2:1 3:1 146:12 sac 118:12 sack 154:22 sacks 159:19 sacs 118:1,18 119:20 sad 74:21 200:14 safe 189:18 190:7 195:5 safety 84:19 85:1 85:2 91:19 92:13 sale 64:18 salt 85:9 sample 22:6,7 24:21 32:16,17 39:6 52:16 55:3 55:14,15,19 58:7 61:9,17 75:4,16 78:14,15 79:21 92:4,15 95:20 106:15 111:3 113:21 135:1 141:20 146:15 164:10 167:17 185:19 186:14 197:10 210:2,3 211:6,11 212:13 samples 24:20 54:17 57:1 58:16 78:7,15 86:19 87:20 92:2,21 95:22 96:2 98:19 111:6,9,16,17,19 120:22 122:4 127:16,17 128:9 128:21 129:17 135:4,16,17,18 | 147:9 148:7,13,17 160:6 177:2 209:14 210:22 211:18 sampling 80:3 113:21 116:6 193:16 210:15 sanchez 103:9 107:19 108:5,18 108:21 110:3,5,9 110:14 111:5 112:4,10,14 113:1 113:6,15 133:10 134:17 181:8 195:15 204:4,8,10 204:17,21 205:21 206:20 207:2,21 208:6,9,16 213:22 214:20 sanford 23:17 satisfaction 179:22 saves 89:1 saw 64:14 66:6,9 67:18 92:7 105:17 136:16 163:13 172:3 saying 34:19 37:22 39:1 44:9 49:11 58:7 59:14 66:22 68:9,10 70:2 144:19 208:14 says 30:16 36:8 37:8 38:2 50:15 50:16 56:10 57:2 58:17 77:22 scale 13:4 15:17 15:18 16:8 21:14 59:18 62:13 scales 13:22 28:12 146:16 scan 21:16 61:11 61:11,18 62:18 | 140:9 scanning 167:6 scary 46:22 scatter 205:4 scattered 22:15 scavengers 119:3 schedule 102:4 schematic 19:17 schematically 20:22 scheme 91:20 92:6 92:12,14 122:5 schemes 92:20 93:2 210:22 school 55:5 76:22 schools 71:21 science 23:18 29:7 114:4 130:2 200:2 sciences 76:21 scientific 115:4 122:8 134:11 222:2 scientist 29:1 scientists 67:2 scope 58:8 68:14 113:12,16 score 60:21 62:12 63:12,21 116:17 screen 8:20 183:7 screening 189:16 189:22 190:5,11 190:12,21 191:12 203:4 scrolled 206:10 se 209:13 seagreg 137:15 search 50:4 seats 3:7 114:15 second 46:18 151:21 182:8 216:16 secondary 152:12 212:18 |
|---|--|--|--|

| | | | |
|---|--|--|--|
| <p>secondly 216:12 secret 192:3 section 151:15 security 72:7 sedentary 26:10 sediment 20:12,13 105:22 sediments 20:11 see 4:7,20 5:10 8:20 9:1 12:3 13:7 18:14 21:16 29:15 29:19 32:20 37:13 38:3,7 40:4,8 41:7 50:21 52:11 54:13 55:3,19 57:8 58:8 58:9,10 59:2 60:3 62:16,21 63:2,11 72:1 74:1 75:6,11 75:18 76:13 79:17 80:4 81:4,8 82:21 84:21 85:3 89:15 90:9 94:3 106:5 110:10,21 111:1 111:10,12 116:9 117:16 118:1,6 119:7,8,11,22 120:8 123:15 124:2,13,13,14,15 135:22 138:11 140:11 141:3 142:8 145:13,18 145:18 146:9 148:4,5,21 149:2 150:14,18 151:11 151:19 152:11,11 152:12 153:5,21 153:21 158:14 160:9 163:6,16 164:14 165:10 169:7 170:9 171:12 173:18,22 175:1 177:4 178:22 180:18 186:5 190:9 199:7</p> | <p>199:10 205:7 209:22 218:8 seeing 63:17 67:10 75:3,10 76:14 97:13 110:12 169:6 seek 71:7 seen 56:6 123:22 124:8,12 127:2 139:13 144:3 153:8 176:4 177:14 205:12 208:16 212:10 sees 55:15 130:10 130:10,11 segregated 106:13 selective 179:8 self 134:6 136:1 selling 86:2 sem 22:4 59:15 63:8,8,10,13,17 70:8 73:22 82:20 87:1 95:6 165:14 165:19 168:15 185:12 186:9 205:8,15 212:18 semblant 210:6 senior 53:20 sense 88:9 164:13 sensed 105:8 sensitive 110:19 127:10 165:16 190:1 202:19 sensitivity 110:20 167:20 179:13 214:18 sent 70:14 89:11 89:22 separate 70:7 99:15,16 111:12 separated 170:14 separation 91:7 194:8 202:11</p> | <p>separations 172:5 sepio 200:9 sepiolite 51:6,8 53:4 series 14:9 117:20 seriously 106:16 serpentine 10:15 10:16 14:15 23:12 23:12 24:5 26:1 28:4 37:8 79:16 164:11 serpentinite 23:11 served 29:6 130:2 service 29:5 115:1 session 1:4 5:3,4,9 5:13,14,16 6:4,10 6:10 115:15 181:3 181:5,7,13,17 183:6,6 192:3 204:11 209:1 212:20 213:17 215:17 216:17 217:20 221:22 224:22 sessions 4:17 5:6,9 5:10,12 6:9 7:3,3 114:10 180:20,22 181:1,16,21 182:8 187:5 191:9 195:20 196:22 216:17 217:13,18 set 44:8,13 74:2 90:4 96:2 132:22 137:8 139:9 145:22 194:4,12 223:19 set's 145:11 sets 139:5 150:16 setting 97:8 180:19 224:4 settings 10:21 settle 89:8 seven 128:21</p> | <p>shake 59:12 shakes 64:14 shallow 20:13 shape 17:19 30:13 48:16 51:16,19,20 52:6 62:1,4 63:11 97:19,20 118:3 146:4 150:3 179:14 216:5 shapes 21:17 51:17 59:3 70:13 179:3 share 4:12 181:18 shared 191:9 217:9 sharp 21:4 shawn 191:10 shedd 147:6 149:22 sheds 39:16 sheehan 1:5 2:2 3:2,10 7:4,10,15 7:19 8:4,7,11,16 9:1,11,15,20 28:20 43:18 44:11 76:18 96:21 102:2 105:12 114:6,14 132:14 136:20 168:22 169:2 176:21 178:20 180:16 181:11 182:7,12,15,19 208:22 210:18 212:15 213:13 215:15 220:8,20 221:14,18 222:10 222:12 224:16 shield 180:12 shipped 22:13 103:17 shipping 86:1 short 46:12 48:18 51:19 70:18 116:2 116:4 119:19</p> |
|---|--|--|--|

| | | | |
|---|---|--|---|
| 124:9 135:19 136:2 144:6,10,13 145:2,6,8 shortening 16:16 shorter 171:8 shortly 6:16 86:9 155:5 shoulder 62:20 150:15 shoulders 46:20 show 14:5,12 16:2 21:7 28:2,13 37:12 39:4 66:22 89:18 91:3 116:13 129:5,19 140:9 146:15 148:3,5 151:19 152:10 156:2,2,4,16 158:4 160:6,15 176:9 177:4 180:8 183:20 196:5 218:8 showed 20:22 36:19 41:14 60:17 142:15 146:8 147:4 171:18 173:21 showing 37:5,18 38:21 40:2,19 68:1 171:15,21 199:9 shown 16:10,12 65:19 80:6 121:2 123:10 132:6 150:22 157:3 158:7 170:21 180:6 shows 18:4 37:11 118:9 141:18 147:10 165:5 174:13 176:4,18 178:16 shut 69:9 75:21 | sib 70:8 sic 30:10 side 21:15 25:10 38:11,13 48:2 51:3 63:14 70:2 91:15 146:16,16 190:22 191:1 199:17 223:11 sideways 68:21 siding 31:16 sieving 60:6 signal 206:7 signature 226:16 227:12 signatures 132:9 signed 180:21 181:1 significant 36:18 81:5 128:2 129:19 significantly 194:7 signified 127:19 signify 64:10 signing 199:11 silence 121:21 silica 14:18,21 15:14 16:18,19,21 17:8 20:5,6 25:7 25:11,17 26:3,3 26:10,11 27:12 101:20 silicate 13:2 siliceous 17:14 silk 21:1 similar 39:5 40:13 67:15 91:4 153:7 159:22 166:6,10 206:18 211:10 220:3 simple 26:2 54:22 87:11 159:6 165:7 simplicity 70:5 simply 108:8 166:11 193:22 | 223:22 simulate 126:12 single 37:8 40:14 53:12 65:11 69:16 95:6,7,7,19 117:11 148:17 156:1 176:4 206:12 singular 97:19 169:6 sir 74:6 189:12 site 6:3 58:16 119:14 203:6 sites 120:12 sitting 20:13 55:6 158:8 172:4 situation 210:13 situations 210:11 six 8:10 29:14 48:7,14 92:9 size 10:18 48:17 66:4 69:16 88:8,8 109:22,22 136:8 136:11,12,13,13 138:4 142:4 162:12 173:11 175:9 179:14 216:5 sized 88:12 135:21 163:19 173:22 sizes 150:4 179:3 sketch 55:5 skills 226:7 skin 102:22 192:20 skinner 126:19 skip 138:22 slab 41:7 sleep 48:8 slide 27:3 36:19 43:2 90:7,8 127:19 130:1 138:21 141:18 147:6 186:5 | slides 73:19 89:11 90:4 106:9 117:17 127:15 167:7 217:20 sliding 13:10 slightly 51:5 slippery 13:11 slow 62:18 slowly 176:15 slugged 56:8 sluicing 106:3 small 12:21 75:10 113:8 146:21 172:14 smaller 16:9 55:18 71:10 117:21 174:20 smallest 106:2 smart 46:13,21 sme 53:5 smith 22:9 smithsonian 214:6 snm 39:17 snow 75:8 106:1 social 72:7 society 77:1 115:5 socioeconomic 223:13 sodic 22:15,18,21 sodium 13:15 20:15 soft 13:5 24:15 softest 21:11 163:21 soil 20:4,22 soils 106:19 sold 12:2 85:16 215:1 soldier 135:11 solicit 219:4 solid 34:4 solubility 139:15 solution 15:15 34:5,5 105:20 |
|---|---|--|---|

| | | | |
|---|--|---|---|
| <p>200:19,22 201:19 solve 72:21 solvent 197:6 somatic 120:8 somebody 8:19 45:21 49:19 73:1 86:2 104:13 125:14 149:17 187:15 somewhat 135:14 138:5 sonicate 81:17 soon 42:5 52:19 88:10 sophisticate 204:22 sophisticated 57:3 59:15 199:21 sorry 14:15 34:14 50:10 74:8,11 148:18 180:18 198:20 205:22 208:6 225:5 sort 13:12 77:11 132:2 137:13 152:11 154:15 164:16 183:12 sorts 147:3 192:5 soul 57:21 sound 189:2 sounded 87:11 sounds 83:17 soup 56:18 216:5 source 17:17 36:10 51:15 sourced 25:11,12 sources 12:20 40:16 125:16 133:6 south 27:9 54:16 84:5,10 149:14 155:13 157:13 southern 18:12 85:9</p> | <p>southwest 11:11 27:21 southwestern 11:10 26:18 space 68:22 118:19 195:16 207:12 208:3 spaces 200:11 spacing 166:13 200:7 spaghetti 142:10 spain 129:18 spanning 79:20 spatial 206:4,13 spatially 10:14 14:11 speak 10:5 71:16 138:2 201:2 speaker 6:18 9:21 70:14 114:18 speakers 77:10 114:12 216:17 217:12,17 225:7 speaking 77:22 153:18 198:22 220:10 spec 185:15 special 41:21 42:18 132:5 183:16 209:22 224:19 225:5 specialize 184:1 specializing 29:2 specially 101:20 species 64:3 125:9 126:6 129:4,7 198:7 specific 34:21 35:2 35:17 94:7 100:20 103:9,19 148:14 155:2 166:15 183:10 198:7 200:20</p> | <p>specifics 215:9 specified 83:15 183:12 spectrometer 22:3 spectroscopy 22:17 101:11 spectrum 12:18 52:20 61:12 67:10 69:19 speculate 97:16 speed 61:18 spelled 200:16,17 spend 50:4 167:22 spending 55:8 spent 39:19 46:1 133:13 spike 111:16,16 112:1 spiked 213:11 spoke 198:19 sponsors 70:16 spot 19:10 32:18 33:11 177:3 spread 59:8 sprint 47:12 sputtered 204:20 squamous 124:16 square 160:12 squares 16:10 160:1 srd 61:11 st 49:16 stable 83:14 151:15 staff 225:4 stages 121:11 stain 199:8 stair 38:4,8 stakeholders 3:18 218:7 219:6,9,18 stall 77:11 stamp 70:10 stana 55:21</p> | <p>stand 94:10,12 140:12 146:2 standard 3:22 4:10 28:14 48:17 63:15 64:4 74:15 82:2,5 87:5 91:9 97:3 160:16 192:22 216:22 218:12,17 219:8 219:10 223:21 standardized 216:18 standards 62:1 74:3 93:3 94:2 131:20 185:3,3 212:20,21,21 213:1,5 218:16,22 219:2,3 222:21 223:19 standpoints 134:9 stands 62:19 stanton 42:17 128:16,20 158:1 stars 60:22 start 17:6 51:13 54:14 56:4 66:19 70:8 79:16,17 153:15 161:20 178:4 211:14 217:7 started 13:1 18:13 45:12 63:9 72:17 77:7 101:17 135:1 166:14 183:20 starting 16:10 17:16 75:20 76:9 81:19 stat 212:11 state 11:15 44:4 123:10 126:17 215:5 226:19 statement 43:14 188:5</p> |
|---|--|---|---|

| | | | |
|---|--|---|---|
| <p>states 4:8,9 11:3,5 16:2 26:20 27:19 61:13 142:18</p> <p>statistical 108:12</p> <p>status 19:2 213:4</p> <p>stay 66:14</p> <p>stays 174:6</p> <p>stem 221:7,14,16</p> <p>stems 119:21</p> <p>step 38:8 66:1 72:9 95:14 124:17 218:3,4</p> <p>steps 38:4,11 182:4 215:19 217:5,8,19 218:6 220:21 224:17</p> <p>stepwise 17:15</p> <p>stereo 58:4,8</p> <p>sterling 81:21</p> <p>steve 218:10,20</p> <p>stick 82:13 181:16 212:18</p> <p>stimulate 130:18</p> <p>stimuli 46:16 47:7 196:11</p> <p>stm 150:12</p> <p>stockpiles 22:12</p> <p>stole 43:2</p> <p>stomata 119:13</p> <p>stone 11:11,14 16:5 26:2 27:2,6,7 27:17</p> <p>stood 46:20</p> <p>stop 69:9 180:12</p> <p>stopped 52:7 84:5 152:17</p> <p>story 64:12</p> <p>stove 34:7 186:14</p> <p>straight 7:9 15:6 19:15 159:22 190:17 214:21</p> <p>straightforward 207:17</p> | <p>strategy 105:16</p> <p>street 1:21</p> <p>strength 30:13 41:22</p> <p>strengths 130:12</p> <p>stress 116:10</p> <p>striking 132:7</p> <p>strong 38:1 169:20</p> <p>struck 97:17</p> <p>structural 61:4 63:13 137:3 151:4</p> <p>structure 33:19 35:5 47:19 57:4 58:22 61:6 64:2 69:5 156:10 166:10 197:7 201:6 206:10 207:8 216:4</p> <p>structures 41:7 118:14 130:12 169:7 201:4 207:19</p> <p>struggle 74:17</p> <p>stuck 82:14 201:20</p> <p>student 55:6,7 185:14</p> <p>students 45:20 51:7 54:7 56:22</p> <p>studied 81:19 117:3 118:22 122:20 144:9</p> <p>studies 87:9 94:4 98:5 120:21 122:14 123:21 124:5 125:5,18 126:17 128:15,15 128:19,21 129:1,3 129:9,12,14 131:1 131:17 132:5,5 135:7 136:2,5 150:22 154:13 155:21 158:5</p> | <p>211:3</p> <p>study 23:19 87:8 100:13,14,16,17 100:18 105:10 127:11,16 128:16 151:9 176:12 213:18,20 214:15</p> <p>studying 18:13</p> <p>stuff 21:22 34:14 34:15,16 39:21 40:20,22 43:6 46:11 49:5,22 54:4,8,9,11,15,17 54:22 55:2 61:3 71:20,21 85:18 86:2,7 95:15,16 97:22 98:3 105:18 135:9 168:8 187:19 213:10</p> <p>stump 46:7</p> <p>stumps 144:11</p> <p>stupid 150:13</p> <p>stutter 77:11</p> <p>subject 184:6 213:21</p> <p>subjective 89:21 90:17 108:9</p> <p>submit 189:9</p> <p>submitted 95:10</p> <p>subsampling 210:14</p> <p>success 205:11,13 205:19</p> <p>sudden 75:18</p> <p>suddenly 110:1</p> <p>suffice 216:20</p> <p>sufficiently 83:14</p> <p>suggested 20:10 105:21 157:21</p> <p>suggestions 131:11 224:17</p> <p>suggests 178:8</p> <p>suitable 20:19</p> | <p>suite 1:21 185:7 190:19 215:12</p> <p>sum 48:9</p> <p>summaries 217:13</p> <p>summarize 129:11 153:9 183:6 196:7</p> <p>summarized 129:15 143:7</p> <p>summarizes 53:5</p> <p>summary 6:6,11 6:16,18 23:19 34:20 43:14 47:21 48:4 69:15 116:11 217:11,18</p> <p>summation 189:9</p> <p>summers 29:22</p> <p>sums 43:3 66:18</p> <p>supplied 125:3</p> <p>supply 75:21 126:20 213:9</p> <p>supplying 122:3</p> <p>support 120:16</p> <p>supporting 3:18</p> <p>supposed 60:20 107:20 199:14 201:7</p> <p>suppressive 121:21</p> <p>sure 7:10 22:12 44:15 45:3 67:11 71:10 72:3 99:4 100:6 128:9,17 140:4,19 141:19 152:2 153:2 156:3 158:13 160:8,18 161:7,19 163:13 176:14,19 178:1 188:10 189:2 196:20 197:3 210:20 214:1 217:19 218:16 221:7</p> <p>surely 26:9 27:11</p> |
|---|--|---|---|

| | | | |
|--|---|--|---|
| <p>surface 38:4 39:11 39:21 54:16,20 130:13 133:12 134:9,14,16 136:6 136:17 158:9 179:21 180:1</p> <p>surfaces 204:15 206:15</p> <p>surprised 102:20</p> <p>surrogate 113:20 201:12</p> <p>surrogates 113:18</p> <p>survey 10:1 29:4 125:15</p> <p>survival 121:10 126:10,14 127:20 128:1,3</p> <p>survivor 126:10</p> <p>suspect 102:12 191:17</p> <p>swear 164:21</p> <p>switched 67:5</p> <p>symbols 52:11</p> <p>symposium 1:2 3:15,16,17,21 4:15 6:13</p> <p>synopsis 189:12</p> <p>system 17:5,6,9,16 20:21 24:1 25:10 25:13,22 26:8 27:11 62:21 105:8 120:9 207:7</p> <p>systems 15:4 16:20 26:9 27:10 66:15 128:4 131:21</p> | <p>taconite 78:20</p> <p>tail 171:8</p> <p>tailored 45:18</p> <p>tails 171:4,5</p> <p>take 3:7 17:2,7 53:3,17 56:6 57:7 57:9,12 67:20 73:5 78:16 82:11 96:5 112:20 114:7 114:15 119:1 122:22 128:17 130:6 131:7 132:11 134:3 158:20 160:5 170:1,1,2,3 174:18 177:5 178:21 188:22 189:5 196:6 202:10 205:6 209:3 210:4,6</p> <p>takeaways 186:2</p> <p>taken 51:21 58:1 62:13 85:15 114:13 120:3 124:10 160:6,10 181:10 226:3,9</p> <p>takes 67:18 71:4 96:8 111:7</p> <p>talc 1:3 4:10,14 5:13 10:11,17,21 11:3,5,14,19 12:2 12:8,9,14,15,22 13:1,8,11,13,16 13:22 14:20 15:2 15:3,5,16 16:7,22 17:14,21 18:1,3,3 18:9,11,18 19:3 19:15 20:8,16,17 20:19 21:2,4,9,12 21:19 22:12 23:1 23:6 24:2,8,9,9,11 24:12,13,15,17 25:1,15,16,20 26:4,14,15,16,20</p> | <p>27:8,8,15,17,18 27:22 28:3,7,8 33:17,21 44:3 49:21,21 50:22 51:9,22 52:8,8 54:6,8,11 57:16 57:18,20 58:9 62:17,19 64:20,21 65:2,2,7 67:6,8,12 67:19 69:3,10 78:16 87:22 92:15 95:20 96:1 102:4 102:11,13 103:10 103:13 104:2,3,13 104:15 112:12 126:21 127:3,8 128:7,14,20 129:7 138:15 139:10,22 140:7,11 141:17 145:14 150:8 161:18 162:6,22 163:2,2,4,7,10,20 163:20 164:11,17 164:22,22 165:7 165:13 166:3,17 172:22 173:9 176:10 183:9 184:14,17 185:1 189:17 192:8,19 194:22 196:4,13 196:16 200:8 201:6,7,8 202:3 202:11,14 210:10 210:11 211:1,11 213:16 214:6,8,9 222:16</p> <p>talcs 18:4 19:5 62:7 67:15 103:17 126:18 127:18 129:18 169:5 210:12 213:19</p> <p>talcum 113:19 198:11</p> | <p>tale 86:22</p> <p>talk 8:15 28:6 29:13 30:20 31:2 32:3 33:15 34:1 44:14,15,16,17 46:10,11 48:21,22 51:17 59:5 60:16 60:19 62:9 68:20 68:21 74:3,8 82:8 82:8 106:14 107:1 107:3 110:16 115:14 117:2 126:16 133:3 137:22 138:18,19 139:4,7,10,21 143:5,6 144:14 157:8 160:18 165:9,11 201:17 203:1 205:12</p> <p>talked 33:21 133:13 152:4 157:10 166:1 184:19 185:2,3 186:3,4,6,7 209:19 212:20 216:10,21</p> <p>talking 21:11 36:11 43:3 45:12 47:2 52:7 58:18 68:12 74:12 86:14 107:6 144:1 145:14 153:14 154:20 163:9 170:10 222:15 223:4</p> <p>talks 58:2</p> <p>tall 51:19</p> <p>target 112:2,5 222:5</p> <p>targeted 91:22</p> <p>targets 111:14,15</p> <p>task 216:15</p> <p>taught 137:6</p> |
| <p>t</p> | | | |
| <p>t 2:1,1</p> <p>tab 22:2 56:18 69:5</p> <p>table 97:6</p> <p>tables 129:13</p> <p>tackle 4:2</p> | | | |

| | | | |
|--|---|---|---|
| <p>taylor 2:7 114:20 115:12 133:3,21 134:21 135:13,21 136:10 176:6</p> <p>teach 56:22</p> <p>teacher 55:8</p> <p>teaching 43:20 45:20 116:5</p> <p>tech 61:2 181:3</p> <p>technical 4:22 8:17</p> <p>technique 58:20 59:16,20 70:4 74:16 95:6,19 97:6 104:10 110:20 111:17 113:22 197:10 206:8</p> <p>techniques 56:5 59:16 60:6 62:22 71:3 78:11 110:17 111:18 184:2,16 185:4 186:4 189:1 189:14 190:16,19 201:12 202:2,8,20 203:9,12 204:14 214:12 222:5</p> <p>technologies 184:2 189:1 205:18</p> <p>technology 19:22 112:20 200:1</p> <p>tectonic 15:17</p> <p>tega 210:16</p> <p>tell 33:6 45:11 62:4 72:8 80:17 89:19 100:19 113:9 139:20 142:13 148:13 149:18 165:7,22 167:5 183:13 187:15 195:15 197:11,13,15,20 198:2,6</p> | <p>telling 114:1 161:14</p> <p>tells 113:10,16 159:14</p> <p>tem 33:18 58:1 59:15 63:15,15,22 64:1,5 73:22 74:15,21 75:12 76:7 81:1 111:3,5 111:9 124:9 163:12 164:17 165:19 166:1 168:13,15 173:8 186:9 191:18,21 199:19 200:5,5,7 200:13,18 201:4 206:17</p> <p>temperatures 23:21</p> <p>ten 182:5</p> <p>tend 37:19 151:3 171:8</p> <p>tens 108:22</p> <p>tensile 30:13 41:22 130:12</p> <p>term 20:5 34:3 35:6,7,10,17 139:8 185:10 190:14 200:10 220:6</p> <p>termed 34:10</p> <p>terminal 100:18</p> <p>terms 4:19 5:19 8:2 10:10 18:3 35:15,18,20 45:22 47:14 51:21 76:11 98:6 115:17 116:2 116:17 120:11,13 122:3,19 127:3 129:6 130:5 134:8 136:14 139:13 142:15,16 143:1 160:11 168:10 169:22 186:12</p> | <p>216:12 217:3,5,8 217:11 218:6</p> <p>tern 76:4</p> <p>terrible 97:5</p> <p>territory 220:18</p> <p>test 4:17 5:5,13 45:1 89:22 94:20 113:3,4,9,10 131:20 135:8 183:9 199:2 210:22 211:11 216:13 219:21</p> <p>testified 114:3</p> <p>testing 3:22 4:13 5:17 79:7 91:19 181:7 196:13 198:12 199:5 201:4 203:3,5 207:16 209:12 211:9 216:8</p> <p>tests 88:18 89:6,8 91:17 113:17 177:15</p> <p>texas 11:7,17</p> <p>texture 25:8</p> <p>thallophyte 197:19</p> <p>thank 3:12 8:11 10:4 28:15,18,20 29:9,11,12,17,18 43:16 46:19 50:7 73:8 74:8,10 76:16 77:13 97:7 114:16 115:12 136:19 137:9,10 146:9 168:20,22 185:13 191:22 215:14,21 218:20 220:20 222:10 224:7 225:2,4,9</p> <p>thanks 96:15 120:16 127:14 134:17 224:19</p> | <p>thanksgiving 163:8</p> <p>theme 39:5 216:16</p> <p>themes 216:3</p> <p>theories 94:5</p> <p>thermo 30:14</p> <p>thickness 20:9</p> <p>thimble 187:16</p> <p>thin 37:13 41:5 51:19,20 117:13 124:12 131:4 143:13</p> <p>thing 4:21 6:21 31:6 34:19 40:19 44:19 48:21 49:13 52:16,17,18 54:2 59:7 60:19,22 64:15,16 70:3 74:18 85:15 103:3 103:5 109:2 112:3 122:16 139:3 152:11 154:15 163:15 171:14 182:16 190:10 196:21 202:12 204:12 209:14 211:22 221:6</p> <p>things 28:13 38:11 41:5,6 43:10 44:17 46:10 51:13 52:15,15 53:6 56:4 60:17 61:9 66:11 71:4 79:15 79:18 81:17 87:15 89:22 96:6 110:15 121:19 130:14 137:21 139:3 140:15 144:16 146:14 147:20 148:15 157:9 163:5 167:3 170:6 184:10 185:11 188:17 190:22 191:1 192:5,9</p> |
|--|---|---|---|

| | | | |
|---|---|---|---|
| 197:21 199:12 200:6 201:19 203:19 213:16 214:11 218:18 think 4:5 8:1 10:10 22:14 23:3 28:10,21 30:5,21 31:1 33:16 34:2,6 34:20 35:21 36:19 36:20 37:6,11,15 38:9 41:9 43:2,11 43:12 45:17 47:5 49:15 51:2,4 54:10,12,21 57:4 62:6 65:7 67:2 68:9 70:8,17 72:8 73:22 75:10 76:9 81:21 85:14 86:1 86:20 87:1 91:4 92:14 94:13 95:1 95:4,4 97:12 103:8 106:6 107:19 108:3 113:1 116:7,18 127:12 132:2,21 133:5,14 134:10 134:11 135:7,14 138:9,20 140:14 141:9,13 143:7 149:17 150:12 151:4 152:9,9 155:21 159:19 161:14,15,21 162:1 163:1 164:4 166:19 167:3,5,17 168:10,11 171:10 172:10 173:3,6,7 173:9,11,21 175:14 176:6,14 177:3,19 179:8 183:5 187:11 192:9,20,21 193:18 194:5 195:1 196:13 | 198:19 201:20 202:6,7 203:5,7 203:15,18,22,22 205:17 206:20 208:12,22 209:19 209:21 210:13,16 211:21 213:22 216:2,14,16,19 217:5,8 218:2,6,8 219:16 220:18 221:10,14,18 222:7 224:12,20 thinking 34:2 101:7 105:19 211:7 third 23:6 181:6 199:3 218:1 thoracic 115:5 thought 11:2 42:10 54:5 55:4 64:22 76:13 82:17 90:5 118:16 131:10 179:1 182:14 186:12 191:13 194:19 196:7 216:7 218:10,11 222:17 224:9 thoughts 218:8 219:8 220:21 224:7 thousand 80:22 108:16 thousands 47:13 108:22 170:21,22 170:22 three 5:4,12 7:12 11:4,4 12:13 47:5 51:11 53:7 70:21 77:10 81:4 92:8 96:10 106:22 115:10 127:17 155:6 157:20 158:14 160:6,19 | 160:20 170:13 180:21,22 181:15 181:20 throw 70:22 71:1 75:8 139:20 162:15,18 tie 186:22 205:15 tight 109:2 tiles 19:6 31:16,16 till 16:12 tim 4:22 7:7,20 8:1,9,11,15 9:2,5 9:9,13,19 44:21 45:1,4 timbrell 149:5 179:21 time 3:6 6:11,14 9:17 16:8 20:1 25:4 28:15,22 39:19 45:17 46:1 46:12 47:8 50:4 52:11 55:8,19 57:11 70:18 76:19 79:3 81:9 96:14 96:21 111:7 119:15 127:3 131:1 133:14 149:7 151:10 152:18 165:10,20 166:3 167:21 175:21 176:8,15 176:16 181:16 182:14 189:5 220:19 timer 44:8 times 42:7 59:11 110:16 184:3 186:21 203:12 216:9 tiny 33:11 83:1 146:13 147:11 163:22 168:3 tired 143:15 144:19 | tissue 98:5 158:5 177:2 178:19 title 149:6 tlm 63:19 tm 150:13 199:18 tms 73:14 today 4:2,12 10:5 13:20 28:17 29:13 30:2,6 31:1,14 33:16 93:12 116:22 120:19 127:14 137:22 138:18 177:20 183:6 196:15 208:13 213:3 215:22 218:3 224:12 told 22:10 60:7 78:20 170:20 tolerability 112:7 tolerable 112:12 195:6 222:1,2,4 222:14,20 223:5,8 tolerance 223:1 tolerate 112:8 186:11 194:22 ton 87:13 tonnage 12:13 tons 11:22 12:6,7 12:8 88:11,11 tool 70:12 toolbox 216:20 tools 69:20 top 17:3 38:11 41:7 167:12 214:4 topic 138:16 155:7 topical 77:1 topics 45:11 208:13 torch 57:10 tossup 64:15 total 43:4 110:21 158:17 |
|---|---|---|---|

| | | | |
|----------------------------------|-------------------------|---------------------------|---------------------------|
| totally 152:2,8 163:13 | transport 120:7 | triggerclet 210:7 | 58:15 62:9,15,22 |
| touch 52:2 116:22 | transvaal 148:20 | triggering 121:5 | 65:11 69:11 73:19 |
| tough 80:22 | 149:9,10,17 | trouble 161:13 | 74:17 75:11 81:4 |
| town 98:20 151:13 | 156:19 157:4 | true 36:11 108:4 | 90:12 91:10 92:15 |
| toxic 42:20 44:1 | trapped 72:19 | 109:3 112:10 | 93:8 99:13 110:10 |
| 220:3 | treasure 27:1 | 113:5,14 199:22 | 118:14 147:17 |
| toxicity 41:20 42:3 | treat 145:7 | 212:1 226:6 | 148:16 149:15 |
| 42:16 89:6 94:21 | treatment 108:4 | truly 66:6 | 150:15,16 151:22 |
| 95:12 98:6 116:17 | treats 36:13 | trump 185:6 | 156:20 160:3 |
| 127:22 157:17 | tremendous 44:18 | truth 140:2 | 165:22 166:5 |
| 168:18 172:12,13 | 84:21 | 143:13 | 175:1,11 178:22 |
| 173:10,17 | tremolite 14:1,9 | try 57:10 101:15 | 180:21 187:7 |
| toxicological 94:4 | 17:8,10,18 18:11 | 107:17 114:1 | 196:2,11 |
| toxicologist 43:9 | 18:14 19:15 20:8 | 139:18 157:19 | type 10:13,20 |
| 97:16 98:8 184:6 | 20:17 21:3,5,18 | 160:4 171:13 | 14:12 18:10 25:16 |
| 184:7 185:18 | 21:21 22:2 23:15 | 193:19 201:16 | 26:17 28:18 53:12 |
| toxicologists | 24:6,17 25:3 32:8 | trying 37:12 56:14 | 68:15 115:16 |
| 95:14 | 37:15 39:14 48:11 | 61:8,10 69:17 | 117:8 121:4 125:8 |
| toxicology 97:13 | 51:1,5 66:13,14 | 71:14 72:4 112:18 | 136:4 153:11 |
| 155:4 | 67:7,7,11 69:6 | 168:6 179:2,10 | 156:14 194:2 |
| tpm 70:20 172:8 | 80:14,15 83:5,8 | 198:19 199:1 | types 10:20 14:6 |
| trace 72:3 80:14 | 84:16,18 85:5,20 | 201:18 202:2 | 53:12 56:17 80:7 |
| 111:14 215:3,12 | 87:17,19 88:2 | 205:5,14 214:14 | 122:9,12,18 |
| tracer 201:15 | 89:3,5 101:16 | 225:7 | 130:16 131:7 |
| trachea 117:20 | 104:11 109:7,8 | tshaffer 9:13 | 132:3 134:15 |
| 124:3 | 128:7,8 131:16 | tubes 118:5 | 136:9 150:9 |
| track 219:16 | 140:5,6 141:15,20 | tumor 117:2,9 | 205:20 |
| traditional 31:11 | 142:3 146:7 | 119:15 120:12 | typewriting 226:5 |
| 34:1 57:5 184:1 | 148:12 150:6 | 121:21 | typically 117:22 |
| trail 101:2 | 153:12 160:20 | tumors 117:13 | u |
| trained 59:10 | 163:22 166:8 | 118:16,21 119:16 | u.s. 9:22 11:15,21 |
| training 115:1 | 167:11 174:19 | 124:18 | 12:10 29:4 44:2 |
| trans 148:18 | 197:22 212:8 | turn 68:4 | 125:15 |
| transcriber 227:1 | tremolite's 14:7 | turned 76:2 87:17 | ubsd 204:7,10,12 |
| transcript 227:3 | tremolites 100:7 | 87:18 188:3 | 204:13 205:10,15 |
| transcriptionist | 132:20 198:14 | turning 188:11 | 206:8 |
| 6:2 | tremolitic 18:3 | twenty 92:8 | uh 176:20 |
| transferred 84:4 | 201:15 | twist 68:3 | uicc 38:15 82:12 |
| transitional 18:7 | triangle 158:20 | twisted 65:2,7 | 82:15,19 84:2 |
| transmission | tridy 20:4 21:1 | 68:1,2 | 86:2 98:18,20 |
| 205:3,4 206:3 | tried 38:5 83:9 | twists 69:3 | 99:5 101:16 121:1 |
| transmitting | 105:16 171:15 | two 5:6,12 7:7 | 135:1,2 |
| 205:3 | 202:5 | 11:9 32:4,18 33:9 | uiccb 80:12 104:8 |
| | | 47:6,21 50:16 | |

| | | | |
|-------------------------|---------------------------|---------------------------|---------------------------|
| uiccs 98:19 | 47:15 93:6 98:1 | 100:12 101:2 | variability 139:13 |
| uk 84:20,22 | 208:10 | 103:13 106:18 | 178:8 180:8 |
| ultimate 70:12 | understood 57:2 | 111:15,17,18 | variation 28:13,18 |
| ultimately 72:11 | unfortunately | 112:6,7 124:4 | 79:4 107:21 |
| 144:14 218:17 | 24:19 59:12 | 139:8 147:15 | variations 142:14 |
| ultrabasic 53:8 | uniform 141:3 | 155:22 156:1 | varies 103:7 131:6 |
| ultramafic 15:11 | 146:11,11 | 157:18 160:4 | 159:20 |
| 23:7 24:4 25:12 | uniformly 145:20 | 161:11 168:15 | varieties 13:8 |
| 53:18 | unique 56:21 | 169:8 178:7,8,9 | variety 14:3 21:17 |
| umbrella 220:2,5 | 177:1 200:22 | 186:10 189:1,7 | 129:4 130:11 |
| unable 8:20 | unit 24:10 | 190:14,15,18,19 | 131:21 142:20 |
| 125:20 | united 4:8,9 11:3 | 194:8,9 195:2 | 144:7 202:4 |
| unacceptable | 16:2 26:20 27:19 | useful 58:20 70:9 | 224:11 |
| 223:1 | 142:17 | 132:22 174:3 | various 125:6 |
| unaltered 25:9 | universities 59:13 | 209:14 211:22 | 126:1 184:1 185:4 |
| unamazing 61:3 | university 30:8 | useless 169:16 | 186:3 191:17 |
| unambiguous | 114:21 136:22 | uses 11:19 12:16 | 213:16,19 |
| 162:14 | 137:4,5,20 215:6 | 34:2 47:16 | variscite 100:17 |
| unanswered 217:6 | unknown 154:14 | usgs 11:20 29:22 | vary 71:13 132:20 |
| unaware 164:19 | 186:21 | 37:16 40:1 97:4 | 159:19 |
| uncertain 114:4 | unroutine 103:14 | usp 46:14 47:2 | vast 177:6 |
| uncertainty 81:6 | unsuccessfully | 196:12 198:21 | vastly 165:5 |
| 107:10,15,16,18 | 124:7 | 209:21 213:9 | vat 70:7 |
| 108:1,4,5 113:22 | unusual 15:2 | 218:22 219:7,8 | vein 78:20 |
| 114:1 209:20 | 30:11 | usp's 215:20 | veins 78:18 164:14 |
| uncharted 220:18 | upa 151:14 | usually 13:6 15:14 | verify 199:4 |
| uncoated 204:18 | update 155:11 | 33:20 157:10 | vermiculite 157:6 |
| uncommon 84:12 | updated 155:3 | 173:16 206:14 | vermont 11:12,17 |
| 142:22,22 | uptake 123:9 | utopia 71:11 | 24:2 53:18 114:21 |
| undatee 94:22 | 136:14 | v | veronica 225:5 |
| underground 16:9 | upward 25:17 | valid 191:12 | version 48:10 |
| 19:13,14 155:17 | 26:10 | validate 128:12 | 106:9 |
| underneath 220:4 | urge 193:18 | validity 175:15 | versus 40:3 49:13 |
| understand 36:22 | urging 73:4 | valley 18:12,19,20 | 56:7 64:19,20 |
| 41:19 48:1 65:19 | usa 103:4 | 18:21 19:19 21:18 | 97:14 109:22 |
| 72:3 93:11 97:7 | usage 48:16 | 23:1 37:15 50:1 | 167:1 184:16 |
| 100:11 113:11 | use 6:2 19:21 | 53:11,12 | vessels 143:21 |
| 131:14 144:17 | 20:19 30:4 31:13 | value 107:16 | view 11:13 20:21 |
| 157:19 177:13 | 32:22 33:4 36:1,6 | 146:1 169:17 | 73:18 75:12 81:2 |
| 180:10 198:17 | 46:8 47:13,15,17 | values 155:2 | 81:3 115:19 |
| 199:15 207:11 | 54:20 63:16 69:3 | valves 177:2 | viewers 66:1 |
| 209:7 | 70:21 71:2 75:17 | van 2:3 9:21 10:3 | vigor 133:15 |
| understanding | 78:11 83:16 88:17 | 56:8 85:11 102:3 | village 96:8 |
| 7:21 11:8 36:9 | 94:2,6,19 95:19 | 104:1,6 | |

| | | | |
|---------------------------|--------------------------|---------------------------|-------------------------|
| villages 142:2 | 166:9 167:20,21 | 188:10 189:17 | western 11:7 |
| vipers 221:4 | 167:22 182:7,22 | 205:11 215:7 | whatsoever 75:17 |
| virginia 155:7 | 183:6 186:10 | ways 33:8 202:4 | 147:18 162:11 |
| virtually 146:12 | 187:13,14 210:1 | we've 48:20 52:6 | wheel 189:7 |
| 148:6 | 212:4 216:13 | 62:22 75:15 78:6 | white 19:10 |
| virtue 104:10 | 224:7 | 80:6 82:6 89:8 | 134:20 150:21 |
| visceral 118:19 | wanted 30:9,20 | 90:10 95:2,3,8 | whoops 34:14 |
| visible 24:2 28:10 | 64:21 85:3,4 | 114:6 117:2 | wi 8:13 9:14 |
| visited 85:14 | 89:22 117:17 | 120:18,21,22 | wicked 71:18 |
| 94:11 | 133:16 137:13 | 121:1,2,17 122:21 | wide 21:17 28:8 |
| visual 5:22 108:8 | 145:13 174:1 | 123:1,18,20,22,22 | 40:15 59:8 142:4 |
| vitro 121:17 | 184:10 211:11 | 124:5,19 125:4,16 | 146:18 147:15 |
| 122:18 129:21 | 215:21 | 125:18 126:2,9,9 | 159:18 162:5 |
| voila 140:5 | wants 102:15 | 126:10,11,16,17 | 168:5 |
| volume 115:22 | 106:7 107:1 182:9 | 126:20,22 127:1 | widely 118:22 |
| 116:6,18 155:5,8 | war 135:10 | 131:16 152:4 | 166:22 |
| 158:7 | warranted 193:18 | 171:18 196:15 | wider 148:22,22 |
| w | warren 19:17 | 204:17 205:5,12 | 149:12,13 |
| | 20:10 | 209:19 | widespread |
| wagner 115:5 | washington 1:22 | weak 13:9 | 214:15 |
| waiting 158:9 | 215:5 | weakness 51:15 | width 90:19 91:7 |
| wake 169:18 | watching 71:14,15 | weapon 192:3 | 91:11 143:6,11,14 |
| walk 212:16 | water 13:15 14:18 | webinar 3:5,13 | 143:18,19 146:8 |
| walked 75:20 | 53:14 64:9 75:21 | 7:17,20,21 8:8,19 | 146:10 147:11,19 |
| walks 58:2 | 76:1,3 165:17,17 | 9:3 45:8 114:11 | 148:2,8,21,21 |
| wall 14:13 | 165:20 | 114:17 | 149:7,14 150:4,15 |
| walls 101:14 | waters 15:14 | website 6:15 37:16 | 153:9,18 154:1 |
| walteare 95:13 | 17:11,14 26:10 | 37:17 217:14,22 | 157:22 158:2,3,19 |
| want 3:19 5:1 10:3 | waxes 203:16 | wednesday 1:6 | 158:21 159:11,11 |
| 27:19 28:6 29:16 | waxy 184:21 | week 163:7,8,8 | 159:12 161:4,7,17 |
| 29:17 31:17 35:21 | way 8:21 33:3 | weeks 32:4 155:6 | 164:2 168:17 |
| 36:1,3,6 48:1 | 34:7 35:4 40:9 | weight 107:6,9,17 | 169:9 170:1,2,2,3 |
| 54:14 70:18 74:3 | 45:18 46:4 49:2 | 110:4 167:1 | 170:15,16,18 |
| 84:6 87:14 92:19 | 52:14 53:1 56:21 | weights 134:12 | 171:1 174:6 177:3 |
| 94:3 95:5 96:7 | 59:3 62:17 68:20 | welcome 3:4,9 | 177:5,9,10 191:17 |
| 97:5 101:18 104:8 | 91:10 93:16 94:22 | 24:20 114:14 | 194:14,15 |
| 112:19,19,22 | 97:4 101:1 102:13 | 169:1 | widths 143:10 |
| 114:3,17 115:19 | 105:21 106:5,14 | wellesley 137:1 | 145:8,19 146:21 |
| 116:10 117:6 | 106:16,16 132:1 | went 54:11,13 | 148:3,19 149:11 |
| 120:10 121:14 | 147:14 149:2 | 68:13 82:18 | 149:13 164:5 |
| 122:16 127:11 | 151:11 154:10 | 128:12 139:22 | 170:16 173:14 |
| 129:14 139:2 | 157:5 159:1 161:4 | 172:9 183:12 | willing 84:10 |
| 143:5,5 146:4,15 | 167:2,16,17 | 187:2 214:6 224:8 | 96:14 211:17 |
| 147:3 148:6 150:2 | 173:21 175:8 | | |
| 156:3 160:15,18 | | | |

| | | | |
|--|--|--|---|
| winchite 22:20 32:10 157:5 159:4 221:12 | 176:7 179:21 195:10 200:15,19 204:13,22 205:1 206:9,11,13 214:8 214:12 215:8 224:8 | writing 58:6 written 62:3 96:9 wrong 56:10,11 70:2 172:10 wrote 30:9 143:15 wylie 2:8 35:22 115:15 126:19 128:9 132:1,15 136:21 137:9 162:17,20 169:1 169:15,19 170:19 172:6,17,20 173:2 174:10,15,18 175:13 176:3,12 177:9,12 178:6,14 179:6,17 180:5,14 181:6 187:8 209:9 209:11,16 221:22 | 182:15 191:16 205:12 208:7,9 209:18 220:22 221:19 223:18 224:3 year 12:6 54:11 99:3 152:17 155:1 155:7 156:5 159:14 196:19 198:12 years 11:15 12:20 16:15 18:13 22:11 27:15 29:5,14 30:3,3,5 31:7 34:10 35:12 41:20 42:7 46:17 47:5,6 54:7,9 77:9 80:12 83:20 84:4 97:22 114:22 115:1 117:3 119:16 123:1,21 125:17 130:19 141:21 152:17 153:1 172:21 189:6 yellow 11:11,14 27:2,6,6,17 yep 191:6 york 14:3 75:21 88:3 126:17 127:18 young 150:13 161:2 younger 72:20 you're 69:8 |
| winter 30:1 | worked 29:3 88:19 93:4 96:12 152:6 | | |
| wisdom 77:10 | worker 140:19 179:8 223:16 | | |
| wise 185:18 | workers 31:18 71:22 147:3 154:15 157:6 179:17 | | |
| wish 147:19,20 150:12 | working 42:4 45:17 48:14 73:4 77:21 83:12 94:8 96:4 118:11 137:15,21 196:13 196:16 197:5 | x | |
| witch 71:18 | workplace 60:15 72:2 | x 61:4,21 62:3 95:8 124:4 | |
| witness 44:4 | works 47:4 59:17 204:12 | xrd 61:19 74:2 184:2 186:8 191:11 197:11 | |
| wittenoom 82:11 83:6 | world 45:21 46:3 74:15 91:3 106:20 113:7 135:10 149:9 207:16 213:20 214:9 | xrd's 197:11 xrf 214:12 xyz 68:22 | |
| wizard 71:7 | worried 193:6 | y | |
| wizards 45:14 | worry 51:1 52:6 170:7,8 | yeah 9:11,12,15 44:15 68:19 73:5 73:13 77:13 78:21 87:14 90:9 97:2 98:12,15 99:4,12 99:14 101:3 102:10,20 103:9 104:1,7 105:3,3 107:3,12 108:4,9 108:20 109:16 110:3,8,8 111:4 133:3 135:13 172:6 176:6 177:12 178:17 179:6 180:14,14 | |
| wollastonite 92:7 92:9,10,16 | worst 188:4 | | |
| won 66:18 | worth 46:16 48:1 70:22 97:22 | | |
| wonderful 116:19 176:12 192:4 200:5 | worthwhile 77:15 | | |
| woods 85:9 | worthy 77:12 | | |
| word 49:17 52:8 89:1 112:6,7 144:22 174:2 183:11 186:10 | wounded 135:11 | | |
| words 47:13,15 165:3 | wow 78:22 81:7 163:10 | | |
| wore 101:18 | wrench 128:20 | | |
| work 4:8,11 10:1 22:19 23:16 28:1 28:14 29:17 46:14 46:17,22 54:15 62:22 67:18 74:5 77:14,18 86:18 88:1 93:19 97:22 117:17 119:18 120:15 122:17 124:5,6,20 126:9 127:5 131:19 132:1 137:11,14 137:17 144:14 158:15,15 173:20 | wright's 19:18 | | |
| | | | z |
| | | | zeolites 93:22 zero 90:7,14,15 104:19 105:1 106:17 112:2 157:15 159:6 223:1 zeros 71:8 171:22 zillion 141:21 161:16 |

[zmi - zun]

Page 53

zmi 106:19
zoltai 36:19 42:6
130:3
zonation 24:2
zone 24:12 166:7
166:14 200:15,18
200:19,21
zoom 58:4,8
zun 51:7