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THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas
Jean H. Toal, Circuit Court Judge

Appellate Case No. 2025-000065
Civil Action No. 2023-CP-40-04072

Michael L. Perry and Lonnie Long,..... Respondents,

v.

American International Industries et al.

Of whom Johnson & Johnson; LLT Management, LLC f/k/a LTL Management, LLC; Kenvue, Inc.; and Johnson & Johnson Holdco (NA), Inc. are the ..... Appellants.

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I certify that this Designation does not contain any matters which are irrelevant to this appeal.

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES, SPRING STREET COURTHOUSE

Coordinated Proceeding Special Title (Rule 3.550) LAOSD ASBESTOS CASES	JCCP 4674
MAE K. MOORE, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.	Case No. 21STCV05513 Certified Transcript (Pages 254 - 504)

DEPOSITION OF EXPERT WITNESS

STEVEN HABER, M.D.

VOLUME II

WEDNESDAY, NOVEMBER 24, 2021

Reported by:

PAIGE I. HUTCHINSON, CA CSR No. 13459,
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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF LOS ANGELES, SPRING STREET COURTHOUSE

Coordinated Proceeding) JCCP 4674
Special Title (Rule 3.550))
LAOSD ASBESTOS CASES)
_____)
)
MAE K. MOORE,) Case No.
) 21STCV05513
Plaintiff,)
)
v.)
)
JOHNSON & JOHNSON, et al.,)
)
Defendants.)
_____)

DEPOSITION OF STEVEN HABER, M.D., VOLUME II, taken on behalf of Defendants, remotely via videoconference, commencing at 9:01 a.m. (PST), Wednesday, November 24, 2021, before Paige I. Hutchinson, Certified Shorthand Reporter for the State of California No. 13459, Texas CSR No. 11222, Washington CCR No. 3336.

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Exhibit 2 Exhibit 6

QUESTIONS INSTRUCTED NOT TO ANSWER

(None.)

WEDNESDAY, NOVEMBER 24, 2021
9:01 A.M.
-o0o-

STEVEN HABER, M.D.,
called as a deponent and previously
sworn in by the deposition officer,
was examined and testified as follows:

MR. MASSENBURG: Let's roll.
MS. DEAN: We did state at the beginning of this deposition that an objection by one defense is good for all, and I also indicated on that record that if an objection occurs after an answer that it won't be an issue, so those two things might help make this less congested.
MR. MASSENBURG: Great.

EXAMINATION (Resumed)
BY MR. MASSENBURG:

Q. All right. Dr. Haber, good morning.
A. Good morning, sir.
Q. All right. Where we left off, according to my notes, was I was asking you some specific information -- well, I talked a little bit about Chanel and your reliance there, and then we got into some radiation-induced mesothelioma conversations.
I just want to start back today, if we could, with your declaration. Do you have that? That's been marked as Exhibit 2 to your deposition.
A. Yes, sir.
Q. Do you have that in front of you, or do I need to put it on the screen?
A. I have it in front of me.
Q. Perfect.
One of the things that you indicated as to Chanel in paragraph 24 that you relied on was the MAS declaration Dr. Longo's declaration from August of 2020?
A. Yes.
Q. Do you have that in front of you?
A. No.
Q. You confirmed when last we spoke that you had not seen any of the actual underlying tests, just the declaration of Dr. Longo and the attached chart. Is that still true today, sir, as far as Chanel goes?
MS. DEAN: Objection. Asked and answered. If we provided additional information, we let

everyone know. The only additional information provided was the medical records, since Mae Moore's living and has ongoing treatment. Reasking questions from day one that you have confirmation on is not going to be an acceptable use of time.
MR. MASSENBURG: You don't determine what's acceptable use of time or not, Ms. Dean. I respect your objection. Please refrain from speaking and coaching objections.
MS. DEAN: The notion that that is a coaching objection when I let you know what reliance material there is and when there are time pressures, I am going to speak up --
MR. MASSENBURG: Paige, let's run --
MS. DEAN: -- there are no additional materials. I let all counsel know this is a continuation. Asking questions from day one on day two is asked and answered and at this point harassing.
MR. MASSENBURG: All right. Ms. Dean, you're not arbiter of what's right and wrong. You put your objection on the record, please, and your statements or what you disclose to us is not on the record, it's not under oath, so I'm asking the witness one question. My one question, which he

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would have answered pretty quickly, you've taken up about three minutes of time with your long-winded objections.

Paige, if you would please --

MS. DEAN: We have only been on the record for a minute.

MR. MASSENBURG: Ms. Dean, I haven't finished talking.

Paige, if you'd please run time on this transcript as well like we did last time, I would appreciate it.

MS. DEAN: No objection.

We've been on the record for a minute. We started at 11:03, Counsel. Three minutes. Go on.

MR. MASSENBURG: Yeah, thanks.

BY MR. MASSENBURG:

Q. Dr. Haber, do you remember my question?

A. Yes.

Q. What was the answer?

A. The answer is that I have not gotten anything additional other than the written report as well as the chart indicating the testing materials and the testing techniques, et cetera.

Q. Okay. Do you have a copy of your notes, which are Exhibit 6, to the deposition?

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A. Yes.

Q. Would you pull that up and look at page 2 under Source Mines Supplier.

Are you there? Let me know when you're there.

A. I'm there.

Q. Okay. You have under there, Chanel pre-1990, Italian only, 1990 to early 2000s, Italian plus Australian blend, early 2000s plus China Guang Xi; is that correct?

A. Yes, that's what I wrote there.

Q. Is that information you were asked to assume or is that information you specifically were provided in some other form in which you rely on?

A. I'm not sure I'm understanding your distinction. I have seen data on the uses of -- the sources of Chanel during these various years and then I think I've also seen other people discussing this issue as well.

Q. Okay. What specific materials to Chanel do you have that you rely on to inform your opinion as expressed in paragraph 2 there on the second page of your notes?

MS. DEAN: Objection. Form.

///

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BY MR. MASSENBURG:

Q. First page of your notes.

MS. DEAN: Objection. Form, vague and confusing, also compound.

THE DEPONENT: Right. I think it's, again, within my declaration and within Exhibit B.

BY MR. MASSENBURG:

Q. I'm looking at paragraph 24 of your declaration where you specifically discuss Chanel.

Are you there?

A. Yes.

Q. Okay. You reference the MAS testing report, but I don't see a citation to your source for what is there in paragraph 24 as to the use of Italian and Italian/Australian, and then the corresponding information on paragraph 2 of the first page of your notes, is it discovery responses? Is it deposition testimony? You said you've seen other people talking about it? I just want to have a little more specificity so I know all of your sources for paragraph 2 of your notes and the first sentence of paragraph 24 of your declaration.

MS. DEAN: Let me object. To some extent, asked and answered, compound, vague and confusing

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to direct to one paragraph in the declaration after reference to Exhibit B and the entire declaration.

THE DEPONENT: My answer would be that, again, it would be contained -- information was contained within exhibits within Exhibit B as well as, again, you know, for example, in the note section, for example, your expert mentions that, you know, the sites Val Chisone, which is one of the sources that I said was pre-1990 Italian, and that was the source that was mentioned even by Mr. Segrave. But that's where I got the information from.

BY MR. MASSENBURG:

Q. Okay. Do you recall whether or not you reviewed any deposition testimony of Chanel's witness, corporate witness, or any discovery responses of Chanel specifically to inform your opinion as to paragraph 2 your notes or what's contained in the first sentence of paragraph 24 of your declaration?

MS. DEAN: Objection. Form, to the extent that's asked and answered and compound.

THE DEPONENT: I don't recall. But to the extent that it's within Exhibit B, then the answer would be yes.

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BY MR. MASSENBURG:
Q. Dr. Haber, I'm showing you what purports to be an August 10, 2020, declaration of Dr. Longo, which is two pages, signed purportedly by him and references two exhibits. Exhibit B is a chart, and Exhibit A, as you see, is a copy of his curriculum vitae.
Do you see that?
A. Yes.
Q. Is this the declaration that you received from Ms. Dean's office as to Chanel?
MS. DEAN: Objection. Form, vague.
THE DEPONENT: That's part of it. I mean, it also came with the attachments, but that part of it, the written part was part of it, yes.
BY MR. MASSENBURG:
Q. Okay.
All right. And do you have any personal knowledge as to Dr. Longo's statements in paragraphs 3, 4 -- I should say 3 or 4 of that declaration or affidavit?
MS. DEAN: Objection. Form, compound, overly broad.
THE DEPONENT: Okay. I'm not -- what did you ask specifically? I --

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BY MR. MASSENBURG:
Q. I asked if you have any personal knowledge as to statements Dr. Longo purports to make this two-page declaration or affidavit?
A. I don't know what you mean by personal knowledge.
Q. Direct knowledge, observation, if -- for example, if you read paragraph 3 --
A. I can't read -- I'm only seeing part of the page, so -- and I can't say what paragraph is what.
Q. Okay. How about that? Is that bigger? Can you see it now?
A. Well, no. Now all I see is just a few words in the center. It's so huge. It's taking up all the screen.
Q. How about now?
A. I'm missing the last of the left part of the page.
Q. How about now?
A. I'm still missing the left part of the page, but it's smaller. Well, now you went too far.
Q. I haven't even moved it, Dr. Haber.
A. Okay.

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Q. I didn't do anything to it.
A. Well, I don't know. It was darting across the screen. Now I see --
Q. I'm trying to make it so you can see it. I don't know.
MR. MASSENBURG: Any defense counsel have any trouble seeing the documents?
MS. DEAN: Objection. Vague. Do you mean the part you're asking about, paragraph 3 and 4, most of which are not on the screen?
MR. MASSENBURG: I've got it on my screen. I've used the same screen with every witness, Mr. Bailey, Dr. Rigler; they had no problem seeing it. Dr. Haber is. I'm just want to make Dr. Haber issue or if it's a me issue. That's what I'm asking.
MR. ULLOA: For what it's worth, I can see it and (inaudible).
(Reporter clarification.)
MR. MASSENBURG: That was Ed. He was trying to helpful.
MS. DEAN: I can see lines 5 through 27 of page 1.
MR. ULLOA: That's what I see, too if that helps.

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MR. MASSENBURG: Perfect.
BY MR. MASSENBURG:
Q. Can you see paragraphs -- lines 5 through 27, Dr. Haber?
A. Oh, I just realized I think I can -- I think it was maybe me that was moving it. But yes, now I can see lines 5 through 19.
Q. Okay.
A. Now 4 through -- all right.
Q. Okay. And are you able to read it? Can you see it comfortably on the screen?
A. Yes.
Q. Okay. So when I ask you do you have any personal knowledge, if you look at paragraph 3 --
A. I'm on paragraph 2, I'm seeing. I've got 7 through 17 or 18 so I just see the top of --
Q. Well, all you have to do then, Dr. Haber, is on your screen under your control, scroll down a little further, and you'll see paragraph 3.
How's that working for you?
A. To be clear paragraph 3, is not fully on the screen. You can see 18 through 27.
Q. That's all that's on that page. Do you see the page number on the bottom?
A. So I can now see -- yes, I didn't realize

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how this was working. So yes, now I can see the part of paragraph 3 that is contained within lines 18 to 27.

Q. When I asked you do you have my personal knowledge, obviously you were not involved in any way on this MAS testing; correct?

A. Correct.

Q. You've never seen the products tested physically; you've never touched them; you've never examined them; correct?

A. Well, not as far as this testing was concerned. I believe in -- I have touched Chanel Number 5 or Chanel products in my lifetime but not in pertaining to testing.

Q. Out of curiosity what Chanel products have you touched personally in your lifetime?

A. Oh, I think my grandmother and my mother used to use those.

Q. Do you remember, was it a body powder that your mother and grandmother used to use?

A. No.

Q. Chanel perfume?

A. I don't remember is what I said.

Q. Oh, okay. So I wasn't asking you about that; I was asking you about the content in

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paragraph 3 where it says 42 containers of Chanel talc-containing loose powder products. You've never physically touched those; you've never physically seen those products; correct?

A. Not those 42, correct.

Q. Right.

You have no personal knowledge about the testing that was done by MAS on those products identified other than what is contained in this declaration and the chart attached; correct?

MS. DEAN: Objection. Form.

THE DEPONENT: Well, other than to the extent that I think there's some descriptions in other MAS testing about their testing technique, for example, the separation techniques that they were using may have been described in greater detail than what was just within the chart or this declaration.

BY MR. MASSENBURG:

Q. Okay. Do you know whether or not MAS and Longo used any type of specific prep method, any type of analysis for these specific products that are identified in this declaration?

A. Yes.

Q. Okay. Do you have knowledge of that for

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any reason other than what is contained in this declaration?

MS. DEAN: Objection. Form, vague and ambiguous, if you're including the exhibits.

THE DEPONENT: For example, it talks about on page -- on line 15 and 16 the Blount prep method in using heavy liquid separation, and I have seen, for example, the papers from Blount in the 1990s as well as I've seen other documents from Longo and from other people who have used the Blount method of heavy liquid separation.

BY MR. MASSENBURG:

Q. Okay. Have you seen any of the underlying reports referenced in this declaration from MAS specific to Chanel?

MS. DEAN: Objection. Asked and answered, day one.

THE DEPONENT: To the -- that, I don't recall. But to the extent that they're within the Exhibit B, then they would be listed.

BY MR. MASSENBURG:

Q. And I understand they're listed in Exhibit B, and we're going to get there in a second. But to your knowledge, you have not ever seen any of the reports detailing the type of

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analysis and the reported findings other than what's contained in the declaration right here and Exhibit B as to Chanel; correct?

MS. DEAN: Objection. Asked and answered.

THE DEPONENT: Well, with the exception of, again, like I just finished saying here, as far as the technique is concerned about, you know, using TEM, about using the heavy liquid separation, I mean, there's other literature that discusses these techniques not specific to Chanel but specific to the testing that Dr. Longo is doing.

BY MR. MASSENBURG:

Q. Okay. Go to Exhibit B, and I want you to look at this one in the same context in which you -- can you see the entirety of Table 1, spelled T-a-b-e-l 1, Chanel body powders MAS chart of Chanel testing. Can you see all three products, 1, 2, and 3 and all eight columns?

MS. DEAN: Let me make clear that you're referencing Exhibit B to the Longo declaration, just because there's some other references to Exhibit B.

MR. MASSENBURG: Sure. Not in this deposition, I don't think, but you're right.

MS. DEAN: His reliance list.

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MR. MASSENBURG: Oh, yeah.
MS. DEAN: Sorry.
BY MR. MASSENBURG:
Q. Dr. Haber?
A. Yeah, I'm trying to get it to -- so that I can get it all the way across the width here. Okay.
All right. I have all lines 1, 2, and 3 and the columns -- 1, 2, 3, 4, 5, 6, 7 -- 8 columns.
Q. Perfect. Thank you, Doctor.
Now, who is -- it says, under Source, eBay for all three; correct?
A. Yes.
Q. It says seal broken by QuanTEM. Who's QuanTEM?
A. I don't recall.
Q. Do you know if that's a lab, if that's a company? Do you have any idea?
A. I said I don't recall.
Q. Okay. Do you know whether or not Chanel had shakers, talc shakers, talc powder shakers with a black top and a gold band and white bottom as depicted in the images in numbers 2 and 3 on this page; do you know if they ever made anything that

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looked like that prior to the 2000s?
A. I'm not sure I'm understanding what you're asking.
Q. I'm saying do you know whether or not what's depicted in picture 2 and picture 3, those products, do you know whether Chanel ever made Chanel Number 5 talc shakers -- well, ever, first? Do you know? Do you have any personal knowledge of that?
A. No. I really have no information or am not going to be able to testify at all as to what Chanel products looked like or what -- how they were packaged. That's really not my area of expertise.
Q. Okay. I'm flipping down a little bit, if we could into -- try to see if I can find a powder. There we go. Okay. Here's one.
Number 13, do you see that one?
A. Yes.
Q. It says here vintage pre-late-1980s.
Do you see that?
A. Yes.
Q. And it says Italian or Italian/Australian blend.
Do you see that?

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A. Yes.
Q. Also sourced from eBay; correct?
A. Yes.
Q. If we go back and look at your notes, the first page under Chanel, it says pre-1990, Italian only; correct?
A. Yes.
Q. And in paragraph 24 of your declaration, the first sentence says: Chanel's body powder used talc from Val Chisone Italy through the 1980s and a blend of Italian and Australian talc in '90s to the early 2000s.
Did I read that correctly?
A. Yes.
Q. If what you say in your notes and what you say in sentence 1 of paragraph 24 of your declaration are correct, then why does Dr. Longo have here Italian or Italian/Australian blend when the vintage is pre-late-1980s?
MS. DEAN: Objection. Form, vague and ambiguous.
THE DEPONENT: When he wrote this, I don't know what information was made available to him. You'd have to ask.
///

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BY MR. MASSENBURG:
Q. Doctor, in paragraph 28 of your declaration, you reference: In studies of over a hundred cases of malignant mesothelioma with no known asbestos exposures other than through repeated exposures to cosmetic talcum powder, all the examined tissues revealed anthophyllite, tremolite, and/or chrysotile asbestos.
Did I read that correctly?
A. Yes.
MS. DEAN: Objection. Form, asked and answered, day one.
BY MR. MASSENBURG:
Q. Do you have any personal knowledge -- other than what's contained in Dr. Moline and Dr. Kradin's case series reports that you previously discussed, do you have any personal knowledge, other than what's in those reports, as to whether or not any of the individuals had alternative exposures to real asbestos-containing products?
MS. DEAN: Objection. Form. First, vague and ambiguous as what is meant by real. Second, in large part, asked and answered. Fourth -- third, misleading as relating to one peer-reviewed

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published paper, and neglecting the second that you asked him about in day one, and fourth, vague as to time.

MR. MASSENBURG: Well, there were two references. One is Dr. Kradin's, which is the second one, and the first is Dr. Moline's. I didn't name all the authors. Dr. Maddox is also a coauthor. Anyway.

BY MR. MASSENBURG:

Q. Dr. Haber, do you know the studies I'm talking about; it's two different case series; right?

A. Well, I thought one was Moline and one was Emory.

Q. Dr. Emory, Dr. Maddox, and Dr. Kradin; right, the second one?

A. I don't recall. I recall Emory.

Q. Okay. Who's Dr. Emory?

A. I don't recall.

Q. Who's she work for?

A. Don't recall. I'd have to look back at the paper.

Q. Do you know any published or peer-reviewed article other than the one you just cited to that you rely on that comes from Dr. Emory?

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MS. DEAN: Objection. Form, overly broad, vague and ambiguous as to what subject.

THE DEPONENT: I don't know.

BY MR. MASSENBURG:

Q. What's her first name?

A. Don't recall.

Q. What kind of doctor is she?

A. Don't recall.

Q. Do you know Dr. Kradin?

A. I've seen articles from him. I don't recall his first name either or what specialty he is either.

Q. Do you know Dr. John Maddox?

A. Not personally, but I've heard the name.

Q. Do you know what kind of doctor he is?

A. Don't recall.

Q. Do you find Dr. Maddox to be a reliable authority in the area of asbestos and asbestos disease?

MS. DEAN: Objection. Form, overly broad.

THE DEPONENT: I guess it just depends on what issue it is that I'm -- we're talking about here. I guess I'd have to look at it on a case-by-case basis, but I don't have any reason to find him unreliable that I know of.

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BY MR. MASSENBURG:

Q. Okay. I'm talking about the area of specifically exposure to asbestos and the causation of mesothelioma. Do you find Dr. Maddox to be a reliable authority in that area?

MS. DEAN: Same objections.

THE DEPONENT: I don't recall any -- anything other than my -- just off the top of my head. I know -- I'm pretty sure he's had a lot of publications but nothing that I can recall that would make me be doubtful of his qualifications or his expertise, but I just don't recall specifically any particular article on that subject.

BY MR. MASSENBURG:

Q. Any experience of -- from reading anything he's published that makes you tend towards saying, I think he is reliable in the area of asbestos exposure and mesothelioma causation?

MS. DEAN: Same objections to overly broad.

THE DEPONENT: Without looking through an article, I mean, nothing comes to mind that as far as being unreliable, so I would say that I didn't really find any issues when I was reading his

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articles.

BY MR. MASSENBURG:

Q. Okay. What about Dr. Richard Attanoos, do you know him and know of his publications in asbestos and asbestos disease?

MS. DEAN: Objection. Overly broad, compound, vague and ambiguous to which -- which articles.

THE DEPONENT: I've heard the name. I don't recall.

BY MR. MASSENBURG:

Q. What about Allen Gibbs; he's a histopathologist from Wales, do you know of any of his publications in asbestos and asbestos disease?

A. Doesn't sound familiar to me.

Q. What about Victor Roggli?

A. Yes.

MS. DEAN: Objection. Form.

BY MR. MASSENBURG:

Q. Do you find Victor Roggli to be a reliable figure on asbestos exposure and mesothelioma causation?

MS. DEAN: Same objections.

THE DEPONENT: I find him to be a pathologist. I don't find him to be necessarily

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reliable on issues outside of pathology.
BY MR. MASSENBURG:
Q. Then why do you rely on him for your background number? When you say there's a background level of asbestos in the air, you cite to page number 26 of his book?
A. Well --
MS. DEAN: Sorry, Dr. Haber.
Let me object to vague, ambiguous, misleading, misstates the testimony.
BY MR. MASSENBURG:
Q. Okay. Did I misstate your testimony --
A. Yes.
Q. -- Dr. Haber?
A. Yes, you did.
Q. So you do not rely on Dr. Victor Roggli, page 26 of his book that the background level is 0. -- make sure I get it right -- I wrote it down -- 0.00005 fibers per cc?
MS. DEAN: Dinosaur. Misleading, changing questions, suggesting it came from a list then going to his book. Enough.
THE DEPONENT: So as I said in prior testimony and multiple times in other testimonies, this is just one citation of -- that is not

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Dr. Roggli's number. This was IARC and Nicholson and others, also data from the ATSDR, and this is just one place where it has been -- the study was cited but Dr. Roggli had nothing to do with the participation or the Nicholson paper or the IARC paper.
MS. DEAN: I want to note for the record that the document that counsel represented to the doctor was not before him when he made said representation. It's not on the screen.
MR. MASSENBURG: No, it's not. It's from prior testimony. And given his answer, I don't need to impeach him with it. That's fine, but I do have that.
And just so I'm clear, let me go ahead and make sure I've got this correct so we can do it this way.
MS. DEAN: While counsel's looking, I'm going to --
MR. MASSENBURG: This is the Hirshberg case, H-i-r-s-h-b-e-r-g, from 2021, page 46, lines 22 through 25. Now, that is an outdoor level.
But what do you want to do, Jessica? I'm sorry.
MS. DEAN: If you were looking, I was

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going to note something. I'll wait until there's a break.
MR. MASSENBURG: Okay.
BY MR. MASSENBURG:
Q. You do rely on the ATSDR, Dr. Bill Nicholson both of those -- well, ATSDR as a group and Dr. Nicholson from Mount Sinai as an individual and their studies and publications on ambient background levels of asbestos in the United States; correct?
A. Yes.
MS. DEAN: Vague, overly broad.
BY MR. MASSENBURG:
Q. Do you know who Dr. Samuel Hammer was?
A. Yes.
Q. Do you find Dr. Samuel Hammer to be a reliable authority to asbestos exposure and mesothelioma causation?
MS. DEAN: Objection. Form, overly broad, vague.
THE DEPONENT: Again, my understanding is is that he was a pathologist, but as far as causation or other things, I don't have any information on it. I've seen information that -- reports of his relating to pathology.

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BY MR. MASSENBURG:
Q. Okay. Do you know Dr. Ronald Dodson out of Texas, I think, at Tyler?
A. Not personally, but I have seen the Dodson and Hammer book, for example.
Q. Have you seen Dr. Ronald Dodson's publications in the late '90s early 2000s where they're called the East Texas Controls, where he did lung digestion analyses of over 30 different individuals who had passed away from non-asbestos-related diseases and had no known occupational or para-occupational exposures to asbestos?
A. I don't recall offhand, no.
Q. Do you know who Dr. Jacqueline Moline is?
MS. DEAN: Objection. Asked and answered.
THE DEPONENT: I don't recall what her specialty is, but she's a physician. I don't recall her specialty.
BY MR. MASSENBURG:
Q. Where does she practice?
A. I don't remember.
Q. Do you know whether or not you have seen any other publications from her in the field of asbestos exposure or mesothelioma?

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A. Don't remember.
Q. In paragraph 28 you say: In studies of over 100 cases of malignant mesothelioma with no known asbestos exposures other than through repeated exposures to cosmetic talcum powder, all the examined tissues reveal anthophyllite, tremolite, and chrysotile asbestos.
Do you have any other studies that you rely on for that sentence other than the two-case series we were just discussing from Dr. Emory and others and Dr. Moline and others?
MS. DEAN: This exact question was asked and answered with other case reports identified, day one.
MR. MASSENBURG: I object to speaking objections and coaching of the witness, which is rampant at this point.
THE DEPONENT: I don't recall if those are the only two or not.
MS. DEAN: I want to take a break and see if we can get the judge on the phone. I understand that he's on vacation, but I at least want to try.
DEPOSITION OFFICER: Off the record?
MR. MASSENBURG: I guess so.
(Whereupon, a recess was held

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from 9:35 a.m. to 9:45 a.m.)
MS. DEAN: Before we start with an examination, when we finished after over six hours of questions on day one of Haber, we reached an agreement that absent exceptional circumstances, we would get done today between 11:00 and 6:00 and also assuming that we had at least no more than an hour and a half of breaks. We have now started day two with Chanel who took the bulk of the time questioning on day one asking entirely duplicative questions down to reading the same parts of his declaration, asking the same questions except in a misleading manner, and entirely wasting time for a trial that was supposed to start on Monday and is only being extended for a week because the Court has indicated he needed time.
This is harassing, prejudicial, and problematic. If it persists, I'm going to suspend the deposition as to Chanel.
MR. MASSENBURG: The record will speak for itself as far as whether I've reasked questions. It will also note speaking objections by plaintiff's counsel and also the answers of Dr. Haber. I'll leave that as it is if we need to take something up. It's up to dispute whether I

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took up the majority of the time on day one, as I was not lead, did not do so. But subject to that as, again, the record will speak for itself, can we begin?
(No audible response from counsel.)
MR. MASSENBURG: Okay.
BY MR. MASSENBURG:
Q. Dr. Haber, paragraph 28 of your declaration, second sentence, you state: The combination of tremolite and anthophyllite asbestos fibers found in tumor tissue is felt to be unique to talc and is a fingerprint for such exposure.
Did I read that correctly?
A. Yes.
Q. What is your sources for that statement?
A. The source would be A and B, the papers that were -- the Moline and the Emory papers, and then C and D would be papers such as papers from Roggli and from Churg and others, as well as my understanding of the fact that anthophyllite in the United States is not a commercially used asbestos and that the combination of tremolite and anthophyllite are -- I've seen the testing of -- numerous testings from cosmetic companies to the people who are test -- you know, third party

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testing and other testers of talc products talking about the fact that they have tremolite and anthophyllite, which, again, are not asbestos products that are commercially used in the United States.
Q. I wrote down Roggli and Churg. Do you know specifically what article or book that -- where Roggli states that tremolite -- I'll say or anthophyllite asbestos fibers in tumor tissue is unique to talc and a fingerprint for such exposure?
A. Well, in -- they're both -- I don't recall the specific citation. I think they were in the '80s or early '90s, but both of the authors talked about the fact that when they were -- they were looking at mesothelioma in women and looking at the tissues and they saw these fibers, and they themselves postulated the source as being from talc, so that, again, was, you know, an indicator to other scientists that the presence of anthophyllite or tremolite, which was different than the type of asbestos fibers that you see in commercially used asbestos with crocidolite or amosite, in that this was leading scientists who postulate the source as being from talc.

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Q. So I was asking about Roggli. Are the articles or papers you're thinking of as to Dr. Churg also from the '80s or '90s?
A. Yes, I believe so.
Q. Okay. What other scientists besides Dr. Roggli and Dr. Churg talk specifically about tremolite or anthophyllite asbestos in tumor tissue being unique to talc and a fingerprint for such exposure?
MS. DEAN: Objection. Form, overly broad.
THE DEPONENT: I don't recall, but they would be within my Exhibit C.
BY MR. MASSENBURG:
Q. A little further down, not the next sentence but the one after, it starts with: An investigation of asbestos bodies.
You see that sentence?
A. Yeah, hold on a second.
Q. Do you see at least the sentence I'm referencing in paragraph 28?
A. No. You said one sentence down, but I didn't see that, so what line are you on?
Q. It's line 11?
A. 11, right. So you missed a couple of sentences. Okay.

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Q. Yeah, that's what I was -- I'm sorry. That's what I was trying to indicate.
An investigation of asbestos bodies in the general population found a high percentage of anthophyllite and tremolite cores in women but none in male blue-collar workers suggesting cosmetic as a source.
Did I read that correctly?
A. As the source, yes.
Q. What is your source that you're relying on for that statement?
A. I don't recall if that was a Churg paper or where that was from. That would be within my reliance list, but I don't recall specifically the exact citation for that.
Q. Okay. Share with you my screen. Take a look over there. Can you see what I've put up? It's a 1999 article from the "American Journal of Industrial Medicine," lead author is Ronald S. Dodson, Ph.D., entitled "Tissue Burden of Asbestos in Non-Occupationally Exposed Individuals From East Texas."
Can you see that on your screen?
A. Yes.
Q. Are you familiar with this article?

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A. I've seen it before, I'm pretty sure.
Q. I want to -- can you read the abstract here clearly on your screen? I can make it bigger, if you need.
A. If you could, please.
Q. Yes, sir. I can make it bigger, if you need more than this.
A. That's okay.
Q. Okay. So you'll see that what they're looking at is they looked at 33 individuals with no work history of occupational exposure to asbestos. They took lung tissue from these individuals and did a fiber burden analysis by digesting the lung tissue, both wet and dry.
Do you see that? Let me know when you're ready, Doctor. I think you might be reading it, but I'm not sure.
A. Yeah, I'm reading it, but it's just abstract.
Q. Yeah, let me know when you're done?
A. Okay. I've read it.
Q. I want to take you to the second chart in the study. I'm going to have to make this a little smaller so we can get it all in there.
Table 2 says: Uncoated fiber data per

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case, fibers per gram dry for non-occupationally exposed East Texas.
Do you see that?
A. East Texas, yes.
Q. Yes.
And it says there's 33 cases. It lists the total asbestos, chrysotile, amosite, crocidolite, tremolite, actinolite, anthophyllite, and nonasbestos fibers.
Do you see that?
A. Yes.
Q. You agree they found, at least Dr. Dodson and his cohorts, found nonasbestos fibers in all of the tissue of all 33 individuals they looked at?
A. It appears to be.
Q. And they found anthophyllite fibers in the lung tissue of 12 out of the 33 individuals; correct?
A. Yes.
Q. They found tremolite fibers in four of the lung tissue data analyzed of the 33 individuals; correct?
A. No.
Q. Actinolite, 1, 2, 3, 4?
A. You said tremolite, I thought.

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Q. I thought I said actinolite. I meant to say actinolite.
Actinolite is four out of 33; correct?
A. Yes.
Q. Yes.
Okay. And tremolite is five out of the 33; correct?
A. No.
Q. Oh, I'm sorry. Eight out of the 33; correct?
A. Yes.
Q. All right. Based on this study, do you agree that some individuals have background levels of anthophyllite, tremolite, actinolite, crocidolite, amosite, and chrysotile in their lungs even though they've not been occupationally exposed to asbestos?
MS. DEAN: Objection. Form, overly broad, compound, vague as to an article he indicated he doesn't recall reading.
MR. MASSENBURG: Object to the speaking objection.
THE DEPONENT: I was going to say that I would need to re-review the specifics of this particular article. And I don't know as far as how

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they determined exposures and/or, you know, whether there were take-home exposures or other sources of exposures besides occupational in this particular group of 33.
BY MR. MASSENBURG:
Q. Understood.
Do you have this article, or do I need to attach it?
MS. DEAN: Objection. Form, asked and answered.
BY MR. MASSENBURG:
Q. I know you said you've seen it.
A. But I don't recall whether that's on my Exhibit C or not.
Q. Okay. We'll attach this as Exhibit 11 That will be 1999 Dodson article.
(Exhibit 11 marked.)
BY MR. MASSENBURG:
Q. On the next page, Doctor, of your declaration page 13 at the top, it's paragraph 30 continuing over, I want to ask you about the first full sentence.
You state: A fiber has an aspect ratio of at least 3 to 1 --
A. Wait. I'm sorry. Where are you? What

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line are you on?
Q. Starting on the second line, the first full sentence.
A. Okay.
Q. A fiber has an aspect ratio of at least 3 to 1 chrysotile, amosite, anthophyllite, crocidolite, tremolite, and actinolite, when in a fibrous form, can cause a spectrum of diseases, including cancer.
Did I read that correctly?
A. Yes.
Q. Okay. What is the source that you're relying on for that statement?
A. Well, the first part -- before you read about the fiber aspect ratio, I was talking about the definition and, in fact, it's even included there, federal government definition of asbestos and which fibers which are the chemical of the six regulated asbestos fibers, amosite, anthophyllite, crocidolite, tremolite, actinolite, and chrysotile, and then as far as -- and that would also be the same source for being a 3 to 1 ratio.
And then my knowledge as far as the second sentence that you read was that there is a whole host of data, and I would point you to many, many

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articles in my Exhibit C list discussing the health effects of asbestos because that chrysotile, amosite, anthophyllite, crocidolite, tremolite, and actinolite as a fiber is respirable and is asbestos and causes disease, including cancer.
Q. I'm asking specifically about the statement: A fiber has --
I think you might have meant a fiber having an aspect ratio of at least 3 to 1, but you tell me if I'm wrong.
But it reads: A fiber has an aspect ratio of at least 3 to 1 -- then you name all six fiber types -- when in fibrous form, can cause a spectrum of diseases, including cancer.
So I'm looking for anything in your reliance specifically that a fiber of an aspect ratio of at least 3 to 1 can cause a spectrum of diseases including cancer.
MS. DEAN: Objection to the non-question part compound, vague and confusing.
THE DEPONENT: So I believe I answered that already. The definition -- and I talk about this in earlier parts of this paragraph, but it's from a medical perspective, if you've got one of these six mined minerals and it's in fiber form and

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it's -- you know, and generally as a fiber, they're talking about greater than 3 to 1, which is what it means by at least 3 to 1 ratio, and that is how asbestos is defined, and those chemicals when they -- these minerals -- when in fibrous form as long and thin and are respirable, they cause disease, and there's a whole host of articles discussing how -- the dangers of asbestos, and that is -- asbestos is these six minerals in fibrous form.

BY MR. MASSENBURG:

Q. Okay. And I get that.

From page 12 of your declaration, paragraph 30, you have a sentence that starts: Geologists or mineralogists may have different definitions, being more concerned about how it was formed; whereas, physicians and scientists are more concerned if the fiber can create a risk of disease.

Did I read that correctly?

A. Yes. Actually, it was risk for disease, but...

Q. Yeah, I'm sorry.

And so and then you go on to define -- say the federal government defines asbestos, and you

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have that sentence, and then there's the sentence I read.

Would you agree with me then that what you're stating is that an asbestos fiber has to have an aspect ratio of at least 3 to 1 for it to create a risk of disease?

A. Well, that's the definition of asbestos, so yes, I mean, if it's asbestos, it is going to be long and thin, and it is going to be respirable.

Q. How many microns long does it need to be in order to create a risk of disease?

MS. DEAN: Objection. Form, overly broad.

THE DEPONENT: I'm not -- I don't know the answer to that question. There are studies that show that longer -- as far as -- and it depends on what the disease is too, but as far as mesothelioma is concerned, there are some studies suggesting that over an average -- an average of over 4 microns are more carcinogenic than fibers under. There's also studies showing that by TEM, a substantial number of fibers in the human lung are -- or pleural tissue are actually below that level.

But as far as having -- I'm not aware of anyone that has said that below a certain level of

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length that asbestos produces no adverse health effects. Plus, in reality, people are getting exposed to a population of different fiber lengths and not just a uniform set, and so there's really no human data on that issue.

BY MR. MASSENBURG:

Q. Are you familiar with the ATSDR's March 17, 2003, Report on Expert Panel on Health Effects of Asbestos and Synthetic Vitreous Fibers: The Influence of Fiber Length?

A. I believe I've seen that before. I'm not sure I could cite any specifics to it without reading it again.

Q. Okay. Do you know who Dr. Brook Mossman is?

A. No.

Q. Okay. As we sit here today, Doctor, are you able to testify to a reasonable degree of medical probability or certainty that asbestos fibers less than 4 microns in length increase a person's risk of mesothelioma?

MS. DEAN: Objection. Form, overly broad.

THE DEPONENT: Well, again, we don't have humans, and so that's when you're saying a person, so I mean, we have the studies of Stanton on rats,

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but even if that paper, they were talking about populations and even Stanton didn't say that below 4 microns, which -- I mean, he even said it was above and below 4 microns, and your question was five.

So, you know, certainly in an animal setting there's certainly evidence that below 5 microns does pose a risk, and, again, I'm not aware of any human study that says that there's zero risk, and, again, it's an unrealistic scenario, since I'm not aware of anyone that has exposed a human to a specific fiber length to see what happens to them 30 or 40 or 50 years later.

BY MR. MASSENBURG:

Q. Do you know of any published or peer-reviewed literature that shows that asbestos fibers less than 4 microns in length increase an individual's risk of disease?

MS. DEAN: Objection. Form, vague and ambiguous.

THE DEPONENT: Again, the only studies that I've seen are going -- with that particular -- because you can't do a human study for that -- are going to be animal studies, and even the Stanton paper, which said that fibers over

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4 microns were more carcinogenic, he did not conclude that the fiber -- the average fiber population of less than 4 microns were not carcinogenic, and I'm not aware of anyone who has come to a conclusion, as far as humans are concerned, that that's true, that there's zero carcinogenicity; it's just presumably less based on animal testing models.

BY MR. MASSENBURG:

Q. Dr. Haber, are you familiar with -- I'll share the screen -- are you familiar with this paper by Dr. Korchevsky and Dr. Wylie published in 2021 in "Inhalation Toxicology," "Dimensional Determinates for the Carcinogenic Potency of Elongate Amphibole Particles"?

I can make it bigger if you need, Doctor.

A. No, I've got my magnifiers on so...

No, doesn't sound familiar. I don't recognize it.

Q. Are you familiar with a paper published in 2020 in "Applied Toxicology," Dr. Wylie, Dr. Korchevsky, Alan Segrave, and Andrew Duane, "Modeling Mesothelioma Risk Factors from Amphibole Fiber Dimensionality, Mineralogical and Epidemiological Perspective"?

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A. I don't recall it. If it's on my Exhibit C, then I would have seen it, but I don't recall it just looking at this one page.

Q. Okay. Are you familiar with the article published in 2015 in the "Journal of Toxicology and Environmental Health," entitled "Methodologies for Determining the Sources, Characteristics, Distribution and Abundance of Asbestiform and Non-Asbestiform Amphibole and Serpentine in Ambient Air and Water," by Dr. Wylie and Dr. Candela?

A. Same answer. I don't recognize it.

Q. Are you familiar with this paper, in "Canadian Mineralogists Journal," by Dr. Wylie, entitled, "Amphibole Dusts: Fibers, fragments, and Mesothelioma," published in 2016?

A. Again, it doesn't sound familiar. And I don't think I recognize the name Wylie, so that doesn't sound familiar to me.

Q. Oh, okay. Do you know of -- this is the abstract I pulled up, the article from 2000, "The Habit of Asbestiform Amphiboles: Implications for the Analysis of Bulk Samples," by Dr. Wylie.

A. Doesn't sound familiar.

Q. Are you familiar with this chapter in "Reviews in Mineralogy and Geochemistry,"

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"Mineralogy of Amphiboles and 1:1 Layer Silicates," by Dr. Veblen and Dr. Wylie, published in 1993?

A. I don't know if I've ever heard of this magazine.

Q. Are you familiar with this article from 1979 entitled, "Fiber Length and Aspect Ratio of Some Selected Asbestos Samples," by Dr. Wylie?

A. What's this published in? Again, I don't recognize it. I can't say that I've never seen it before, but I don't recognize it.

Q. Can you turn to page 15, please, of your declaration, sir.

A. Okay.

Q. In paragraph 34, the last sentence of that paragraph, you say: The occurrence of disease also depends on individual susceptibility.

A. Yes.

Q. Would you agree with me that based on your review of the medical records in this case, you found no evidence that Ms. Moore had a greater susceptibility than the general population to mesothelioma?

A. I don't understand your question. There --

Q. I can rephrase it?

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A. Well, okay. It's nonsensical to me, from a medical perspective, but go ahead and rephrase it, please, sir.

Q. Okay. You found no genetic susceptibility, no tests that indicate that Ms. Moore has a greater risk of mesothelioma than the general population based on any genetic testing?

MS. DEAN: Objection. Vague and confusing.

THE DEPONENT: I don't, A, recall that they did any genetic testing. And B, that's not what I'm talking about in that sentence.

BY MR. MASSENBURG:

Q. What are you talking about in that sentence?

A. So we recognize that you can have -- and this is -- this goes back decades -- you can have two individuals exposed to the same amount of asbestos, for example, two insulators. One of them gets asbestosis; one of them doesn't. One of them gets asbestosis; one of them gets lung cancer. One of them gets asbestosis; one of them doesn't get anything. And they're working side by side, day in and day out, exact same exposures,

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shoulder-to-shoulder working.
And same thing with cigarette smoking. You can have an individual who has the same smoking history as another individual, one person gets lung cancer; another person doesn't. And the reason is is that for reasons we don't understand -- and it doesn't necessarily have to do with any sort of test that we can perform. In fact, generally almost all of the time we don't have any sort of test in science to even see why it is that this happens, but it's a recognized fact that some individuals seem to have a predisposition to a certain response versus another.
I mean, you may have someone who seems to be more of a scar former in their lungs versus someone who seems to be, you know, other reactions. You can -- again, and this is not specific to asbestos, but certainly it definitely applies to asbestos, that there are factors that we don't recognize why but that people can be more sensitive to a particular toxin and have a more exuberant response than another individual.
Q. Other than what you've just stated, you have no evidence from the medical records that Ms. Moore has a genetic predisposition to

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mesothelioma from any testing that has been done or any of the records that you have available to you; correct?
MS. DEAN: Objection. Form, asked and answered, vague and confusing.
THE DEPONENT: Again, you know, as far as -- the few genetic tests that might be done in an individual with mesothelioma, I'm not aware that they were done in her case in particular, since there was no family history of cancers that would make one suspect. But, again, the individual susceptibility issue is not necessarily a genetic one. It could be epigenetic; we just don't know.
But as far as specific genetic testing, I'm not aware that any was done in this particular case. I cannot tell you that there's no evidence that she was more susceptible, because there's never any evidence of why one person gets the disease and another person doesn't.
BY MR. MASSENBURG:
Q. The next paragraph, paragraph 35, the last sentence says: There is an increased susceptibility to cancer from early-in-life exposure to carcinogenic hazards such as asbestos.
Do you see that?

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A. Yes.
Q. Are you of the opinion that earlier exposures have a greater risk or contribution to mesothelioma than more recent exposures prior to diagnosis?
MS. DEAN: Objection. Overly broad.
THE DEPONENT: There's so many factors that are also involved, I can't just give you a yes or no answer. But certainly I am of the belief that in general, younger growing individuals seem to have, in general, increased susceptibility generally, probably because of cellular growth, as we are -- when we're in either childhood or adolescence.
BY MR. MASSENBURG:
Q. Are you familiar with what is generally referred to as the Peto model as far as attribution of earlier exposures as being more significant for causation of mesothelioma, Dr. Julian Peto?
A. Right. I've heard or read that some time ago, but that's not the issue that I'm discussing here. But, again, there's so many -- even with that it -- it's a little bit disingenuous because, yes, the latency is an important issue, but you have to also look at dose.

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You have to look at, you know, are we talking about chrysotile versus amphibole. There's so many other factors that you have to look at. You really can't just say in a vacuum, well, the longer the latency, those ones are more important than a later with a shorter, as long as the latency is sufficient. And even after cancer, continued causation still does genetic changes, and it can affect -- can still affect the clones of the cancer.
Q. I want to go to the next page, page 16 of your declaration.
A. Okay. I'm there.
Q. Paragraph 41: A background incidence of malignant mesothelioma has been estimated to suggest or suggested to be one to two per million per year.
Is that in the U.S.?
A. Yes.
Q. Other data support a much lower background level.
You mean a less than one to two per million per year of background non-asbestos-related mesotheliomas?
A. Well, not nonasbestos. What we're talking

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about is a background of people that -- in just the general population, so it may, in fact, include people that had exposures that were just not -- but they're not -- they're testing a large population, and so therefore, you know, presumably, you know, if you test -- if you've got a million people, they don't, suddenly -- you know, and you randomly are picking them, they're not all insulators, but even if the background doesn't mean that there's no asbestos exposure or there wasn't some from some other source somewhere, but it's not a -- you're looking at, this is the best we can. There is no population that has zero possibility of ever having any sort of asbestos exposure, at least. You know, maybe as time goes on there will be less and less in the environment and certainly less being used.

Q. And, in fact, isn't that what we have seen over the course of the epidemiology studies in populations across the world and specifically in the United States, that as asbestos use has waned, the rates of mesotheliomas in men and women have fallen?

MS. DEAN: Objection. Form, compound, overly broad.

THE DEPONENT: Well, actually it's only

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been very, very recently that the rate in men and women has started to decline a little bit, but there's still very, very high levels.

BY MR. MASSENBURG:

Q. So the general latency I understand from your publications is somewhere in the 30- to 40-year range?

A. Mine was, I think, 48 years, sir, was the mean.

Q. So by the mean, you're talking about not quite average, but from your population that you studied, that many years after the use, after the exposure is when you're seeing the disease; correct?

A. No. Well, no, that's not what latency is.

Q. What do you mean?

A. What I do I mean by what?

Q. By what you said. You said the mean latency for your group that you studied. What do you mean by that?

A. Okay. Well, because you had said I was trying to -- when you said what do you mean, I thought you were asking about why did I say that what you said was wrong.

So the latency is the time from first

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exposure until manifestation of disease, not last exposure until manifestation of disease, which is what you said. So after 48 years on my study, 50 percent, basically, that was the average, so, you know, that the peak, if you will, of occurrence was 48 years. So there's going to be people that get mesothelioma before the 48 years, and there's going to be a lot of people that are going to be getting mesothelioma after that 48 years of latency.

Q. Right.

And 15 was your lowest latency, 15 to 20 years; right?

MS. DEAN: Objection. Form.

THE DEPONENT: I'd have to go back and see where -- you know, in my study which was the absolute bare bones minimum. I don't specifically recall off the top of my head what it was. But generally speaking --

BY MR. MASSENBURG:

Q. Here you go.

A. Okay. Great.

Q. I'll show you the front cover. I'm going to scroll up real quick, so you see what I'm looking at.

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That's you?

A. Yes.

Q. Okay. So I'll take you to Table 4.

A. Right. So out of -- well, 191 of the 238, there was, yeah, one case between 15 and 20, so I don't -- I don't recall where that was in between 15 and 20 offhand, but yeah, so not very, very common to be -- and certainly I didn't have any in that particular study under 15 years.

Q. Okay. And you've touched on that a little bit in my questioning of you in the first day, so I won't -- if I recall correctly -- so I won't hit that again.

But what wanted I to focus on here on paragraph 41 of your declaration, the second sentence says: Other data support a much lower background level.

What other data? What sources are you relying on for that sentence?

A. Well, you know, there -- was just off the top of my head, I think there was a paper by Hillerdal. There have been others by, I believe, IARC, but there have been others that have -- because these data of the one to two per million were dating back from -- I believe, that was a

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paper back in -- by McDonald in the mid-'80s, so that's, like, what, 40 years ago, and I think they've had some more -- some updated numbers that suggest, you know, with less use, that it may be less than that, even.

Q. Okay. Other than the Hillerdal paper and something from IARC, are you able to tell me from your reliance or otherwise any other papers that say there's a lower background incidence of mesothelioma in the U.S. than one to two million per year?

MS. DEAN: Objection to the extent it's asked and answered, also overly broad.

THE DEPONENT: Yeah, I mean, I would just refer you to my list C which, you know -- and, you know, certainly a lot of articles discussing mesothelioma within there. I can't say any more specifically off the top of my head, but I point you to that list C.

BY MR. MASSENBURG:

Q. Okay. All right.

All right. You go on to state in paragraph 42: There is no evidence of a threshold level below which there is no risk of mesothelioma.

Did I read that correctly?

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A. Yes.

Q. And then you say: Mesothelioma has been reported to occur with brief or low-level asbestos exposure.

And the next sentence: There is no completely -- and you put in quotation marks -- safe level of asbestos exposure that has been established.

Did I read that correctly?

A. Yes.

Q. Okay. Do you still agree with me that exposures to asbestos need to be at least an order of magnitude above background levels in order to have a statistically significant increase in the risk of mesothelioma?

MS. DEAN: Objection. Form, vague, overly broad, misstates testimony.

BY MR. MASSENBURG:

Q. Dr. Haber?

A. I'm thinking.

Q. Oh, sorry. Are you reading something?

A. No. I'm thinking.

Q. Okay.

A. But I'm -- actually, I was reading -- partly reading my -- that sentence that you just

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read from my declaration, but I'm also just trying to think here.

The -- in order to have a demonstrable increase over background, the exposure in a large population would need to have exposures that are reasonably above that background such that there's a detectible difference. I don't know what that mathematical number would have to be, but it would need to be demonstrably different than the background; otherwise on a large population, you would not be able to detect a difference.

Q. What is the lowest number in the published peer-reviewed epidemiological literature, to your knowledge, that has been shown to statistically significant -- cause a statistically significant increase in the occurrence of mesothelioma?

A. Well, there are a number of studies showing below .1 fiber per cc years and going down to -- you know, it was basically -- I believe it was between zero -- above zero and below 0.1 fibers per cc years. Again, I think you already just read one of the sentences here, which I already said was, is that there's no evidence of a threshold below which there's no risk, and I've never seen someone put forth any evidence to demonstrate that

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you can have, you know, some sort of safe level when it comes to carcinogenicity.

Q. What do you mean by no risk?

MS. DEAN: Objection. Form.

THE DEPONENT: That it's safe. I mean, so that -- where you're -- you have no risk of getting disease from exposure to asbestos. OSHA and others and the scientific literature has never established any sort of level that you can say, okay, you don't have any risk. You can, you know, as long as you're below this level, you're A-okay. There's never been any sort of established level. And, again, there are plenty of papers, case reports and case series, showing very low, very brief low-level exposures were capable of inducing mesothelioma.

BY MR. MASSENBURG:

Q. What is the level of exposure established through medical science to date and published and peer-reviewed literature of a level of exposure to radiation that has no risk?

MS. DEAN: Objection. Form, incomplete hypothetical, overly broad.

THE DEPONENT: Risk of what?

BY MR. MASSENBURG:

Q. Cancer.

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MS. DEAN: Same objections.
THE DEPONENT: You know, I don't think I can -- I couldn't tell you the answer to that because it is -- that's so broad.
BY MR. MASSENBURG:
Q. Is there a risk of cancer from getting x-rays?
MS. DEAN: Objection. Form, overly broad, vague and ambiguous to cancer. Dinosaur.
THE DEPONENT: Again, I don't -- I'm a lung doctor. As far as other cancers, you know, I'm really not going to be able to tell you, as it's outside of my area of expertise. It also depends upon what type of x-ray, what type of radiation. There's a lot of different factors involved.
(Reporter clarification.)
MR. MASSENBURG: She said dinosaur, I think.
MS. DEAN: The word dinosaur was included. I'm going to be seeking sanctions, and so that's a kind of a QN word, but I'm not sure if you missed anything else. Sorry.
We've also been going for about an hour, including an hour from when I was trying to get a

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hold of the Court, so when we get to a point where we can take a break, I need to go to the bathroom.
MR. MASSENBURG: Yeah, we can take a break now.
MS. DEAN: Okay.
(Whereupon, a recess was held from 10:34 a.m. to 10:47 a.m.)
BY MR. MASSENBURG:
Q. You ready, Dr. Haber?
A. Yes, I am, sir.
Q. Do you agree with me that there are no published or peer-reviewed studies in the scientific literature, to your knowledge, that show an increased incidence of any form of cancer from chest x-rays?
MS. DEAN: Objection. Form, overly broad.
THE DEPONENT: I'm not sure I can answer that as far as any cancer, so I don't know.
BY MR. MASSENBURG:
Q. Do you know of any safe -- and I'll use the same -- in the same form that you're using it in 42. Do you know if there is a completely safe level of radiation exposure that has been established in regards to any form of cancer?
MS. DEAN: Objection. Overly broad,

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particularly in terms of scope of cancers.
THE DEPONENT: Again, you know, there may be issues as far as other cancers like skin cancer or other things that I'm just not up on because it's not my area of expertise, so I don't really think I can answer as far as any cancer, sir.
BY MR. MASSENBURG:
Q. To your knowledge, based on your specialty and your review of the medical and scientific literature, is there any completely safe, in quotation marks, level of radiation exposure that has been established?
MS. DEAN: Same objections.
THE DEPONENT: I don't know.
BY MR. MASSENBURG:
Q. Can you name and identify any exposure to anything that we as humans encounter, anything that is completely safe?
MS. DEAN: Objection. Extraordinarily overly broad, vague and ambiguous.
THE DEPONENT: I would probably say the air that we breathe, as long as it's not contaminated with dangerous toxins would be safe. Without it, we die.
(Reporter clarification.)

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BY MR. MASSENBURG:
Q. It's your expert opinion that the air that we breath, absent some solution or toxic agent in that air, is completely safe?
MS. DEAN: Objection to the same thing. Safe from what? Safe in what regard, to what disease? Incredibly overly broad.
I'm very close to suspending the deposition as to Chanel.
THE DEPONENT: Yeah, as opposed to diseases like mesothelioma from asbestos where we recognize that low levels cause disease, I've never heard of any scientific basis for me to say, to a reasonable degree of medical certainty, that the air that we breathe is unsafe.
BY MR. MASSENBURG:
Q. And that's slightly different. So I'm not asking whether you're saying -- I can say something is unsafe. But your words are -- and this is paragraph 42: There is no completely, and then you put in quotation marks, safe level of asbestos exposure that has been established.
What I was asking is, is there any exposure to anything that any of us encounter that is, quote, completely safe?

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A. Well --
MS. DEAN: Let me -- sorry.
Let me state the same exact objections and to some extent, asked and answered.
THE DEPONENT: Right. In this context, I was talking about the development of mesothelioma. There's no evidence that air causes mesothelioma absent contamination with asbestos or some other substance that causes mesothelioma. So yes, in the context that I've written here in paragraph 42, air and a lot of other things are going to be completely safe when it comes to development of mesothelioma, which is what we're talking about today.
BY MR. MASSENBURG:
Q. So what you mean by safe is the same thing you mean by no risk?
MS. DEAN: Objection. Form, vague and ambiguous.
THE DEPONENT: Well, it even says no risk of mesothelioma. That's what the first sentence in paragraph 42 specifically says.
BY MR. MASSENBURG:
Q. Right. And the third sentence says completely safe. So I'm trying to find out if you

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what mean -- because you wrote this -- whether what you mean by safe is no risk.
A. Of mesothelioma.
Q. Okay.
A. But, again, we do recognize -- you know, we don't know -- we recognize that low doses are dangerous of asbestos. We don't know how low, but we certainly have evidence that very low doses, very brief doses are sufficient to induce mesothelioma.
Q. Okay. Then let me make it more specific as to radiation.
Based on your review of the published and peer-reviewed literature, do you know of any level of exposure to radiation that is completely safe as to mesothelioma?
MS. DEAN: Objection. Form, overly broad, vague and ambiguous, relevance.
THE DEPONENT: I'm not aware of how much radiation -- and, again, this is not a radiation that particularly is pertinent to today, but in the past, there's -- I'm not aware of any sort of study that looked at the level, so I have no idea what the levels that were felt to be related there -- these were typically case reports that had people

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that had gotten radiation that -- again, that was the type that was no longer in play today, but as far as what the dose was, I don't know. It's certainly not an issue in this case because Ms. Moore, there's no evidence that she had any sort of radiation.
BY MR. MASSENBURG:
Q. Do you know whether she had any x-rays and therefore was exposed to radiation in her chest at any time in her life?
A. I know that she had chest x-rays and CAT scans, but there's no evidence at all that -- of development of mesothelioma from getting an x-ray or a CAT scan that I'm aware of.
Q. Okay. So would you agree with me that the amount of radiation that a person encounters from getting a CAT scan or a chest x-ray is not sufficient to induce mesothelioma, based on your review of the published and peer-reviewed literature?
MS. DEAN: Objection. Form, incomplete hypothetical.
THE DEPONENT: No. I'm saying that the problem with when you start getting into a question like that is that you'd have to have a study that

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is so huge to be able to detect a change. I just -- I've never heard of anyone stating that there's a risk of mesothelioma from getting a chest x-ray or CAT scan. I can't tell you that -- if there is a risk I wouldn't know. I've never -- I don't have any studies to be able to support that -- what that level of risk would be, if there is one.
BY MR. MASSENBURG:
Q. Understood.
I'm sharing with you my screen, Dr. Haber, I'm showing you a deposition in the James Robert Rittenberry, R-i-t-t-e-n-berry, versus Guardline, Inc. case, January 30th, 2006, oral deposition of Steven E. Haber, M.D., FCCP.
Is that you?
A. Yes.
Q. I'm going to take you to page 27 of the deposition testimony. You're being asked here -- and I'll give you the full context. It's asked about thresholds and minimum levels of exposure that cause asbestosis, lung cancer, and mesothelioma -- or 29, I think.
All right. And let me make sure I've got my -- yeah.

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Page 28, line 19, just for context: Let's start with asbestosis. What's the dose for asbestosis?

And you go on to answer.

Do you see that, lines 21 through 25?

A. I do.

Q. Okay.

MS. DEAN: Could you send me this transcript?

MR. MASSENBURG: I will want it now.

MS. DEAN: Yes.

MR. MASSENBURG: Yeah. All right. Typing, typing, typing. All right. Jessica, it's out to you.

MS. DEAN: Thank you.

MR. MASSENBURG: You're welcome.

BY MR. MASSENBURG:

Q. Dr. Haber, your answer was: To any sort of increased number -- I'm sorry.

To see any sort of increased number for asbestosis, bare bones minimum, you're looking in around 10 fibers per cc year, and that's not a statistically significant; that's just below that you're not going to see a case.

Did I read that correctly?

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A. You did. But I no longer agree with that. There's been more recent data that that's not correct anymore.

Q. Okay. And you go on and they ask you about, same question for mesothelioma, page 29, lines 6 through 14.

And your answer -- and, again, this is to be clear, what is the dose below which you don't see disease, the same question for mesothelioma: I don't think anyone knows what the absolute floor is. Realistically and reasonably, it's greater than 1 fiber. I think most of the studies you see heightened amounts of mesothelioma in people where they're getting objective evidence, such as with asbestos-related pleural disease so, you know, somewhere around 4 or 5 fiber years could increase your risk of mesothelioma.

Did I read that correctly?

A. You did. And I would disagree with that as well. I think the data, as I've cited to in my declaration I've already talked about in this deposition, shows that you get statistically significant risks well below that level.

Q. Okay. And when you say in this paragraph asbestos-related pleural disease, you mean pleural plaques; correct?

A. Yes. Well, it can be pleural plaquing, pleural thickening, pleural effusion. Those are all asbestos-related pleural disease, and they do have very similar exposure levels as it does for mesothelioma as opposed to asbestosis.

Q. Okay. And you're asked about lung cancer, and there's a discussion about that. I want to take you to page 31 and line 1.

MS. DEAN: Chris, what you sent won't open.

MR. MASSENBURG: It's an E-tran. That's the only format I have it in. Do you have E-tran as a viewer?

MS. DEAN: Apparently not, and I converted the text. It looks like gibberish.

MR. MASSENBURG: Hold on. Let me see if I -- all my copies are -- let me do a separate search.

I'll send this to you, Jess. It looks like it's the same thing, and I think it's PDF.

MS. DEAN: Thank you.

MR. MASSENBURG: No problem. Let me know if you have any trouble with that one.

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BY MR. MASSENBURG:

Q. Okay. Dr. Haber, starting with page 31, line 1 -- I've got that on the screen -- the question to you was: For mesothelioma, it's your opinion that there is no known floor threshold at which exposure to asbestos increases one's risk for developing mesothelioma.

And your answer was: Well, the problem with trying to get a study at very low levels of exposure is very difficult to do, if not impossible. And there's really -- there's no way to be able to ascertain, but if you look at studies of mesothelioma that are attributable or attributed to asbestos, usually these people have evidence of -- objective evidence of their exposure such as, at a minimum, pleural disease, and that's not to say you couldn't attribute it, but that's just getting into the general low end, in my opinion, where you can start seeing a statistically significant increase in mesothelioma would be in around that area. It might be that it's a little lower, but there are no data, and so it would be -- it would be just supposition at below that level.

Did I read that correctly?

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A. Yes.
Q. What new studies since this deposition in 2006 do you rely on that changes your opinion as you've expressed it in this testimony?
MS. DEAN: Objection. Form, overly broad, misstates testimony.
THE DEPONENT: All right. So first off here, I'm just going to reread this as far as what it says here. It says that it's difficult to get studies at low level. I think that is still true that I agree that the development of pleural disease is plus or minus in the range that you can still get a risk for meso.
I would point you to Mensi's article in 2016 or '17 or so, a huge study of mesothelioma cases, over 4,000 cases that showed the minority of mesothelioma cases, only like -- it was under 20 percent; I don't remember the exact number -- but it was the minority of cases had pleural disease. So I don't think that it's true that the majority have pleural disease.
And then, again, the rest of that was just talking about the fact that you can get pleural disease and meso at a significantly lower dose than we were previously talking about in this deposition

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as far as asbestosis is concerned.
BY MR. MASSENBURG:
Q. Okay. Besides the Mensi article, are there any other articles that you rely on that inform your opinion that changes your testimony as expressed in the deposition in the Rittenberg [sic] case from 2006?
A. Well, I'm sure --
MS. DEAN: Objection. Sorry.
Same objections, plus to some extent, asked and answered. Sorry.
THE DEPONENT: I think the one that I just cited, but -- as far as not needing pleural, but there are other articles that stand for the same proposition, that you don't have to have pleural disease. If you look at Helsinki, 2014, you know, Helsinki criteria say that you don't have to have pleural disease; you can just go, you know, based on the history of occupational or environmental or para-occupational exposure to asbestos suffices.
And there are, you know, other articles on mesothelioma citing the same proposition of Helsinki. So, again, I don't think that it's true that you have to have pleural disease, but, again, the levels are such that you certainly could be at

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risk for pleural disease if you have mesothelioma.
BY MR. MASSENBURG:
Q. And as you expressed here, the levels that put you at risk for pleural disease, on page 29 lines 13 through 14: So, you know, somewhere around 4 or 5 fiber years would increase your risk of mesothelioma.
That's the level that increases your risk of pleural disease; correct?
A. No. Again, as I said the -- you know, if you look at Lacourt, you look at Jiang, you look at all these studies -- and they're in my declaration in Exhibit C -- but there's a number of studies that have shown that you can have a significant risk of mesothelioma well below 4 or 5 fiber years. And there are also studies showing that you're at risk for asbestos-related pleural disease below that level as well.
Q. What is the study you rely on for the level of .1 fiber years, as you expressed in your testimony earlier, showing an increase -- statistically significant increased rate of mesothelioma?
MS. DEAN: Same objections.
THE DEPONENT: So my recollection is going

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to be Lacourt, and then I think -- I'm pretty sure -- I'm not sure how they pronounce it but, J-i-a-n-g, Jiang. It was just a year or two ago or three years ago out of China, and this was chrysotile asbestos.
(Reporter clarification.)
BY MR. MASSENBURG:
Q. Dr. Haber, would you agree with me there are several publications in the literature with Dr. Lacourt as leading author?
A. Probably. But all you'd have to do is just look at my -- if you want to know the specific title, it would be within my Exhibit C. My recollection it's been within the past six or seven years, so it was past -- it was later than this deposition as well.
Q. Yeah, there are some -- generally, my recollection, my knowledge is Lacourt 2014 has certain references that there are a few studies from that year. I'll look at your reference list. I won't belabor that point. I just want to make sure I had the authority you're relying on there.
A. Okay.
Q. In this deposition in 2006, you go on to state -- the question is on line -- page 31, line

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20: And so your opinion is one that aligns with OSHA's opinion, that there is no known safe level of exposure to asbestos with respect to the development of mesothelioma.

That was the question posed; right?

A. Yes.

Q. And your answer was: Well, I think from all -- from a practical and reasonable standpoint, there is.

Meaning there's a safe level; right?

MS. DEAN: Objection. Form.

THE DEPONENT: But then I go on to say that I can tell you what it is, and --

BY MR. MASSENBURG:

Q. Yes, sir. I just want to make sure -- I just want to make sure when you say there is we're talking about the same thing. At the time, at least in 2006, you're saying from a practical and reasonable standpoint, there is a safe level?

MS. DEAN: I ask that the witness be allowed to complete one answer before the next question is posed.

BY MR. MASSENBURG:

Q. Did I interrupt you, Doctor? I'm sorry.

A. Yes, you did.

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I was saying that earlier on, one of these other paragraphs we were just answering here, I had said, well, 1 fiber, there's no evidence that 1 fiber would cause a problem. And I said that I wasn't saying that 1 fiber was an unsafe level. I'm just saying that there's been no safe level that's been established.

You can't study somebody who -- you know, a group of people who have all been exposed to 1 fiber or 2 fibers or whatever the dose -- low dose is. So I'm telling you I don't know what it is. I'm still saying, you know, that there probably is one. How ridiculously low that is, again, once you start getting into levels that are not appreciably different from a background, given, although, that the background is small fiber, less than 1 micron generally, and chrysotile.

But, you know, if you're looking at, you know, a similar type of exposure, once you start getting very, very small exposures, you need huge, huge populations to be able to depict the risks, and there's no studies that can follow millions of people like that.

Q. All right. You go on to complete your answer. You say: I can't tell you how many fiber years or how many years that is because those data are not available, but I think for all practical and reasonable purposes, there is a floor.

Did I read that correctly?

A. Yes, you did. Just not one that's been established, and I did didn't know what it was then. I still don't know what it is today.

Q. Okay.

MS. DEAN: Someone has a dinging that's occurring, that -- if they can turn that off.

THE DEPONENT: I'm afraid that actually might be me, but I don't know.

MS. DEAN: Dr. Haber.

THE DEPONENT: I don't know where that's coming from, but I'm hearing it and unless it's somewhere else and --

BY MR. MASSENBURG:

Q. Sir, and I'm not disclaiming -- there's not sufficient evidence for me to say that it's not me. I don't know either, so we'll just leave it at that.

MS. DEAN: If there's a way to turn if off, that'd be great, but if not, that's fine.

MR. MASSENBURG: I'll say this. I can't mute my computer because then I can't hear you, but

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my phone is muted, so I at least have that going on.

BY MR. MASSENBURG:

Q. Let me just do it this way, Doctor. So this is --

MR. MASSENBURG: And this one, Jessica, I only have by E-tran. I don't know what to do, but I'll try to convert these to PDFs at a break.

BY MR. MASSENBURG:

Q. But, Doctor, I'm going to show you deposition of Dr. Haber, yourself, February 2013 in the Gerald Crawford-Toon, Crawford hyphen T-o-o-n case.

Do you recall that case offhand? I can try to pull up the plaintiff's expert -- I mean the plaintiff that was there. But ring any bells? It was in Houston, Texas.

A. Well, that's where I live, but --

Q. Well, I'm taking you here specifically and the questioning is along the same lines, and I'm specifically going to page 55 and they ask you on line 21: What do you mean by a non-de minimis -- what do you mean by non-de minimis reasonably above background.

And your answer on lines 23 through line 6

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on page 56 is: Well, there are -- we don't know what the threshold -- there is no known level below which asbestos cannot cause mesothelioma, but in order to be able to determine that there was an increased risk, that exposure needs to be significantly above or recognized above what we term a background level, is that there's asbestos -- low level of asbestos in the air that we all breathe, so I need to see an exposure level that is recognizably above that level.

Did I read that correctly?

A. Yes. Which pretty much says what I already testified to today, that if you're -- in order to look at from a -- to establish some sort of a statistical analysis, unless you have some huge, huge, huge population, you need to have levels to be able to compare to the background rate.

Q. Okay. And then this is in the Carl Nix case, I'm showing you now. This is in -- I'm sorry Russell Nix case, May 24, 2011, your deposition, and I'm taking you specifically to page 206 of that deposition, and they ask you kind of an open-ended question, and I wanted to talk about your explanation. We can start above it, just for

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context.

I'm asking about a general scientific proposition but you can apply it to mesothelioma if you like.

You go on to explain -- and I'll give you a second to read that, but my questioning really focuses starting on line 17 of page 206.

A. Could you -- let me just see if I can just -- could I go up a little bit more on page 2-0 -- right there. Let me just stay there for a second.

Q. And I can increase the size a little bit as well.

A. No, no. It's fine. It's fine.

Q. Let me know when you're ready; I'll go back down to the --

A. I will.

Q. Yes, sir.

A. Okay. Move down a little bit again.

Q. Okay. I'm going to move down until it gets to 206, 1. All right. And the question I want to focus on, Doctor, when you get there is 206, line 17. And as you're reading, if you don't mind, I'll read just so we don't have just silence.

Can you give me an example of anything

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we've been talking about today, particularly issues of how much it takes to cause mesothelioma, et cetera, where you may have changed positions?

Your answer: That, I don't think I've changed my position. I've always felt you can get mesothelioma at a low dose.

Question: All right. Have you ever taken the position in the past that it would take 4 to 5 fiber per cc years to increase the risk of mesothelioma?

Scroll down and get to your answer.

Your answer: I think what I said -- and this is -- I mean, we're talking seven years or six or seven years ago -- that the order of magnitude was on the order of magnitude that one sees for causation of asbestos-related pleural disease rather than asbestosis and that you can see asbestos-related pleural disease as low as 3 fiber years.

Did I read that correctly?

A. Yes.

Q. You go on to say: I don't think I've ever said that it was impossible to get either of those diseases with less, but I think I was just giving a general order of magnitude.

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Did I read that correctly?

A. Yes.

Q. Is that still your opinion today, Doctor?

A. Is what my opinion? There's a lot of things here.

MS. DEAN: Objection. Form.

BY MR. MASSENBURG:

Q. What you discussed in the answer from lines to 2 to 11?

MS. DEAN: Objection. Form, compound, overly broad ambiguous.

THE DEPONENT: Okay. So the question was had I ever taken the position that it would take 4 or 5 fiber years to increase the risk, and my answer was that I don't know if I had said something like that a long time ago six or seven years before but that it's still my opinion that you can get mesothelioma and asbestos-related pleural disease at orders of magnitude far below that that you -- that seem to be necessary for asbestosis. And, again, it looks like I even -- and giving reference to the fact of that Rottenberry [sic] 2016 where I said I think I was just giving general orders of magnitude issues here. So, you know, a difference of magnitude

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between asbestosis and mesothelioma, as far as causation, the amount of asbestos.

Q. Is your opinion no longer today that for -- as to causation of mesothelioma, that it would have to be of the order of magnitude that one sees for causation of asbestos-related pleural disease rather than asbestosis and that level is as low as 3 fiber years?

MS. DEAN: Same objections. Compound, to some extent, asked and answered.

THE DEPONENT: Well, first off, I think you're misinterpreting -- I'm talking about -- the low as 3 fiber years was talking about, I think, when he was talking the 4 or 5 and that was talking about in the past. No, as I've already said before that, you know, you can get mesothelioma at levels below this.

I say again that, you know, you can -- and I don't think I've ever said it was impossible to get these with less, and I do leave that the evidence -- the science shows that you can get both ARPD and mesothelioma at levels below 3 fiber years.

BY MR. MASSENBURG:

Q. You go on to state on page 208, lines 7 through 17, question is -- well, it looks like it has a -- reading the question before, it looks like it has an answer no, question mark, and then a statement that reads as a question, so let's just read it for context.

I'm saying it the other way around, is the question. Have you taken the position that you need to see objective evidence of pleural plaques before you would conclude that the exposure increased the risk of asbestos-induced disease.

I read your answer as no, and that you're not answering with a subsequent question after that answer. Am I right?

MS. DEAN: Object to form, calls for speculation.

(Noise interruption.)

(Reporter clarification.)

MR. MASSENBURG: Ed -- Ed, can you mute.

MR. ULLOA: Yeah, sorry.

BY MR. MASSENBURG:

Q. The way I read it, Doctor, is that on line 7 after the answer of "no," there's another question: Have you taken the position that attributing causation to asbestos, mesothelioma below 3 to 5 fiber -- fibers per cc years would be supposition.

And your answer: I don't know if that was data before more recent studies that we've just been talking about show lesser exposures, but I guess it would depend on the individual -- on the individual case, but I think there are more recent data -- that if I said that in the past, that would show that, and I think I've always said that we've never -- we've never known how low the exposure can go before there's no increased risk.

Is that still your opinion today?

MS. DEAN: Objection. Form, overly broad, vague and ambiguous, compound.

THE DEPONENT: Wait. Again, so, you know, so this was from 2011, you know, three years even before Lacourt. But, again, I think I'm saying very similarly that there's not been an established dose that doesn't increase your risk but that certainly as more science evolves that we are finding increased risk at lower and lower doses.

BY MR. MASSENBURG:

Q. Let me make sure I'm clear, as far as the last sentence. But I think there are more recent data that -- if I said that in the past, that would show that, and I think I've always said that we never -- we've never known how low the exposure can go before there's no increased risk.

As far as that last two lines, we've never known how low the exposure can go before there's no increased risk, is that still your opinion today?

MS. DEAN: Same objections.

THE DEPONENT: Well, this is -- I don't even know if there was -- you know, because this whole sentence doesn't even make sense here. I don't know if there was some sort of correction to this or what. I don't really understand what this is, but to me, this is saying that -- what I've been saying here all along, that as science has evolved, we're finding lower and lower doses causing, you know, establishing significant risk.

BY MR. MASSENBURG:

Q. Doctor, based on what you have been provided and what you've read specifically to -- as to Ms. Moore, are you of the opinion that she had direct exposure to asbestos from cosmetic talc use?

A. Yes.

Q. Are you of the opinion that she had daily exposure to asbestos from cosmetic talc use?

A. Yes.

Q. Are you of the exposure [sic] that she had

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heavy exposure to asbestos from her daily talc use?
MS. DEAN: Objection. Form, vague, ambiguous, confusing.
THE DEPONENT: Am I of the -- I don't think you said opinion, so if you could maybe rephrase your question.
BY MR. MASSENBURG:
Q. Right.
Are you of the opinion that Ms. Moore had heavy exposure to asbestos from her daily use of cosmetic talc?
MS. DEAN: Objection. Form.
THE DEPONENT: Well, I -- you know, I don't know what you mean by heavy, and -- you know, I mean, in comparison to what? I think in comparison to, you know, short fiber chrysotile at the level, you know, less than -- generally less than 1 micron chrysotile that's in -- of levels that are in the air, yeah, I think her exposures were significantly above that. Compared to, you know, an insulator who is, maybe, working, you know, cutting amphibole pipes every day, no. But even Selikoff was -- you know, he called those people light, so it just depends on what you're comparing it to.

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MS. DEAN: And let me -- I said objection. Form. But let me say compound, overly broad as to time, vague.
BY MR. MASSENBURG:
Q. What are the levels of exposure at a fiber per cc level that insulators were exposed to, from your review of the published and peer-reviewed literature?
MS. DEAN: Objection. Form, vague as to time.
BY MR. MASSENBURG:
Q. You can give a range, of course.
MS. DEAN: Form, overly broad.
THE DEPONENT: I mean, it would depend upon what the insulator is doing, what specific material that they're working with, what the percentage of the asbestos in the material, even if they're working with any asbestos material, so I'm not sure I can give you a specific number. It would just depend on the circumstance.
BY MR. MASSENBURG:
Q. Do you -- are you familiar with the publication by Dr. Selikoff and Dr. Seidman regarding the insulators they followed, the cohort they followed of over 17,000 insulators?

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A. Right. I've seen a lot of the Selikoff papers over the years. I'm not sure I can -- which particular paper you're referring to, but yes, I'm aware that Dr. Selikoff and others followed the number of over 17,000 insulators in the United States and Canada.
Q. And the first publication was in the mid-1960s as to that cohort, and they continued into the 1990s; did they not?
A. Well, actually, there's been publications into the 2000s of that same cohort.
Q. Okay. And several of those --
MS. DEAN: I -- sorry. You know, there was an agreement to finish day two, two full days. If defendants wait and allow Chanel to ask four to five hours of questions about insulators, x-rays, and verifying numbers in published that he doesn't rely on, you're making a choice. We're not going to offer another day.
BY MR. MASSENBURG:
Q. Dr. Haber, my question to you was, do you recall that in several of those studies by Dr. Selikoff outlining the -- outlines the exposures to those insulators from the various crafts -- I'm sorry -- various operations in both

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construction and onboard ships; correct?
MS. DEAN: Objection. Form, vague as to time.
THE DEPONENT: I don't recall.
BY MR. MASSENBURG:
Q. Okay. Do you generally rely on the publications by Dr. Selikoff to inform your opinions as to asbestos and asbestos disease, mesothelioma?
MS. DEAN: Objection. Form, overly broad, vague, ambiguous.
THE DEPONENT: Well, as it pertained to the insulator cohort and as it pertained to information at the time. A lot of the citations that I've cited to from Selikoff, you know, has been information that we know now has been changed or modified or even proven wrong. But certainly from a historical perspective, I've certainly relied on the work and particularly, like I said, related to the insulator cohort.
BY MR. MASSENBURG:
Q. Would exposures to asbestos from cosmetic talc at a level of 6 fibers per cc every day for 30 years be a heavy exposure, in your opinion?
MS. DEAN: Objection. Form, incomplete

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hypothetical.
THE DEPONENT: For what period of time?
BY MR. MASSENBURG:
Q. I just said 30 years.
A. So 24 hours a day for 30 straight years?
Q. No.
A. Eight hours a day? What are we talking about?
Q. No. An exposure -- somebody powdering themselves with cosmetic talc every day and being exposed to asbestos at 6 fibers per cc during that powdering every day for 30 years, would that be a heavy exposure to asbestos, in your opinion?
MS. DEAN: Same objections.
THE DEPONENT: Again, that would certainly be a significant exposure depending upon -- you know, assuming that it's going to be a minute, two minutes, three minutes, whatever that exposure would be, plus the compounding of additional exposures once you start getting asbestos contaminated within the home. Well, we know that, you know, this is a powdery product in an indoor situation without respiratory protection, generally; I think that's safe to assume that someone's not going to be wearing a mask while

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they're putting on talcum powder.
Then, again, depending upon, you know -- so those are -- that's a level of exposure that is substantially, thousands-fold above -- tens of thousands fold above background, if not even more, so that compared to the background, which again -- and then we're also talking about amphiboles involved here, which are, you know, probably mesotheliogenic and certainly than, you know, short fiber we were talking about earlier here, chrysotile of less than 1 micron. Compared to a background, yeah, that's -- that's quite heavy. Compared to someone who was doing some different job in the 1940s, then it might be it just depends what the comparator it.
BY MR. MASSENBURG:
Q. Showing you the screen, Doctor. This is your article from 2011, "Malignant Mesothelioma: A Clinical Study of 238 Cases"; right?
A. Yes.
Q. You distinguish between various types of exposures in your article including moderate and heavy exposures; correct?
A. Right. Those were, again -- these were -- this was not with an industrial hygienist, and

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these were based on some of the doctors that were seeing the cases, trying to describe them in a relative qualitative sense based upon these were primarily people that were in heavy industry in the shipyards and in the refinery industry and in the Houston and shipyard areas.
Q. Okay. But you stated in here that you had individuals who had been exposed to asbestos -- let me just -- I'll start and we'll get there. This is on page 167. It's the second page of seven pages of your article.
Under occupational setting and exposure, it reads -- and I've highlighted: In the mesothelioma cases with a history of occupational asbestos exposure, there was a 35 to 1 male to female ratio. In those cases with non-occupational asbestos exposure, there was a female preponderance with a female to male ratio of 8 to 1.
In that second sentence, Doctor, do you mean para-occupational take-home exposures?
A. I don't know if those were -- I mean, back then we weren't questioning about talc use, what -- the questioning -- and again, this may have been -- you know, a lot of these were taken from histories from other physicians that had done the history,

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but there was no recognized occupational source so the -- I guess it was considered to be either a take-home or some other non-occupational source. I don't recall.
Q. You don't recall what you meant by non-occupational exposure?
A. It would have been something that wasn't from their own occupation. I don't recall whether it was solely from a husband or someone else's take-home or if there was some other source, but I know that we weren't asking -- no one was asking about talc use in that paper.
Q. Okay. Yeah, there's no reference to any potential exposures from nonasbestos sources including any exposure to talc; right?
I'm sorry. Did you --
A. I don't know what you mean by nonasbestos exposures. But the issue was primarily looking at, in this paper, 91 percent of them were occupationally exposed. We had a lot of, again, pipefitters and insulators and welders and shipyard workers.
Q. Pipefitters and welders and shipyard workers and insulators, those were heavy exposed individuals; correct?

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MS. DEAN: Objection. Form, compound, overly broad.
THE DEPONENT: Based on our somewhat qualitative assessment, based on the described exposure histories and, again, as a comparative to some of these other exposures. We grouped people into those three groups.
BY MR. MASSENBURG:
Q. Right.
It says: Of all men, 97.8 percent had a history of occupational asbestos exposure in contrast with only 23.8 of women.
Did I read that correctly?
A. Where are you reading?
Q. The last sentence.
A. Yes, yes, yes.
Q. That's highlighted. Okay.
A. Right.
Q. And you go down and you talk about, under exposure data: Based upon the patient's lifetime occupational history and details of their asbestos exposure including intensity, frequency, nature, and duration, the TOMI, T-O-M-I, all caps, physician was able to categorize the exposure as heavy, moderate, or light in most cases.

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Did I read that correctly?
A. Yes.
Q. Most individuals with mesothelioma in our series had heavy asbestos exposure, 50 percent, followed by moderate, 37.1, and then light, 12.9 percent.
The next thing I wanted to focus on, Doctor, is the bottom of this page carrying to the next: The estimated exposure strongly correlated --
You have to get through all the charts here and then follow the yellow.
-- with the presence of asbestosis.
66.1 percent of the folks in your group here that had heavy exposure had asbestosis; correct?
A. Yes.
Q. 32 percent of those who had moderate exposure had asbestosis?
A. Yes.
Q. And less than 2 percent who had asbestosis were the light exposure folks; right?
A. Less than two percent of the light exposures had asbestosis.
Q. Correct. I -- thank you.

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You go on to state in your article: The level of exposure also correlated with the presence of radiographic pleural plaquing.
Is that a pleural disease?
A. Yes.
MS. DEAN: Objection. Form.
BY MR. MASSENBURG:
Q. Those with heavy asbestos exposure had plaques in 57.4 percent of cases. 37 percent of moderate exposed had pleural plaques, and 5.6 of light exposed had pleural plaques.
Did I read that correctly?
A. Well, you kind of -- sort of.
Q. I won't belabor it because it reads there. I guess that's -- if you take issue with how I read it, I appreciate that.
Most individuals in our study with occupational exposure had daily 61.7 percent rather that weekly, 18.9 percent or intermittent, 19.4 percent asbestos exposure.
Did I read that correctly?
A. Yes.
Q. Those with daily exposures were more likely to have a heavy exposure 70.2 percent than those with weekly or intermittent exposures. As

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with degree of exposures, frequency correlated with the presence of asbestosis and pleural plaques.
Did I read that correctly?
A. Yes.
Q. You did this as a qualitative assessment as far as quantifying it's heavy, moderate, or light exposures; correct?
A. Correct. Based on the -- the frequency, the intensity, the nature, the duration of the exposures. And, again, so there may be people who were light or heavy that -- or whatever they were in this group but a different group might -- they might not correlate with this. This is just the way we kind of split these, again, that the majority of these were the more heavily exposed shipyard workers, pipefitters, insulators, that sort of thing. And so based on their description, we called them heavy and then went down to moderate and light.
Q. Okay. You're familiar with and you rely on the article in 2014 by Dr. Gordon, Mr. Fitzgerald, and Dr. Millette "Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in women"; correct?
A. Yes.

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Q. And they outline the exposures from their application experiment; correct?
A. Yes.
Q. They even have nice pictures. Have you seen the videos associated with this powdering experiment?
A. I think you or someone else last week asked me that and I said no.
Q. Okay.
MS. DEAN: Asked and answered.
BY MR. MASSENBURG:
Q. Their range here on page -- sorry. I need the page number -- it's the 6th page of 15 under Figure 4: Short-term samples in the breathing zone of the applier had a PCM value of 60 fibers per cc.
Do you see that?
A. Yes.
Q. In your opinion, as described here and outlined in this study, would that exposure and the exposures outlined from use of the powder puff with asbestos-contaminating cosmetic talc powder every day for 30 years be a heavy exposure to you, qualitatively?
MS. DEAN: Objection. Form, overly broad.
THE DEPONENT: I'm not -- and so first

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off, I mean, this goes on talking about the TEM derived percentage of asbestos, and it gives us 13 fibers per cc. And so are you asking is an asbestos exposure of 60 fibers per cc heavy or what are you asking?
BY MR. MASSENBURG:
Q. I'm going to break them down one at a time so I don't get a compound objection, Dr. Haber.
First, right now I'm asking you if an exposure of PCM measurement of asbestos-contaminated cosmetic talc at 60 fibers per cc every day for 30 years, as Ms. Moore described her applications of cosmetic talc powder, in your expert opinion, qualitatively, is that a heavy exposure?
A. Again, it would be --
MS. DEAN: Same objection. Sorry.
THE DEPONENT: -- substantial exposure because it's far above background. But as far as what -- how to describe it from a qualitative perspective would depend upon what the comparators are, what the rest of the group.
BY MR. MASSENBURG:
Q. What do you mean what is the rest of the group?

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A. Well, in my study and when you're talking about -- again, we had people that we called heavy, moderate, and light. I guess I could have called them moderate, light, and very light you know or 1, 2, 3, and 4, but, you know, if you -- a heavy exposure in one group of people of, you know, whatever their exposure was and if you're looking at -- but it depends upon, like I said, what the population of people that you're looking at with that -- with some exposure.
A 60 fibers per cc exposure to asbestos would be, you know, very heavy in some circumstances, and it may, I suppose, not be, depending upon -- it may be moderate. You know, it just depends on what the -- what the duration of exposure is, the frequency, the regularity, but certainly that's a substantial level. But how it compares to heavy, quote/unquote, depends upon compared to what exactly. Compared to background, yeah, that would be heavy.
Q. Okay. So I want to make sure I'm clear. I want you to -- my question is specifically as to 60 fibers per cc of exposure from powdering using cosmetic talcum powder contaminated with asbestos just like this study reports with the same

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frequency, with the same duration and time as Ms. Moore described her use of cosmetic talc powder, and I've put a bracket on that of 30 years. You said it's a significant exposure; I understand that, significantly above background. I'm asking you, is it a heavy exposure, to you?
MS. DEAN: Same -- sorry. Chris, I don't know if you were done.
MR. MASSENBURG: I'm done.
MS. DEAN: I want to object to the same objections, and this has been asked and answered.
THE DEPONENT: My answer is that I think I just answered that as best as I possibly could.
BY MR. MASSENBURG:
Q. What you said was, as I understood your answer, is that in order to call it heavy, you'd have to see who that was being compared to, what other exposures I was comparing to or you were supposed to compare it to.
Did I understand your answer correctly?
A. In order to give a qualitative judgment, you have to have it compared to what. Is it heavy compared to what, or is it light compared to what or it moderate compared to what? And so my answer still holds it depends upon what this is being

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compared to.
Q. Okay.
A. So substantially above background.
Q. Going back to your 2011 study, you list in Table 1 occupations in 202 cases of malignant mesothelioma, and you list pipefitter, operator, laborer, insulator, electrician --
A. Hold on. I'm not -- hold on. Sorry. My thing was shifted over. I was looking at Table 3.
Q. No problem.
A. So Table 1, you're saying? Yes.
Q. Okay. Which of those occupational categories were the heavy-exposed people?
MS. DEAN: Objection. Compound, document speaks for itself.
THE DEPONENT: I don't recall.
BY MR. MASSENBURG:
Q. Okay. So it's your testimony that in this study in 2011 when you said heavy exposure, you were saying heavy compared to the other people in that cohort only?
A. Yes. Yeah, this was strictly related to the people in this group.
Q. And there were heavy, moderate, and light, and that means that there were some in this study

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that had no known exposure to asbestos; correct?
MS. DEAN: Objection. Form, compound.
THE DEPONENT: No. I think we -- I think as far as I recall, they were either -- they all had -- or the vast majority had a recognized occupational or para-occupational, but I'm not a hundred percent certain on that. But if not a hundred percent, pretty close to most -- the vast majority were -- I may be misremembering. That was ten years ago.
BY MR. MASSENBURG:
Q. Okay. And in this -- is this a case series?
A. Yes.
Q. Okay. In this case series, your sample size is 238 cases?
A. Yes.
Q. Do you feel that was a sufficient population size in this case series in order for you to come to the conclusions that you reached and as expressed in this study?
A. Well, at the time, that was -- there was no clinical study of anywhere close to that range. Most of the case series were very small numbers in the order of 10s or 20s, so this was one of the

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largest, if not the largest at the time. But it was enough cases to provide a lot of information. If we had had a bigger study, we might have been able to refine some numbers or get more, you know -- you know, get more information, but it is what it is. That's how many cases we had.
Q. What level would you categorize exposure as heavy in compared to your cohort group here -- or case series here, heavy, moderate, and light, an individual who had a cumulative exposure around 5 fiber/cc years of exposure to amphibole asbestos?
MS. DEAN: Objection. Form, vague and confusing.
THE DEPONENT: Yeah, I don't know. I did not do -- we did not have an industrial hygienist. We did not do any dose reconstructions at all. But 5 fiber per cc years, that's a significant dose. I mean, that's -- that even -- I mean, there's data that that can increase your risk for asbestosis at that level, so that's a significant level of exposure.
BY MR. MASSENBURG:
Q. You agree with me that there are -- and you cite just to some in your reliance, Dr. Wagner study in 1960 as to the 33 cases of mesothelioma in

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South Africa. You're familiar with that study?
A. Yes.
MS. DEAN: Asked and answered, day one.
BY MR. MASSENBURG:
Q. You're familiar with -- you mentioned already Dr. Selikoff. You mentioned Dr. Nicholson. Both of those doctors have published in the peer-reviewed literature on exposures to individuals that worked in shipyards and in construction industry where they are occupationally exposed to asbestos, including insulators and those around insulators like pipefitters; correct?
MS. DEAN: Objection. Compound, form.
THE DEPONENT: I'm sorry. You kind of lost me. The "correct" is that I've -- what's the -- I'm not sure what your question was, what I'm -- what you're asking me was correct.
BY MR. MASSENBURG:
Q. Are you familiar with publications by Dr. Selikoff and Dr. Nicholson in the published peer-reviewed literature that outlines mesothelioma at a substantially elevated rate among insulators and pipefitters?
MS. DEAN: Same objections.
THE DEPONENT: I believe that there

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were -- I've seen papers by Selikoff showing that the insulator cohort had an elevated risk for mesothelioma.

BY MR. MASSENBURG:

Q. You're familiar with studies by Dr. McDonald -- or the Drs. McDonald in Canada out of the Canadian asbestos mines showing elevated rates of mesothelioma among those miners and millers?

A. Yes.

Q. You're aware of studies by Karjalainen and others in Finland showing elevated rates of mesothelioma among anthophyllite miners and millers?

A. Yes.

Q. And, of course, Dr. Wagner's original study was of crocidolite miners. But are you also aware of studies coming out of the amosite mine in South Africa showing elevated rates of mesothelioma among the miners and millers from that mine?

MS. DEAN: Object to the premise of question and also overly broad.

THE DEPONENT: So first off, the Wagner paper was not just with miners and millers of crocidolite mine, so correcting you on that

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premise. And then yes, I am aware of studies showing that -- I'm pretty sure I remember seeing studies of amosite miners at increased risk for asbestos-related disease.

BY MR. MASSENBURG:

Q. And you're familiar with the studies out of Wittenoom, Australia of crocidolite miners and millers and family members, take-home of those miners and millers having an increased rate of mesothelioma; correct?

MS. DEAN: Objection. Form, compound.

THE DEPONENT: Yeah, and, again, I'm not sure if there's also people in those cohorts that are just environmentally exposed and not take-home. But yes, that -- crocidolite exposure increases your risk of mesothelioma. I do not disagree with that.

BY MR. MASSENBURG:

Q. Can you identify any published peer-reviewed epidemiological cohort that shows any cosmetic talc miner or miller having an increased rate of mesothelioma?

MS. DEAN: Objection. Form, overly broad, vague as to cosmetic talc, the meaning of that.

THE DEPONENT: Well, yeah, I'm not sure

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what -- I mean, there's no such thing as a cosmetic talc mine, but if you're talking about --

BY MR. MASSENBURG:

Q. Oh.

A. -- talc miners?

Q. Yes. I'm talking about talc mines where cosmetic and pharmaceutical-grade talc comes from, not the Gouverneur mine in New York. I'm talking about cosmetic pharmaceutical talc mines whether that's Italy, Austria, France, Australia, Vermont, Montana.

THE DEPONENT: All right. Well --

BY MR. MASSENBURG:

Q. There are others.

MS. DEAN: Let me -- let me insert some objections first to compound. Second, vague and ambiguous on what you mean by cosmetic-grade talc, and third, overly broad.

THE DEPONENT: And so I was going to say, you know, again, I'm not sure that I agree that there's such a thing as a cosmetic or cosmetic and pharmaceutical mine. But to the extent that if you look at, for example, Vermont and yes, I'm aware that Fordyce, A, did not count the two cases, one pre, one post-1974 in his paper, despite saying

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that they took great effort to include everyone with mesothelioma. I believe that, you know, even if you look at just the one that he took and if you used -- depending upon what you call your background, that could even be statistically significant, certainly close to it. But at two cases in that cohort of a little -- around 400 or so, yeah, that would have been statistically significantly increased had he included both of those case.

BY MR. MASSENBURG:

Q. Outside of the Vermont Fordyce cohort that you cite, can you identify any incidence of mesothelioma in cosmetic or pharmaceutical talc miners or millers in the published and peer-reviewed literature aside from the Vermont one you cited, which I won't take up because it doesn't apply to Chanel?

MS. DEAN: Same objections.

THE DEPONENT: Well, in the Italian studies, you know, they talk about peritoneal cancer but don't really tell you what it is that they're talking about if it's not peritoneal cancer, i.e. primary peritoneal cancer. And other than that, no, because the -- at least the studies

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that are at issue -- I'm not going to talk about France or Norway. Those are irrelevant to the issues at hand today with Ms. Moore -- but as far as Italy is concerned, those studies had significant issues with -- related to healthy worker effect and low -- short latency and other issues as well.

BY MR. MASSENBURG:

Q. You do agree there are other peritoneal cancers besides peritoneal mesothelioma cancer; correct?

MS. DEAN: Objection. Vague and ambiguous in terms of primary cancer.

THE DEPONENT: In terms of --

MR. MASSENBURG: Let me just object to, again, speaking objections and coaching of the witness. Dinosaur.

THE DEPONENT: She was not --

MS. DEAN: Before that goes on, the notion repeatedly had been made there's coaching. I disagree. That's not a legal objection. If you want to discuss it or meet and confer, I'm always available. But it's an improper suggestion to the parties that listening to this, it's not a proper objection under the law, and it's delaying matters.

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MR. MASSENBURG: I've asked repeatedly for you to stop doing it, and you keep doing it I'm happy to --

MS. DEAN: I disagree.

MR. MASSENBURG: -- separate from this, but the record speaks for itself.

BY MR. MASSENBURG:

Q. I'm sorry. You can answer my question, please.

A. Yeah, I think the record does speak for itself that I had actually already said before Ms. Dean -- so she was not coaching me because I'm already fully aware of this.

But your -- now I've lost my train of thought here -- your question was.

THE DEPONENT: Maybe I can have the court reporter read it back.

Court Reporter, could I just it that back. I'm sorry.

(The record was read as follows:

"QUESTION: You do agree there are other peritoneal cancers besides peritoneal mesothelioma cancer; correct?")

THE DEPONENT: Okay. So as I had already

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said in my previous answer when I said primary peritoneal cancer, that was not identified. So primary peritoneal cancer is mesothelioma, and so you can have a secondary, but you don't -- we don't call cancers based on metastatic disease. They're -- and, you know, if you look -- before the ICD-9 or ICD-10 code for mesothelioma, it was peritoneal or pleural cancer. The primary cancer of the peritoneum is mesothelioma. If you have a metastatic disease, by definition, we don't call that peritoneal cancer. If you have a lung cancer then that metastasizes to the peritoneum, that's not peritoneal cancer; it's lung cancer.

BY MR. MASSENBURG:

Q. Do you have any knowledge as on whether or not in the Italian tall miner studies that site two peritoneal cancers, whether those are peritoneal mesotheliomas or not? Do you know?

MS. DEAN: Objection. Form. To some extent, asked and answered.

THE DEPONENT: All I can say is what they reported as being peritoneal cancer, and I think it was more than two cases, but all they cited was peritoneal cancer. They don't say what it -- they think it was, if not primary peritoneal cancer,

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then it would be standard for a medical doctor to refer to peritoneal cancer as being that -- as being a primary peritoneal cancer.

BY MR. MASSENBURG:

Q. I'm almost done, Doctor.

If you could go to your declaration in page 20, paragraph 53.

A. Hold on. Paragraph what?

Q. 53 on page 20.

A. There is no paragraph 53 on page 20.

Q. I have your declaration, asbestos --

A. Oh I'm sorry. I'm sorry. I was looking at lines. Oops. Sorry. I looked at the line numbers.

Paragraphs, yes, okay.

Q. Are we there?

A. Yes.

Q. Okay. You say: There are hundreds of tests evidencing asbestos in cosmetic talc spanning many decades, including cosmetic talc from Vermont and Italian mines.

Did I read that correctly?

A. Yes.

Q. You also agree there are hundreds of tests evidencing no asbestos in cosmetic talcs spanning

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many decades including talc from Italian mines.
MS. DEAN: Objection. Form, vague and ambiguous.
THE DEPONENT: No, it would be evidencing non-detects. A negative test does not establish no asbestos. It's not evidence of no asbestos; it's just a non-detect. And particularly if you're using a technique that either allows you to see asbestos fibers and not count them, like 7024 or you're using a weak analysis method like J4-1, which, you know, even when they did spike testing, missed, you know, almost 90 percent of the asbestos that they knew that was there.
So there are -- yes, there are definitely negative tests, but you have to -- and I take them into consideration when I look at any sort of test results. You have to look at the strength and weaknesses of tests in order to come to conclusions, but certainly a test is not evidence no asbestos. A negative test might just demonstrate either a non-detect or an ignore.
BY MR. MASSENBURG:
Q. Is it true, Dr. Haber, in fact, you've been provided with documents and seen documents that number in the thousands of tests of cosmetic

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talc from Italy and Vermont and Montana that show no asbestos detected?
MS. DEAN: Objection. Form, overly broad, compound.
THE DEPONENT: I don't know what the number is, but yes, there are -- I have seen testing that reports no detection whether that, again, was allowing techniques -- even if they're using a better method like TEM but using a 7024 that allows them to ignore fibers or their definition of a fiber is such that it doesn't comport with my definition of a fiber and, you know, and/or the medical definition of a fiber or if they're using a weaker method such that they are missing asbestos either because the method is -- does not have a level of detection that's sufficient or it is just incapable of detecting, for example, chrysotile asbestos. Unless you're doing the pre-concentration methodology, my understanding is that, you know, even with TEM you're not going to be seeing the chrysotile.
BY MR. MASSENBURG:
Q. Well, isn't it true, Doctor, that of the hundreds of tests that you've shown that have shown positive for asbestos, most of those have been done

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by the J4-1 method or by XRD and therefore haven't actually established that it's asbestos, just that it's suspected for asbestos or maybe non-asbestiform minerals?
MS. DEAN: Compound, misleading, overly broad.
THE DEPONENT: So what's supposed to happen is if the XRD sees it, then it's being confirmed afterwards by optical microscopy, and/or they are following it up with other testing like TEM. And so no, I don't know if I ever tried to tabulate it. But certainly if you have a weaker test that shows asbestos, then that's significant.
And secondly, we know that when you have tremolite fibers, for example, that are not asbestos tremolite that you're going to have in the same population of fibers, you're still -- you're also going to be getting the full spectrum, including the asbestos tremolite.
Q. You're aware that Whittaker, Clark & Daniels' corporate witness Mr. St. George testified that if they detected, by x-ray diffraction, a potential for tremolite or for asbestos or it even could be non-asbestiform, they would not sell that lot. Meaning if it was a positive finding by XRD,

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they did not do additional PLM on every lot in order determine whether it was actually asbestos or whether it was nonasbestos?
MS. DEAN: Objection. Compound.
BY MR. MASSENBURG:
Q. Have you been provided with Mr. St. George's testimony?
MS. DEAN: Let me -- I'm sorry. There's two sets of questions, so compound, misleading, misstates testimony.
BY MR. MASSENBURG:
Q. Could you answer the second first, Dr. Haber?
MS. DEAN: Same objections.
THE DEPONENT: Okay. What was the second one? You got me --
BY MR. MASSENBURG:
Q. Have you been provided with Mr. Saint George's -- the corporate witness for Whittaker, Clark & Daniels, have you been provided with his corporate testimony on behalf of the company?
A. If it's -- if I have it, it would be within Exhibit B. I don't remember.
Q. Okay. Last question I have is --
A. But I'm not going to answer the first

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question? You removed the other question. Okay.
Q. Well, I don't remove it. I'm trying to get done.
A. Okay. Fair enough.
Q. So if you want to answer it, that's fair, but otherwise, it's fine --
(Simultaneous speaking interrupted by the reporter.)
MR. MASSENBURG: Just put unrecognizable. Otherwise, I think I know where we'll go, is what I said.
Thanks, Paige.
BY MR. MASSENBURG:
Q. Dr. Haber, I'm showing you a 2020 Stimuli to the Revision Process: Modernization of Asbestos Testing in USP Talc, Part 2.
Have you ever seen this document before?
A. What's this from?
Q. This is a -- this is a publication -- and you can see the experts. It's Rustein, Pier, Crane, Gunter Sanchez, Poye, Segrave, Van Orden, James Webber. This is a -- it's just a publication "Stimuli to the Revision Process"?
A. And what is this pressure?
Q. 2020?

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A. Yeah, I don't recognize this.
Q. Okay. That's fine.
Doctor, in the interest of time -- I do have other questions, but hopefully others will pick those up for me. Thank you very much for your time.
MR. MASSENBURG: Reserve my right tender. The witness.
MR. SLAUGHTER: I'm happy to go next. Do you want to take a little break first?
THE DEPONENT: Yes, please.
MS. DEAN: Yeah. We've been going for an hour and 20 minutes; that's be great.
MR. MASSENBURG: Ten minutes or longer?
MS. DEAN: Let's go off the record.
(Whereupon, a recess was held from 12:09 p.m. to 12:29 p.m.)
MR. SLAUGHTER: We can go on the record.

EXAMINATION

BY MR. SLAUGHTER:
Q. Dr. Haber, this is Ed Slaughter. I'm going to pick up here and try to move quickly.
Would you get your declaration opened to page 4. Just tell me when you're ready.

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A. Okay.
Q. So, Doctor, you've got listed, starting in paragraph 8, various chest films and CTs. Did you -- I take it from this you actually received those and actually examined them yourself; right?
A. Yes.
Q. And were the x-rays digital, electronic, or an old school copy?
A. Well, digital is electronic, but that's how they all come, yes. CTs and chest x-rays are all done digitally nowadays and read on a DICOM viewer. That's D-I-C-O-M.
Q. Okay. That's what I thought. I just wanted to make sure.
So if you get down to your paragraph 10 that starts at line 16, it indicates -- this is at line 18: Her chest x-ray revealed a right pleural effusion. Her chest CT confirmed the presence of a large right pleural effusion along with diffuse pleural thickening.
A. And compressive atelectasis.
Q. I was just trying to avoid pronouncing that last word.
So is this your finding --
A. No.

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Q. -- from the CTs?
A. No. This was from the medical record.
Q. Okay. Did you look at that same CT scan yourself?
A. I looked at a lot of them. Let me just go back to the -- page 4 -- so yes, CT of November 16, 2020, and then March 1, 2021, and July 6th, 2021.
Q. Did you make an evaluation of whether or not diffuse pleural thickening was present in any of those CT scans?
A. Yes.
Q. And what did you conclude?
A. She did.
Q. What methodology did you utilize to evaluate those CT scans for diffuse pleural thickening?
MS. DEAN: Objection. Form, overly broad.
THE DEPONENT: Well, just on the CT scan would be my expertise, training, and experience as a pulmonologist reading tens of thousands of CTs. As far as the chest x-rays, would be using the same, in addition to the definition of diffuse pleural thickening as set forth by the ILO.
(Noise interruption.)
(Reporter clarification.)

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BY MR. SLAUGHTER:

Q. Okay. So, Doctor, let me back up and try the question again.

First, just with reference to the CTs you looked at, is there a methodology or a standard that you follow in evaluating CTs to identify diffuse pleural thickening?

MS. DEAN: Objection to the extent it's asked and answered and unclear.

THE DEPONENT: Yeah. The diffuse pleural thickening is -- the pleura is a normal structure. If it becomes too thick, and we recognize that as being generally anything over about 2 to 3 millimeters -- in this case it was far beyond that, so it's irrelevant -- but if the pleura becomes too thick and if it covers a diffuse area of the chest wall, then that is diffuse pleural thickening. It is based on, you know, textbooks on radiology, on my training and experience, education, everything. It's really not a difficult concept to appreciate radiologically.

BY MR. SLAUGHTER:

Q. So let me stay focused on the CTs. Can you point me to anything in your reliance material that you're using as your standard or methodology

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for evaluating the CT scans?

MS. DEAN: Objection. Form, overly broad, unclear.

THE DEPONENT: Well, I mean, my CV was also attached, which includes my education, training, and experience. And but to the extent that -- yes, I'm sure that there are articles within C that discusses the radiological findings of asbestos-related disease, and so yes, I'm sure that there's going to be articles within that that discuss that issue.

BY MR. SLAUGHTER:

Q. So, for example, you indicated a moment ago that for there to be something you'd call thickening, you would need to see 2 to 3 millimeters of thickness; right?

A. Well, the normal, based on, you know -- and this has all again been published widely here -- but just off the top of my head, Fraser and Pare, which is one of the largest textbooks in pulmonology, note that the pleura is usually 1 to 2 millimeters of thickness.

And so if you start seeing levels above that -- and now the ILO uses 3 millimeters and that's pretty consistent with, you know, what is

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pretty much standard for, I think, most clinicians or radiologists would agree that, you know, there's a normal thickness, and then if it becomes too thick, then it's thickened.

Q. Okay. So the next part of your answer had to do with the word diffuse and how spread out the thickening is. Is there a metric you can give us for that that would support a methodology for making a diagnosis of diffuse pleural thickening?

MS. DEAN: Objection. Form, overly broad.

THE DEPONENT: Right. It basically is either going to be a localized phenomenon or it's not. If it's localized, you can kind of see the beginning and the end of it. Typically for diffuse pleural thickening, it tends to just taper off and you don't see a kind of a defined beginning and defined end, and that also comports with the findings of the ILO and there's no requirement of how diffuse it needs to be.

So for the ILO methodology, for example, it can be, you know, within just the first quarter of the chest wall or it can be half -- it can -- you know, with mesothelioma, you know, you can have it completely encompass the lung.

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BY MR. SLAUGHTER:

Q. And what do you believe you saw in Ms. Moore's case?

A. As far as what? There's lots of things I saw in her case, so...

Q. What amount of thickening in millimeters did you measure in Ms. Moore's case?

A. As far as the diffuse pleural thickening, I don't recall what it was.

Q. Did you take a measurement?

A. I don't remember whether I did or didn't. And, again, it's also on the, you know, it's on the chest x-ray as well, but it certainly would have fallen above the -- above the normal level of 1 to 2 millimeters for sure.

Q. How does one go about taking a measurement of that?

A. Well, after reading thousands and thousands and thousands of x-rays, you don't have to necessarily, and you can recognize when there's just -- it's not a questionable call, but if you want to, yeah, there's methodologies for -- you can measure on a CAT scan. You can measure anything very easily, but that is really only necessary when -- if you've got a -- where it's a

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questionable call.
It's kind of like saying, you know, if I'm going to, you know -- to look at, you know, the thickness of a watermelon rind and I don't need to measure it to know that it's over 2 millimeters. I mean, I can -- you can -- after looking at thousands of examples, you can tell that it's not normal and that is the methodology that most radiologists do is based on their experience with looking at thousands and thousands of normal x-rays and recognizing what has been abnormal, but certainly yes, I would have measured it if it was a questionable call.

Q. I think I heard you to indicate that there are methodologies for how'd you do --

A. Sure, yeah, actual measurements, yes.
(Noise interruption.)
DEPOSITION OFFICER: Can we go off the record?
MR. SLAUGHTER: Yeah.
(Discussion held off the record.)
BY MR. SLAUGHTER:

Q. Doctor, I think I understand you to say there is a methodology for measuring pleural thickness. Can you give us the name of that?

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Identify the paper or somehow just tell me how to find it.

A. Right. So, again, the methodology is to take a ruler or using -- when you're electronic, you can -- there are -- there's measurement tools on DICOM viewers that radiologists standardly use and I standardly use to measure, and you can measure the thickness if that is necessary or measure whatever else you want to decide to measure, so that would be the methodology to measure it.

Q. In Ms. Moore's case, you did not follow that methodology; correct?

A. No, I didn't say that at all. I just said in this case, my recollection is that it wasn't even a close call. That's, like, again, looking at something that's 2 inches thick and going, well, gee, is it more than a millimeter. You don't need to measure it; you can plainly tell. But, again, I can't tell you that I didn't go ahead and measure it because it's irrelevant anyways. There's no question about it. I don't think anybody would think that she did not have diffuse pleural thickening. I mean, this is a lady with mesothelioma.

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Q. You did not record anywhere the extent of thickening that you believe you saw with your naked eye; correct?

A. Well, I -- you mean -- by naked eye, you mean looking at her radiology? Because I did not look inside of her chest.

Q. Yeah.

A. I did not describe it in my report because I think it's irrelevant to my opinions in this case.

Q. And you did not see any pleural thickening on the left lung; correct?

A. No, incorrect.

Q. Okay. Tell me what you saw on the left lung.

A. She had a pleural plaque on the left lung.

Q. Okay. Is that here anywhere in your report?

A. I don't think so.
MS. DEAN: Let me also object to misleading and vague and confusing, referencing the declaration for SJs as a report.
MR. SLAUGHTER: Oh, I'm sorry.
BY MR. SLAUGHTER:

Q. I'll take that back then, Doctor, and

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let's talk about this declaration that you've done.
Did you report anywhere in this declaration that you saw a pleural plaque in her left lung?

A. I did not do any of my own radiology readings and so -- on that, because it's irrelevant to my opinions that I put forth in the declaration, and so the answer would be no.

Q. Okay. So let me see if I'm following you. Did you look at any radiology yourself of her right lung?

A. Of course. I looked at both lungs. I looked at the whole chest.

Q. I'm sorry. That was a bad question.
Let's get to the left. I don't see anything in your declaration about you reporting on her left lung; right?

A. I didn't -- none of these -- none of the reporting of the chest x-ray in the paragraph 10 is from my review. That's from her medical records. I did not put in -- I indicated the radiology that I reviewed. I did not put a separate section of what my findings were because it is not pertinent to my opinions about her having mesothelioma or to the causation, but I'll be happy to discuss my

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findings with you. I did not put them into this declaration.

Q. Well, let me start here, and maybe this is a better way for me to understand it. If you did not believe you had a credible history of asbestos exposure in Ms. Moore, do you think you have sufficient information in her radiology and CT materials to attribute her disease to asbestos?

MS. DEAN: Objection. Incomplete hypothetical, vague.

THE DEPONENT: I'm not aware of anything on -- that would be present on a chest x-ray that would allow somebody to declare causation of mesothelioma in the absence of clinical history or if you had some other thing, I suppose by pathology, which we don't have in this case.

BY MR. SLAUGHTER:

Q. You agree Ms. Moore did not have asbestosis -- does not have asbestosis?

A. Clinically or radiologically, I agree that she does not have asbestosis. I can't tell you whether or not subclinical.

Q. And she does not have bilateral pleural plaques; fair?

A. I can't tell you yes or no because she

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definitely has on the left. The right lung is so involved with the diffuse pleural thickening and the cancer and the pleural effusion and the atelectasis that it would be impossible to see any discrete pleural plaquings because they would be completely obscured by everything else.

Q. You did not see bilateral pleural plaques in Ms. Moore; correct?

MS. DEAN: Objection to the extent that it's been asked and answered.

THE DEPONENT: I think I answered it as best I could here. She clearly has pleural plaque on the left, and on the right side, I can't say that she doesn't have them also on the left [sic] because of the object securing of the pleura based on the extensive cancer.

BY MR. SLAUGHTER:

Q. I understand where your head is on it.

So you've talked about a little bit about the Helsinki criteria earlier, and that's what I'm trying to get at here. I understand you believe that you have a credible history of exposure here, so set that aside. Looking at the other criteria in the Helsinki papers, both of them, could you -- if you completely set aside the history, could you

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with that clinical information attribute this disease to asbestos?

A. What clinical information?

Q. Her x-rays and CT scans.

MS. DEAN: Objection. Form. Improper hypothetical.

THE DEPONENT: All right. So I think you just asked me that and I said that if you don't have -- in the absence of pathology where, you know, at autopsy, there's no information on a chest x-ray or CT absent the clinical information that anyone would be able to make a causation statement, or at least I'm not able to.

BY MR. SLAUGHTER:

Q. Thank you.

You do understand that there was a biopsy done in this case?

A. Right. She had cancer.

Q. And did you -- do you in the regular course of your work look at pathology, or is that something you don't do?

A. It depends on the case. I won't do it independently, but I might do it with a pathologist.

Q. You've not done that in this case; right?

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A. No. I don't think anyone is questioning that this is a mesothelioma, and certainly radiologically and clinically, this is entirely consistent with the pathological findings.

Q. There's been no report of anyone identifying asbestos bodies in her tissue; correct?

A. No one has attempted to -- when you say in her tissues, there was just the one biopsy of the cancer, usually you don't see asbestos bodies within mesothelial -- mesothelioma, and I don't think that anyone, as far as I know, even attempted to look, but certainly there was no sampling of her lung.

MS. DEAN: Only when Dr. Haber is answering and usually end, but there is some weird feedback happening. I don't know if there's anything to do. To me it's manageable, but I'm also not on day two of very long depositions so -- in terms of transcribing. It's, like, echoing.

THE DEPONENT: It sounds like someone is, like, hitting their microphone or something.

MS. DEAN: It seems associated with movement because it's not consistent, but I just -- sorry to interrupt. If there's a quick fix, I would love to do it; if there's not, I want to keep

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plugging along.
DEPOSITION OFFICER: Can we go off the record?
MS. DEAN: All right.
MR. SLAUGHTER: All right.
(Discussion held off the record.)
MR. SLAUGHTER: Okay. Back to where we were.
BY MR. SLAUGHTER:
Q. Doctor, you ready to continue?
A. I am, sir.
Q. So let's talk through pathology and cytology. You indicate in the declaration that the first cytology that was evaluated revealed mesothelial cells and cellular atypia with no malignant cells; right?
A. From the thoracentesis, yes.
Q. All right. And do you have any opinion about why in a case like this you might see no malignancy on citology but then see it later on tissue?
A. Yes.
Q. What is that opinion?
A. Well, and this is particularly common with lung cancer and with mesothelioma, but with pleural

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effusion that has -- is not necessarily freshly delivered into the pleural cavity, the initial thoracentesis or even thoracenteses can show atypical cells but not enough for the pathologist to make a conclusion.
Sometimes also you can actually have cancers in the chest but that the pleural effusion is being produced by other either inflammatory or obstructive purposes or mechanics such that they don't have malignant cells, but it's still from a mechanism related to cancer.
Q. And the --
A. And the third thing would be that, particularly with mesothelioma, that can be a very difficult diagnosis from a pathological standpoint in and of itself without additional tissue.
Q. Did you make an evaluation yourself about whether or not the immunohistochemical staining done on the biopsy was correct?
A. I'd have to go back and -- I'm sure I looked at what the -- what the pathologist reported, but I don't recall offhand.
Q. Is that something that you routinely do in your practice outside of consulting in litigation?
MS. DEAN: Objection. Form, vague as to

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context.
THE DEPONENT: Looking to see what immunohistochemical staining shows, yes. I don't actually look at the slides myself to make that determination. Again, I would rely on pathologists but, you know, again, I might view a case with a pathologist, but generally I would just -- I would look to to see what the pathologist said and what the immunohistochemical staining shows.
BY MR. SLAUGHTER:
Q. You had a conversation with Ms. Moore sometime ago; correct?
A. Yes. July 15th of 2021.
Q. And I don't mean this to be a hide-and-seek game at all, if you want to flip through your declaration. Can you just tell me what, if anything, about her claim that she used Cashmere Bouquet or that others around her did?
A. So particularly with Cashmere Bouquet, we did talk -- I mean, this would be in paragraph 14. And although it also talks about what they testified to, we also discussed this. She did tell me that she was, you know, using it on a daily basis, and she did tell me that -- and I even wrote this here -- based on my own interview, you know,

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she talked about that her grandmother and her two aunts with whom she lived were users of Cashmere Bouquet and that she was, you know, around them when they were using it, and that they would sometimes use it on her when she was a little girl living in that family of the three women.
And then -- let me just -- and I believe my recollection was -- is that, you know, it was similar, that it was at least into the 1980s is my recollection of what she told me.
Q. Would you have any other information you could testify to about that conversation besides what you just told me and what's in your declaration?
A. No.
Q. Fair.
If you look at page 9, paragraph 23, starting about line 21, you reference some MAS testing reports related to Colgate.
Do you see that?
A. Yes. Let me just pull it up here.
MS. DEAN: What paragraph again?
MR. SLAUGHTER: We're in paragraph 23, starts at line 21, at least what I was looking at.
MS. DEAN: Thank you. Sorry.

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THE DEPONENT: Okay. I'm there.
BY MR. SLAUGHTER:
Q. Have you talked to Bill Longo about any of his tests?
A. No.
MS. DEAN: Objection. Asked and answered.
BY MR. SLAUGHTER:
Q. Have you ever -- have you ever talked to Bill Longo about any of his Cashmere Bouquet tests?
A. No. And I think we did discuss this at the last deposition, but the answer's still no.
Q. Okay. I didn't think we had discussed it regarding my client, so I'll cover it, but I'll be brief.
Do you have an understanding about whether or not you have permission to use MAS's testing studies from MAS?
MS. DEAN: Objection. Form, vague and confusing.
THE DEPONENT: I don't know what you mean.
BY MR. SLAUGHTER:
Q. Has anyone told you that you have been given permission to use this work product from MAS to support your testimony or for any other reason?
MS. DEAN: Same objections.

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THE DEPONENT: Well, this was information that I received through the Dean Omar Branham law firm.
BY MR. SLAUGHTER:
Q. Okay. And no one's provided you with any information about whether or not Bill Longo has given permission for it to be used in this case?
MS. DEAN: Same objections.
THE DEPONENT: I do not know the answer to that.
BY MR. SLAUGHTER:
Q. Fair enough.
So you've never actually done any bulk sampling of anything to identify asbestos in it; right?
A. Correct. Yeah, that's not something that I do.
Q. And you've never participated in any kind of an analysis to see if asbestos fibers were being released from a product; right?
A. Again, that's -- yeah, that's not something that I do as a medical doctor.
Q. Have you ever used an XRD machine?
A. I have not.
Q. Have you ever seen an x-ray diffraction machine in person?
A. I don't know.
Q. You don't have a recollection of having ever even seen one; right?
A. No, I'm saying I don't remember.
Q. Fair enough.
Have you ever used a transmission electron microscope for anything?
A. No, don't think so.
Q. Have you ever used an electron microscope of any sort for anything?
A. Myself personally, I don't think so. I know I've seen them used and have had education on TEM, but I'm not sure I've ever done it myself. I don't remember doing so.
Q. It's my understanding that you've had some education about TEM. Do you feel that you would be qualified to analyze something via TEM for the presence of asbestos?
MS. DEAN: Objection. Vague, overly broad.
THE DEPONENT: By analyze something, I don't know what you mean. But I would be the one that looks at -- you know, figures out how to run the machine to or to determine what it -- what it

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finds, but I would feel comfortable looking at someone who does issue their findings to understand what those findings and the context of understanding the strengths and weaknesses of a testing methodology just like I would, you know, for a CAT scan or a chest x-ray or any other sort of medical test.
BY MR. SLAUGHTER:
Q. You agree that you're not qualified to do TEM analysis to identify asbestos in a material; fair?
MS. DEAN: Objection to form. Again, to some extent, asked and answered, but also vague and ambiguous.
THE DEPONENT: I don't know what the qualifications are. I certainly wouldn't expect anyone to want me to do it, and I certainly wouldn't -- I wouldn't want anyone relying on my reading of a -- you know, performing of a TEM of asbestos, but I -- as far as what qualifications one needs to be able to run it, that, I don't know. I mean, it's probably maybe some people just have more experience with it than necessarily some sort of paper qualification, but I'm certainly not going to be someone who's going to do that in my career,

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for sure.
BY MR. SLAUGHTER:
Q. Would you agree that you're not qualified to make an evaluation about whether or not one TEM analysis is better than another or more accurate?
MS. DEAN: Objection. Form, remarkably overly broad, incomplete hypothetical.
THE DEPONENT: Yeah, so I think I'm qualified based on my understanding of the strengths and weaknesses and -- of the testing to know that if one person is using a methodology, for example, 7024, that I have cause for concern. If someone is, you know, not doing as many grid openings as another person is doing, if someone is spending more time or less time. So there are definitely issues that I think, even as a medical doctor and just again, you know, as I would, as a doctor/scientist, knowing the strengths and weaknesses can have some opinions based on comparing -- and, you know, also, I guess another thing would be magnification as well and other techniques that, you know, may be done including whether pre-concentration techniques are done beforehand. So there's a lot of things that might influence my opinions as to compare one person's

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results to another's.
BY MR. SLAUGHTER:
Q. So I understand that you've read some things on testing methodologies and that they're listed in this document or the various Exhibit Bs and Cs and whatnot, so I understand that. Going beyond that, can you tell me what training or education you actually have that you think qualifies you to comment on that what testing methodology for identifying asbestos is right or wrong?
MS. DEAN: Objection. Overly broad, vague and ambiguous, and to some extent, asked and answered.
THE DEPONENT: So I never said anything about right and wrong, so that's kind of misrepresenting my testimony. You asked me whether I could, you know -- if I had any qualifications to compare one person's to another, and I explained that knowing, you know, about TEM and, you know, that there's different magnifications, there's -- you know, the amount of time.
I can tell you from personal experience that, you know, radiologists looking at x-rays miss things all the time if they are rushed. And so

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spending more time is better than spending less time. Having more magnification may be better than to have it at a lower magnification. Having a pre-concentration method, I know is going to decrease the problem of missing the presence asbestos, particularly chrysotile and, you know, if you have a counting technique that allows you, by definition, to say that there could be 4 fibers of each fiber type, in other words, 16 fibers and say that there's none detected, that's a problem for me as well.
BY MR. SLAUGHTER:
Q. I understand what you're telling me. And I don't mean to quarrel with you. What I'm asking you is this: What actual qualifications do you believe you possess to make an evaluation of the strengths or weaknesses of any of these testing methodologies we've been talking about?
A. Well, I think it would be --
MS. DEAN: Sorry, Dr. Haber. Just the same objections. To some extent, asked and answered and compound. Sorry.
THE DEPONENT: My education, training, and experience, college degree, medical degree, post-graduate education, reading thousands and

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thousands of articles and textbooks on asbestos-related disease, on testing methodologies, on asbestos, on various techniques. Also, I'm fairly skilled at -- one of my favorite subjects was in mathematics, and so, you know, to the extent that, you know, issues about magnification or -- and issues of, you know, if you can count -- if you can say 4 fibers are equal to zero, you know, I don't think you need to have some advanced degree to say that there's something fishy going on.
And so, you know, I think all of those things but, you know, most of them are just common sense or things that I've experienced in my reading on the testing of -- for asbestos, on my readings of numerous documents on testing of asbestos in talc, the published literature and more.
(Reporter clarification.)
BY MR. SLAUGHTER:
Q. So, Doctor, throughout all of your education that you just described for us, can you tell me if you ever discussed in any class on a single day how to go about evaluating test methodologies for the bulk sampling and analysis of asbestos composition in anything?
MS. DEAN: Objection. Overly broad,

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vague.
THE DEPONENT: I can't remember back 30 years ago in medical school, the lectures. We certainly had lectures on asbestos and asbestos content. That was a really big thing when I was in medical school. I trained after that with some of the experts in asbestos, and I know we had conversations as well, but I'm not going to be able to point to you any specific conversation or lecture going back that far.
BY MR. SLAUGHTER:
Q. Fair enough.
You worked with Gary Friedman for a great many years, and during that time, he was consulting with plaintiffs in asbestos litigation; is that right?
A. That wasn't who I was referring to, but yes, I did work for Gary Friedman for about five or six years.
Q. And I'm not trying to be difficult about it, but what I'm hearing you telling me is you can't remember any class you ever took while you were in your formal education where you learned about a test methodology for analysis for asbestos composition?

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MS. DEAN: Objection to the extent that it's asked and answered and misstates testimony.
THE DEPONENT: If you're saying that I -- if you want me to name the exact day, day of the week, hour, classroom, of course, that's silly. I can't remember back that far, but I know that we had lectures on a number of subjects, including on asbestos-related disease and testing methodologies. I mean, testing is a big part of medicine.
BY MR. SLAUGHTER:
Q. Sure.
So I'm not asking you to attempt the silly exercise of giving me a day or time, so I apologize if it sounded like I was. I'm asking you -- and I just don't feel you've answered me -- have you ever had any coursework during your formal education where you were actually studying the question of the methodology for analyzing things for asbestos content?
MS. DEAN: Objection. Asked and answered.
THE DEPONENT: I believe I -- I don't think I can answer it any more clearly. I'm certain we had lectures on a number of subjects including on the testing methodologies, but I can't have a specific recollection going back over

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30 years ago.
BY MR. SLAUGHTER:
Q. Would you know even the name of a class where you might have studied something like that?
MS. DEAN: Objection. Vague and ambiguous. I don't know what you mean by something like that. Goes back to my compound.
MR. SLAUGHTER: Let me rephrase it.
BY MR. SLAUGHTER:
Q. Can you even give me the name of a course you have taken in any of your formal education where you believe you were trained on analyzing test methodologies for identifying asbestos in anything?
MS. DEAN: Objection. Asked and answered.
THE DEPONENT: Well, and actually now you're asking about being trained. I mean, originally you were asking about had any education and now you're asking about being trained --
BY MR. SLAUGHTER:
Q. I mean that as a synonym.
All right. Let me try it again.
Can you even give me the name of one course you took during your formal education where you studied or discussed in any way test

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methodologies for analyzing anything for asbestos content?
MS. DEAN: Objection. Asked and answered.
THE DEPONENT: I'll try it one more time. Again, I cannot tell you the name of the course or what day it was or what year it was, but I know that we discussed in medical school and in my training and in my post-graduate training, the issues of asbestos and testing of asbestos and asbestos disease, but I cannot cite for you any sort of specific name of a course or what classroom it was in or who was the lecturer. It's too far back for me to remember 30 years ago.
BY MR. SLAUGHTER:
Q. Will you flip over to page 25, paragraph 64 of your declaration.
A. 6-4.
Q. Yes, sir.
A. Okay. I'm there.
Q. You have a Footnote 20 that you cite at the -- in the middle of line 6, and down at the bottom it lists four or five things.
You see that?
A. Yes.
Q. Is that all of the material you rely on

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for the statement that there can be a range of 1 to 4 fiber ccs and release?
A. No.
Q. What else do you have?
A. All right. So we've got here Sussman and Gordon.
MS. DEAN: Dr. Haber, just so I can object, to the extent that it's overly broad and unclear, just the testing data or the connection to cosmetic talc question?
MR. SLAUGHTER: Let me try to rephrase. Let me try to narrow it.
BY MR. SLAUGHTER:
Q. So I'm really just trying to see what documents you might rely on. You've listed several here in Footnote 20. Is there any other document that you have in this collection you've given us that you think supports the idea that there's a range of 1 to 4 fiber/ccs of fiber release for most cosmetic talc use?
A. All right. So -- and actually, I'm looking -- so, again, first off, the issue of a -- there is a range. I'm not saying that that's the only -- I just want to make it clear that that's not where everything is contained within

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that range. I'm saying that there are certainly studies showing within that range but there are studies that are lower; there's studies that are higher. So I don't -- if I -- inartfully wrote that -- but that is not to mean that you can't see outside of that range.
Now to the -- now to the question to add to that, so the FDA talked about, in '71 or '72, saying that trace asbestos in talc would produce levels above the PEL, which at that time was at 5 fibers per cc. You had, I think, in -- I think this was maybe referenced in Sahmel's as well but Addison -- I don't recall the year -- that it was, like, 1 to 3 fibers per cc. There was a report by Mattenklott. There was -- if and I'm not sure exactly how Sahmel's version necessarily related, but she listed some Exponent papers that had, like, .2 or .3 fibers per cc of exposure. Finkelstein was also in that range. Those are the ones I remember off the top of my head right now.
MS. DEAN: And can I clarify, when you said most exposures, you meant for the Mae Moore case?
THE DEPONENT: Yes.
MS. DEAN: I'm asking Ed, just in terms of

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the question; otherwise, I need to insert an objection. I think that's what was being answered, but it occurred to me without context, somebody who used dry shampoo might construe this.
MR. SLAUGHTER: Yeah, that's how I meant it.
MS. DEAN: Thank you. Sorry to interrupt, but then I don't have any interruption.
MR. SLAUGHTER: Okay. And I'm real close to done here, so...
BY MR. SLAUGHTER:
Q. Doctor, have you attempted to calculate a dose of asbestos to which you believe Ms. Moore was exposed from Cashmere Bouquet products?
MS. DEAN: Objection. Asked and answered.
THE DEPONENT: As in the total fiber per cc year?
BY MR. SLAUGHTER:
Q. Yes, sir.
A. No, I have not.
Q. Would you -- do you have all of the information you need to attempt to calculate a dose?
MS. DEAN: Objection. Form, vague and ambiguous.

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THE DEPONENT: Well, you know, there would be -- there would be certainly an ability to make an approximation based on her testimony of her frequency. I think you'd -- I don't know if she testified as to time but there's certainly studies looking at averages of time and using -- depending upon what the -- which range of fiber per cc exposure, you know, probably that there would be a way to come up with -- with that information.
BY MR. SLAUGHTER:
Q. In order to calculate a dose, what you need to know is the fiber release of asbestos in a person's breathing zone, how long it was there for each episode, and how many episodes it occurred; correct?
MS. DEAN: Objection. Form.
THE DEPONENT: Well, over, you know, over what period of -- you know, you need to know what the fiber per cc was, the frequency, the regularity and the duration.
BY MR. SLAUGHTER:
Q. And do you believe that you have all that information relative to Ms. Moore?
MS. DEAN: Same objections.
THE DEPONENT: Again, they're -- even

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though Dr. Sahmel also made some sort of dose reconstruction, it was based on just varied times not necessarily specific to Ms. Moore, and certainly the duration wasn't specific to Ms. Moore. I don't know if I have specific information as far as -- we have duration. We certainly have frequency. How long she was exposed for, I don't have necessarily specific information, and I certainly have approximate information based on studies of how long people on average are using product.

BY MR. SLAUGHTER:

Q. And you do sometimes in your consulting work calculate doses of approximate exposures that you believe occurred to a person; right?

A. Not really. That's not usually something that I -- I might, but it's not something that I usually do, no.

Q. Is that something you would defer to an industrial hygienist on?

MS. DEAN: Objection. Vague and confusing.

THE DEPONENT: No. Generally it's not necessary. I mean, from a -- you know, Helsinki says if you have a -- you know, a history of

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exposure, that suffices, and all the information we talked about earlier today with Mr. Massenburg, very seldom do I see an industrial hygienist coming in and doing any sort of dose reconstruction. It's the exception rather than the rule.

BY MR. SLAUGHTER:

Q. Can you testify within a reasonable degree of medical or scientific probability that Ms. Moore had an exposure to asbestos from Cashmere Bouquet that exceeded .001 fiber/cc years?

MS. DEAN: Objection. Form, vague and confusing.

THE DEPONENT: Well, I don't remember what -- you know, going to a specific -- I have not calculated it out here. I know that the total range that, you know, based on the Sahmel reconstruction went up to -- up to almost .3 fiber/cc years, so her use of the Cashmere Bouquet was on a daily basis for a long time.

BY MR. SLAUGHTER:

Q. Can you say within a reasonable degree of medical or scientific probability that Ms. Moore had an exposure to asbestos from Cashmere Bouquet that exceeded .3 fiber/cc years?

MS. DEAN: Same objections. Vague and

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confusing, comparing it to a mathematical calculation absent doing the math.

THE DEPONENT: I have not calculated. I've already said that I don't do that, but to me that -- her exposures, because she's being exposed on a repeated basis every day with a dusty respirable product that is going on for decades, that her exposures from the Cashmere Bouquet were substantial, but I don't have and have not prepared any sort of dose -- specific dose reconstruction. That's not what I do.

MS. DEAN: Sorry. To interrupt. But what number did you give in the last question? I heard the .001; I just missed the second number.

MR. SLAUGHTER: .3.

MS. DEAN: Thank you.

MR. SLAUGHTER: Thank you, Doctor, that's all I have. I appreciate your time. I hope you have a good Thanksgiving.

THE DEPONENT: You too, sir.

Are we ready for a -- it's right at an hour -- want to take a --

MS. DEAN: Thank you for enforcing.

DEPOSITION OFFICER: Off the record?

MS. DEAN: Yeah.

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(Whereupon, a recess was held from 1:27 p.m. to 1:42 p.m.)

MR. ULLOA: Let's go on the record.

EXAMINATION

BY MR. ULLOA:

Q. Dr. Haber, good afternoon and happy holiday to you. My name is Ed Ulloa. I'm here for Revlon today, and I'm not going to bother you very long.

First question I had is earlier today you mentioned an understanding of the Blount methodology using heavy liquid separation.

Do you remember that testimony?

A. Yes. Blount? Yes.

Q. Yes. Blount/blunt, tomato/tomato. All right. We'll say Blount. I appreciate that.

In reviewing the Blount heavy liquid separation methodology, do you have an understanding as to -- excuse me one second. I apologize. I lost power earlier today, and I'm kind of in places where I usually wouldn't be.

So in talking about the Blount methodology, you've reviewed the 1991 paper where she discusses that Blount methodology; correct?

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A. Yes.
Q. Okay. You have an understanding of the sample preparations, methodologies, and protocols that she used in evaluating the presence of amphiboles in cosmetic talc samples; correct?
A. Can you be more specific of what you're asking?
Q. Sure.
You have an understanding of what she was looking for using her heavy liquid separation right?
A. Yes.
Q. She was looking for amphiboles; right?
A. Right. She was trying to help improve the ability to see the amphiboles that were present within the talc.
Q. Okay. What I'm going to do is I'm going to ask you to refer to your reliance list.
MS. DEAN: You may have been just getting there. I'm sorry if I jumped in. But do you mean B or C? I was just going to pull it up myself.
MR. ULLOA: It's the really long one. I think it's C.
MS. DEAN: The medical? Okay. Okay.
MR. ULLOA: And if it's B, I apologize.

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I'm on page 15 of the reliance list, and the numbers are around 345.
THE DEPONENT: No, C is not numbered; it's alphabetical, so you're talking about B.
BY MR. ULLOA:
Q. I'm talking about B. I was led astray by Ms. Dean. So yeah, I'm talking about B.
A. Okay. So I don't have that in front of me, but if you have a specific question, you can --
Q. Sure.
I'm talking about analyses of a Jean Nate product. Items 345 through 350 are three entries of MAS reports of Jean Nate body powder analyses done by MAS or Dr. Longo, and then 348 is a chart of MAS testing that Dr. Longo did that set forth 15 items, and then Dr. Longo did a declaration, and then 350 is another supplemental report, 70629, I believe.
So what I'm asking you is, do you have an understanding of whether or not Dr. Longo used the Blount methodology in his analysis of Jean Nate products?
MS. DEAN: Objection. Form, overly broad.
THE DEPONENT: I would have to go back and look. I know that in some preparations he does the

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Blount; in some he does the Colorado School of Mines preparation which also gets rid of the -- helps bring out the -- or see the -- identify the chrysotile. But off the top of my head, I don't recall if it was one or both.
BY MR. ULLOA:
Q. Okay. And it could have been one --
MR. ULLOA: I'm sorry, Jessica. Go ahead.
MS. DEAN: So there is, which has been asked and answered in this deposition, but a B and C that was attached to his declaration and then an updated version that was given before day one. What you were referencing but not shown to the doctor doesn't match up with what I'm looking at, which is the updated list, so I am fairly confident you're looking at Exhibit B to his declaration, just so we can all make sense of it later.
MR. ULLOA: I appreciate that. Thanks for that help.
BY MR. ULLOA:
Q. Yeah, and I think I am looking at Exhibit B, and what I'm asking you is, Dr. Haber, were you able to look at Dr. Longo's reports all of the reports underlying these entries and determine whether or not he followed the protocols set forth

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by Alice Blount?
MS. DEAN: Objection to form --
THE DEPONENT: You're talking about --
MS. DEAN: -- objection. Form, compound, overly broad, vague.
THE DEPONENT: So you're talking about the MAS testing?
BY MR. ULLOA
Q. Yes.
A. Okay. So on the MAS testing I would have to go back and look to see, you know, whether it was -- I think, you know, I already said whether he was following that or a modified version or, again, the Colorado School of Mines. I don't particularly recall, but I do recall that he was using -- he was doing a pre-concentration to do a heavy liquid separation technique. Whose particular version it is, I really don't have opinions as to a specific technique.
Q. Okay.
A. Like I said, what's being done is important, but which particular technique, for me -- I mean, it's better to do one, you know, than to not do one.
Q. All right. But when you do analysis using

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a technique, any technique, anything involving something that's going to call for you to do testing and analysis, you find the appropriate protocol or the protocol that you think you're going to use; right?

MS. DEAN: Objection. Form, overly broad.

THE DEPONENT: That is so broad. I don't even know what testing it is you're talking about, and, you know, as a pulmonologist, I really didn't even think of something that would -- that I would relate to being even as broad as that is.

BY MR. ULLOA:

Q. Okay. Let's say you're doing an analysis of cosmetic or asbestos fibers in a cosmetic talc product. If you were going to do it using the Colorado School of Mines methodology, would you first look to the Colorado School of Mines methodology to determine the protocol that you would follow for sample preparation?

MS. DEAN: Objection. Form, vague and confusing.

THE DEPONENT: I wouldn't do any of those because I wouldn't do that. I already testified I don't do that sort of testing, and so I'm not going to give testimony of what you should or shouldn't

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do. I don't do that. I never would do that.

BY MR. ULLOA:

Q. Okay. Are you going to offer any opinions at trial that Dr. Longo followed the appropriate protocols for use of the Blount methodology to analyze cosmetic talc samples for the presence of asbestos?

MS. DEAN: Objection. Form, vague and confusing, compound, unclear what testing.

THE DEPONENT: Again, you know, you're saying Dr. Longo, but there's other people at MAS. And I'm not going to be talking about how a particular -- I'm not going to be commenting on the use of --

BY MR. ULLOA:

Q. Perfect.

A. -- how they specifically did the liquid separation technique.

Q. And that's kind of where I'm going.

With respect to the MAS testing of a cosmetic talc product, you're not going to testify that MAS or Dr. Longo or any of the personnel at MAS followed or did not follow the protocol that their reports called out for, whether it be ISO 22226-2, Colorado School of Mines, or the Blount

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heavy liquid separation; is that correct?

MS. DEAN: Same objection.

THE DEPONENT: Are you objecting?

MS. DEAN: I just said same objections. Go ahead.

THE DEPONENT: Okay. I didn't want to talk over you.

Or if they were using some sort of combined technique that was perhaps superior. I'm not going to comment on that at all.

BY MR. ULLOA:

Q. Okay. You're not going to comment as to whether or not the Colorado School of Mines or Blount methodologies are generally accepted within the scientific community, are you?

A. Well, I don't -- I'm not even sure what that means. I know that these techniques have been around and were used by Johnson & Johnson and other cosmetic companies dating back to the '70s, so we're talking this is 50 years old, so I don't think this is something new and, you know, unexplored. I mean, this has been around for almost as long as -- well, ten -- I was ten years old when this was first starting being used, so it's been around for a long, long time. But as far

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as, you know, specifics as to, you know, how many people use it or should use it, no, I'm not your guy to give testimony on that.

Q. Fair enough.

And with respect to the Colorado School of Mines methodology, had you even heard of it before the -- Dr. Longo started using it in 2019?

MS. DEAN: Objection. Form.

THE DEPONENT: Yes.

BY MR. ULLOA:

Q. Okay.

A. I believe so.

Q. Where did you hear from it -- hear about it?

A. Oh, this would have been in, you know, after I started -- after 2017, when we learned about -- from the information that came out from Johnson & Johnson in the newspaper and Reuters and started seeing some of these documents, and then I went into a deeper dive into a lot of the testing, and I believe that was in -- within those testing. I know I saw a bunch of stuff -- a bunch of tests from Colorado School of Mines.

Q. And Colorado School of Mines, when they came out in 1972, you said you were ten years old?

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A. I would have been 12.
Q. I thought we were almost the same age there pretty close. Okay. That's neither here nor there.
Additionally, you list some other source mine documents related to the sale of talcs to Charles of the Ritz, a company called Charles of the Ritz, in items 340 through 344 -- you know what? Let me just go to your declaration.
Do you have your declaration in front of you?
A. I do.
Q. Okay. Easier just to do it that way. Now, this is a declaration set forth on page 3, paragraph 5 that you prepared for plaintiff's counsel in preparation for in opposition for several motions for summary judgment; is that correct?
A. Yes.
Q. Okay. In preparing this declaration as it relates to Revlon's motion for summary judgment, were you given any information as to what the declaration needed to include?
MS. DEAN: Objection. Form, vague.
THE DEPONENT: Well, I think we did

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discuss the declaration a lot during the first deposition last week, but, you know, I did talk about that, you know, it was going to include the information that I typically include in a report, which is the medical history, the social history, the occupational history some issues about an overview of opinions, some issues about -- that we've talked about today and last week ad nauseam in regards to asbestos in talc and testing. Those were, you know, kind of the generalities of the issues that I was asked to discuss, which were, like I said, generally the types of issues that I generally discuss.
BY MR. ULLOA:
Q. Yeah, I'm not trying to plow new ground here. I'm asking you specifically as to Revlon.
Let me ask you, first, is this the first declaration that you recall executing related to Revlon?
MS. DEAN: Objection. Form.
THE DEPONENT: I believe so. I think it's the first declaration -- yeah, I think, for Revlon. I don't remember doing this before for Revlon.
BY MR. ULLOA:
Q. Okay. And prior to this, the drafting of

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this declaration, were you given documents specific to Revlon that you did not have before?
MS. DEAN: Objection. Form, vague, overbroad.
THE DEPONENT: So with regard to -- I think in the Garcia case, which was exposures that ended, like, in '87 or so, since then, I think I've seen additional information with regard to late '80s and into the '90s and the 2000s, and I think that's in my notes which is Exhibit 6, that this was mostly from an area of Ontario, which I'm very familiar with, called Timmins.
BY MR. ULLOA:
Q. Okay. I want you to go to page 9 of your declaration, if you would.
A. I'm there.
Q. Okay. Page 9 of your declaration on paragraph 22, you start talking about cosmetic talc sources and exposures, specifically as to which mines, 22 and 23.
Does that sound about right?
MS. DEAN: Objection. Form, vague.
THE DEPONENT: Well, 25 is to -- it keeps going, but I mean, you know, paragraphs 22, 23, 24, 25, 26. I mean, it goes on and on.

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BY MR. ULLOA:
Q. And I understand that. You're talking about -- so with respect to paragraph 24, you're talking about Chanel; 25 you're talking about Jean Nate; 26 you're talking about Avon. Sound right?
A. Those did -- that is correct.
Q. Okay. So going to 25, the paragraph as it relates to Jean Nate, the first sentence says, quote, I do not have complete information for the talc source used in Jean Nate during all years pertaining to Mae Moore's use; however, there is likely talc source -- there is information of likely talc source for many of the years and that's applicable to Mae Moore?
A. Yeah, it should have been -- that's a typo, actually, yes. Applicable.
Q. Okay. Did I read that right?
A. Yes. Thank you for the typo correction as well.
Q. I didn't correct the typo. You corrected the typo.
Okay. You say you do not have complete --
Well, let me start with this: Do you have an understanding that the Jean Nate product was made by different entities during different periods

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of time? Do you have any information about that?
A. Yes.
Q. Do you know when Revlon, the party that's sued in this case, started making Jean Nate?
A. Right. I wrote it here, Revlon began doing so in around 1987.
Q. Right. Now, the allegations in this case are that Ms. Moore used Jean Nate product in 1987; right?
A. Let me just go back and refresh my memory. I'm sorry.
So the Jean Nate, by her recollection was in the '60s and '70s, but her daughter had her using it going into the mid-1990s.
Q. Okay. So the lady that used it said she stopped using it in 1972, but her daughter said she used it longer; does that sound right?
MS. DEAN: Objection. Misstates testimony.
THE DEPONENT: Not really. I mean, the person who used it was unfortunately dying and still is dying of mesothelioma and is -- was deposed for a long time, and it was -- there was certainly some -- a lot of, perhaps, memory issues, but that her daughter specifically recalled her mom

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using this product later, and so I don't think I can discount Ms. Pratt's specific recollection over Ms. Moore's.
BY MR. ULLOA:
Q. Sir, are you going to offer any opinions that Ms. Moore, at the time of her declaration, suffered from a medical condition that affected her ability to testify truthfully?
A. No. I'll leave the jury to decide of, you know, who to -- you know, who to necessarily put certain weight to. I'm just saying that I'm not going to discount Ms. Pratt's recollection over Ms. Moore. I'm just saying that -- or vice versa. I'm just saying that I'm not going to, you know, say that her exposure stopped in '72, based on the information from her daughter.
MS. DEAN: Ed, your last question said, if I heard correctly, declaration. Did you mean Ms. Moore's deposition?
MR. ULLOA: Yeah. I'm sorry. I did.
MS. DEAN: Thank you. With that clarification, I didn't have an objection, but I wanted to make sure we were on the same page.
MR. ULLOA: Yes. I apologize for misspeaking.

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MS. DEAN: Sorry to interrupt.
BY MR. ULLOA:
Q. Okay. So as you sit here today, do you have any information as to who manufactured the Jean Nate product prior to 1987?
MS. DEAN: Objection. Form, overly broad.
THE DEPONENT: So I wrote here it was my understanding that Lanvin and Charles of the Ritz made Jean Nate before Revlon in around 1987.
BY MR. ULLOA:
Q. Okay. Where did you receive that information from, if you recall?
A. I don't -- it would be within Exhibit B of my declaration.
Q. Okay. Now, your first line here, you say I do not yet have complete information for the talc source used in Jean Nate. Do you have any information for the talc source used in a Jean Nate product?
MS. DEAN: Objection. Form, vague as to time, overly broad.
BY MR. ULLOA:
Q. At any time.
A. Well, from -- I've seen information from '89 through '03 that it was a product called

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Timato, which comes from Timmins in Ontario and perhaps with some other blended, too, but certainly it indicated Ontario. And then as I talked about in Garcia, that I had seen frequent, many, many records going over a number of years primarily in the '70s and the '80s showing sales of tons of Italian talc from Whittaker, Clark & Daniel and from Cyprus.
Q. Okay. So looking at this page 10 of your declaration, you have a head note one at the bottom.
Do you see that? Or footnote. I should say footnote.
A. Yes.
Q. This footnote, this is where you set forth that you have reviewed and considered the sales record of Whittaker, Clark & Daniels to Charles of the Ritz from '75 to '87; is that correct?
A. That's part A, yes.
Q. Part A. Part B is Cyprus Industrial Minerals Company to Charles of the Ritz, '82 to '87; is that correct?
A. Yes.
Q. And then C is from both Whittaker, Clark & Daniels and Cyprus to Revlon in the late '80s and

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summaries of such records; is that correct, that includes D?
A. Yes.
Q. In any of those documents that are listed in this sentence from A through D, is there any information or indication or information that any of those talcs were actually used in a Jean Nate product?
MS. DEAN: Objection. Form, compound, vague confusing.
THE DEPONENT: I don't know what else -- I mean, these were indications of what is being sold for this purpose. You're right. I wasn't there to witness what they were putting into it; although, it certainly does -- the MAS testing does support the findings of not only the Italian but of the Canadian with the presence of chrysotile.
BY MR. ULLOA:
Q. Okay. Let me -- all right. So the records that I just referred to in A through D of this first sentence, these essentially are just records that Whittaker, Clark & Daniels or Cyprus sold the talc to a company called Charles of the Ritz; right?
A. Yes.

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Q. You have no information as to how many products were made by Charles of the Ritz that called for the use of any grade of industrial or cosmetic talc; is that correct?
MS. DEAN: Objection. Form, vague.
THE DEPONENT: Right, I don't -- unless it's within Exhibit B of my declaration, I don't recall.
BY MR. ULLOA:
Q. In the period of time between 1975 and 1987, you've seen no -- for that period of time not in that period of time -- for that period of time, you've seen no formula cards or any sort of formulation documents that would show what Charles of the Ritz used what type of talc they used to make the Jean Nate product; is that correct?
A. I don't recall seeing any formulations. If they've been provided, I don't remember, but I don't remember seeing anything like that.
Q. Okay. So without that, you're not going to testify to any degree of scientific or any degree of scientific certainty that any of the talcs reflected in these sales records were used by Charles of the Ritz in any particular product, including Jean Nate; is that correct?

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MS. DEAN: Objection. Form, misstates testimony, also just compound, overly broad.
BY MR. ULLOA:
Q. Do you understand my question?
A. No.
Q. Yeah, you're not going to testify to any degree of scientific certainty that based on what you've seen, Charles of the Ritz used this Whittaker, Clark & Daniels talc in a Jean Nate product?
MS. DEAN: Different question but same objection.
MR. ULLOA: Very well. Thanks. Sorry.
THE DEPONENT: I don't believe so unless there's been some other information that I'm just not recollecting.
BY MR. ULLOA:
Q. Okay. Going down to -- and I'm trying to move along, so I know there's a lot of people that got to go -- on line 15, you say the talc used in Jean Nate in the late '80s throughout the 1990s was predominantly Canadian talc. What do you base that on?
MS. DEAN: Objection. Form and asked and answered.

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THE DEPONENT: Yeah, I believe that I just testified that I recalled seeing that Revlon documents that is Timato from Timmins, which is -- that's the Canadian that I'm talking about -- and I say about like a Canadian, because it's actually where I grew up, and I have cousins in Timmins, so I know the area very well that -- that's what was mainly being used as long as some other sources being blended in.
BY MR. ULLOA:
Q. Let me ask you, why do you associate Timato with Timmins?
A. Well, that was the -- it was like a code number, I think, and then it was -- it called it Timato, but it said it was from Timmins and I mean, I don't know what the Timato necessarily stands for, but it, you know, certainly something to do with the name Timmins, but I do know that it said it was from Timmins.
Q. But you don't whether the name Timato is a Revlon's name or a Timmins name (inaudible)?
A. No, I don't know where --
(Reporter clarification.)
MR. ULLOA: Timato is a Revlon's name or a Timmins name or anything like that, was my poorly

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phrased question.
THE DEPONENT: I do not know the source of who came up with Timato as opposed to Timato -- that's a joke. No, I do not know where that name came from.
BY MR. ULLOA:
Q. Jessica's not laughing, but I appreciate it.
MS. DEAN: I smiled.
BY MR. ULLOA:
Q. Then the next sentence down, you say: In earlier years evidence indicated Jean Nate used Italian talc or blends of talc involving talc from North Carolina, Montana, and Australian.
What's the basis --
Well, let me ask you first, what earlier years are you talking about?
A. Well, so if you look down on -- that's where it shows subheading 1 and then it gives -- it talks about -- these are sales records, Charles of the Ritz purchasing Italian and some Montana, such as 1745 or sometimes it has North Carolina blended with Montana from '83 to '87, then purchasing talc from Cyprus and Whittaker, Clark & Daniel as well as listing Australian and blends of Montana, and so

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those would be the sources, and those would be all within my declaration, Exhibit B.
Q. Got it.
This everything that you just listed here in Footnote 1 here, you're talking about the Charles of the Ritz; right? There's no company called Jean Nate; right?
A. Right. That's, my understanding, is a product name.
Q. Right. But in this sentence here on line 17 on page 10, you say Jean Nate used Italian talc. Is it more correct to say that Charles of the Ritz used Italian talc?
MS. DEAN: Objection. Form, vague.
THE DEPONENT: I would have to go back and look at that document, if they said something about specific to Jean Nate. I don't remember now.
BY MR. ULLOA:
Q. Okay. Well, we just established a few minutes ago that you don't know what Charles of the Ritz used for talc with -- to make right -- withdraw --
A. I said I didn't remember. I think I said it could be or not.
Q. Okay. I'll move on.

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On line 21 you talk about the 15 historical Jean Nate cosmetic powder products that were -- there was also testing on 15 historical Jean Nate cosmetic powder products spanning decades that found asbestos in all samples tested. Five of the products tested positive for tremolite, and all 15 tested positive for chrysotile asbestos.
Is that correct -- did I read that correctly? I'm sorry.
A. Yes.
Q. Okay. And what you're talking about here is all of the MAS or Dr. Longo testing; correct?
A. The MAS testing, yes, that's what I'm referring to.
Q. Okay. Have you seen or been shown any of either TEM or PLM testing wherein there was analysis of Jean Nate product that either came out no asbestos detected or asbestos-free?
MS. DEAN: Objection. Form, vague.
THE DEPONENT: Well, first off, I don't know what you mean by asbestos-free because a -- as we talked about earlier, certainly PLM and, you know, even to some degree, you know, TEM is not perfection but significantly better, depending on the methodology, that you can find a non-detect but

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that you can't report that it's asbestos-free.
But, again, I think I already did discuss that I have seen a lot of tests -- I'm sure some of them relayed to this product as well -- that reported non-detects, but whether they're using a methodology that, you know, allows for not counting or depending on what the definition of asbestos is or how much time is being spent or what the -- you know, whether it's -- you know, a method like J4-1, which fails over and over and over and over again with spiked testing and has been shown to be, you know, unreliable. So I'm sure there's testing that I've seen and probably related to Jean Nate as well as well as others that have reported non-detects.
BY MR. ULLOA:
Q. All right. Then that's a long way to get to where I wanted to go, but let me ask you something -- you just brought up something real quickly about counting.
Are you familiar with the counting methodologies for quantifying the amount of asbestos fibers in a sample of cosmetic talc either by PLM or TEM?
MS. DEAN: Objection. Form, compound, at the end, but also just vague and ambiguous.

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THE DEPONENT: I'm not sure what you're asking.
BY MR. ULLOA:
Q. Sure.
Do you know what point counting is, like pursuant to NIOSH 7402?
A. Right. I'm not your guy that -- as I said, I think, that testifies -- you know, I mean, I'll look to see results are, and I know how to incorporate results based on my understanding of weaknesses and strengths of methodologies, but I'm not the one that actually does the analysis.
Q. Okay. So you're not going to testify whether or not Dr. Longo or anyone else actually properly followed the methodologies for quantifying asbestos in the sample; is that correct?
MS. DEAN: Objection. Vague and ambiguous, compound.
THE DEPONENT: I'm not even sure what -- I'm not even sure I understand necessarily what it is that you're asking.
BY MR. ULLOA:
Q. Sure.
Let's say that a methodology -- let's say ISO 22262-2 sets forth the criteria for quantifying

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asbestos in a sample that calls for point counting, which is looking at a field of vision on a graticule, which is like a bullseye kind of thing, then assigning points for portions or full fibers observed. Are you aware of any of that?
A. No.
Q. Okay. So you're not going to testify then that the failure to use point counting is an appropriate or not appropriate methodology in determining the amount of asbestos in the sample --
A. Right.
Q. -- would that be fair to say? Fair enough.
Okay. So then back to where I was. These 15 positive tests for chrysotile that Dr. Longo found, are you aware that those were all done using the Colorado School of Mines heavy liquid separation PLM methodology?
MS. DEAN: Objection. Form.
THE DEPONENT: Yeah, this is -- the MAS testing, yes, I'm aware that the -- or, again, I'm not -- I'm giving reference to Colorado School of Mines. I'm not sure if there's been modifications or whatever; it's not my area. But I am aware that there was a technique used by MAS in order to do

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heavy liquid separation but to maintain the ability to detect the chrysotile, which was what was actually found in all of the samples.
Q. Okay. Are you aware as to whether or not Dr. Longo or MAS is currently using the same technique that they used when they tested these 15 samples in August of 2020?
MS. DEAN: Objection. It's vague and ambiguous in terms of technique.
THE DEPONENT: I have no idea, sir.
MR. ULLOA: Okay.
Yeah, you know, that's all I got. I appreciate it. Chris asked all those other questions. Thanks. Have a great Thanksgiving, Dr. Haber.
THE DEPONENT: Thanks. You too.

FURTHER EXAMINATION
BY MR. BERKES:
Q. Hi, Dr. Haber. Let me turn my screen on.
A. There.
Q. You see me?
A. Yes, I can see you.
Q. Okay. I can see you.

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And you can hear me all right?
A. I can, sir.
Q. Very good.
MR. BERKES: And more importantly, can Paige hear me all right?
DEPOSITION OFFICER: Yes, thanks.
BY MR. BERKES:
Q. I just want to ask you a few questions in a couple of different areas, so I apologize if I kind of skip around a little bit. Let me just ask you, have you done any work on the Mae Moore case since your last session of the deposition in this case?
MS. DEAN: Objection. To some extent, asked and answered, overly broad.
THE DEPONENT: Yes.
BY MR. BERKES:
Q. What have you done?
A. Well, I got additional updated medical records, which we already discussed earlier -- that I had done that, earlier today. I've also looked at billing records, and I've probably spent a little bit of time re-reviewing my file looking back at my declaration in preparation Volume II.
Q. Have you been provided any additional

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information about this case from any source, whether it's somebody from Ms. Dean's office or anyone else that you did not previously have, other than the medical records and the...

MS. DEAN: Objection. Asked and answered today.

MR. BERKES: It was? I didn't hear anybody --

THE DEPONENT: Yeah, I'm pretty sure that we talked about that, and I think that there was some additional -- I don't remember what all else it was but --

BY MR. BERKES:

Q. Okay. If you already answered it, I don't want to go into it.

With respect to the updated medical records, what is the latest date of any record, medical record for Ms. Moore, that you now have?

A. July of this year.

Q. And the billing records that you received, what is the last date of any billing records that you have seen?

A. I would -- I don't have them in front of me, so I don't -- I can't tell you.

Q. Do you know if they post-date July of this

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year?

A. Right. I just finished saying I don't remember, so I don't want to start testifying to something I don't remember.

Q. Okay. And the billing records --

A. I can try to see if I can pull it up, but I don't have it in front of me here.

Q. Okay. The billing records that you received, are they actual records from the facilities, or is it a chart of medical expenses?

MS. DEAN: Objection. Form.

THE DEPONENT: I've actually seen the actual billing records from all of her various providers, plus I've seen a summarizing chart, so both.

BY MR. BERKES:

Q. And have you been able to verify what the charges that are reflected in the billing records, what treatment it is for or if it's not a treatment, whether it's an office visit, a hospital stay, in other words, have you been able to link up what the charges are for?

A. Yes. Yeah, I've seen -- I've seen all the, I mean, you know, CAT scans and PET scans and IVs and procedures, all of those.

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Q. Okay. With respect to St. Joseph's hospital, are you familiar with that facility, one of the facilities that she's received some treatment for in the last few years?

A. Yes.

Q. Do you have an amount from that facility that you understand has actually been paid to date that you will be offering an opinion on as to whether that amount is reasonable and necessary for treatment for her mesothelioma?

A. Off the top of my head, I don't, but yes --

MS. DEAN: Dr. Haber, let me just insert an objection there.

It's vague as in confusion to date.

But sorry. Go ahead.

THE DEPONENT: Okay. I was going to say that, A, I do not have a number off of the top of my head, as we sit here right now, but yes St. Joseph's hospital was -- I have seen the billing records, and I would be providing testimony as to what was actually paid for the needed medical services related to her mesothelioma from that facility.

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BY MR. BERKES:

Q. Did you also see charges for which there was actual payment for services that you agree are not related to her mesothelioma?

MS. DEAN: Objection. Vague.

THE DEPONENT: Yes, I believe I did see, within some of the billing records, billing that would -- I would not relate to her mesothelioma.

BY MR. BERKES:

Q. And can you give us a general description of what services or what conditions you saw charges for that did not relate to her mesothelioma?

A. For example, I believe, and I'm 99 percent certain -- not certain of the date, but this was well before her -- her, Ms. Moore's, mesothelioma and related to, I think, one of her own medical conditions, but antedated the mesothelioma and, in my opinion, wouldn't -- was not related to any symptomology that I feel would have been, based on the timing, related to the mesothelioma.

Q. Have you ever -- have you seen any medical procedures, office visits since her diagnosis of mesothelioma that you believe is not related to the mesothelioma?

MS. DEAN: Same objections.

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THE DEPONENT: No, not really, because even though she had, I think, one episode of syncope, it became much more complicated because of the presence of hypoxemia and respiratory failure and the cancer issues and malnutrition issues from the cancer, so even if it wasn't a hundred percent the meso, it certainly is relatable to a great degree. Same thing, you know, she developed at one point a urinary tract infection, but that was because, you know, the presence of immune compromise and the cancer.

BY MR. BERKES:

Q. She also had shingles; correct, since her diagnosis?

A. I believe that that is correct. And, again, herpes zoster is absolutely relatable to people that are under emotional or physical stress, having cancer, et cetera, and dealing with that can definitely bring about a reoccurrence of herpes zoster.

Q. She's had a longstanding history -- by that, I mean decades -- of syncope and fainting spells; correct?

A. Right. It's not "and" it's a -- she has a -- this probably a hypersensitivity of the

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carotid that leads to episodic syncope.

THE DEPONENT: And for the court reporter, that's s-y-n-c-o-p-e.

BY MR. BERKES:

Q. And so other than the point that you just made, that since her mesothelioma, that condition could be impacted by hypoxemia or other difficulty breathing, at least the onset of that condition had nothing to do with her cancer; correct?

A. The original onset from decades ago, that is correct. She had this -- this was a preexisting condition that was exacerbated by the development of the cancer.

Q. With respect to the plaque that you saw, Doctor, when you looked at the radiology, is it correct that none of the treating radiologists or other physicians noted the presence of a left pleural plaque in the medical records?

MS. DEAN: Objection. Form.

THE DEPONENT: Yeah, I don't know whether any of the other doctors noted it. I don't recall the radiology -- I know they focused, as most radiologists do, on the presence of the right-sided disease and the diffuse pleural thickening and the diffusion on the right side. I don't recall as far

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as anyone else necessarily looking for what was going on on the left chest.

BY MR. BERKES:

Q. When you stated earlier that in your declaration when you summarized the radiology in the first few paragraphs of that declaration that you were only memorializing what the records said as opposed to what you personally had seen, my question is if any of the physicians had noted the presence of a left pleural plaque, would you have included that in your recitation of the records?

A. So, well, first off, my history that I provided in paragraph 10 or section 10 is not memorializing all of the radiology. In fact, it's just -- there's just, you know, several discussions. You know, it's not every CAT scan; it's certainly not every chest x-ray, and so it's definitely, you know, it was hitting some highlights of findings, for example, the most recent one showing the tumor progression. But I don't know if I was looking -- in fact, I know I wasn't looking at her treating doctor's records to such a degree that that couldn't have been something that was there and I just didn't note it because it's really not important in this case. I

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mean, there's no question she has mesothelioma.

Q. Will you be -- or can you say to a reasonable degree of medical certainty that the plaque that you saw on the left side was caused by her use of cosmetic talc products?

MS. DEAN: Object to the form.

THE DEPONENT: Well, in the absence of any historical reason for her to have a plaque, that the appearance of it looks fairly characteristic of an asbestos plaque, and in the absence of exposures to asbestos from any other source that I've been able to either glean from her volumes of depositions, looking at all of the medical records, and with me personally interviewing her, it would be from -- in my opinion, from asbestos that she got from inhaling asbestos from her use of cosmetic talc products over decades and decades.

BY MR. BERKES:

Q. I want to switch to a different topic, and this may be my last topic.

Are there any products -- and I'm not sure what the most efficient way to ask this question is, so I may have to struggle through it initially, but let me just ask it on a product-line basis.

Are there any particular products of which

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you understand Ms. Moore -- cosmetic products of which you understand Ms. Moore used where you are not able to say to a reasonable degree of medical or scientific probability that it is more likely than not that that use was a significant contributing factor?

MS. DEAN: Objection. Form, vague, compound.

THE DEPONENT: You know, let me make sure I'm understanding. When you say product, I mean, what are you --

BY MR. BERKES:

Q. I was concerned when I used the word product that it may cause some consternation.

You've listed on Exhibit 6 to your deposition which are your notes, the typewritten notes, if you look at the first page, you have nine categories by company or in the case of Jean Nate, we know from Mr. Ulloa's that that's actually a product not a company -- but you list these companies.

So let's just start with Colgate Cashmere Bouquet. That's the only Colgate product that you understand is at issue and that you've been told is at issue in this case; right?

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A. Yes.

MS. DEAN: Let me just -- to the prior non-question part object as misleading and not proper question format.

BY MR. BERKES:

Q. So just looking at this list of the names that you have put there, whether they be company names or product names, is there any category in those first nine where you are not able to say to a reasonable degree of medical or scientific certainty that it is more probable than not that her use of product by that company or by that name is a substantial contributing factor?

MS. DEAN: Objection. Form, compound.

THE DEPONENT: I would say without a hypothetical or without more information, that the Charlie, which I don't have source information on, would be the response to that. The rest I have information as to the source that is asbestos-containing and all the other information we've talked about for two days now and her frequent use. But the Charlie, even though I have the use for decades, I do not have the talc source at this time yet.

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BY MR. BERKES:

Q. So that is the only one that you are not able to say to a reasonable degree of medical or scientific probability contributed to her mesothelioma; correct?

A. Not without some sort of hypothetical or without additional information.

MS. DEAN: Same objection.

BY MR. BERKES:

Q. And have you asked counsel or anyone else for additional information specifically to Charlie? Have you asked for that information?

MS. DEAN: Objection. Asked and answered.

THE DEPONENT: Yes. It is my understanding that they're attempting to get that information.

BY MR. BERKES:

Q. Now, there are other names or products that Ms. Moore used that are not on page 1 of this list that, in your opinion, would be a substantial contributing factor to her mesothelioma; correct?

MS. DEAN: Objection. Vague, overly broad.

THE DEPONENT: I'm not sure.

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BY MR. BERKES:

Q. Well, you were certainly aware that Ms. Moore used, for the better part of 80 years, Johnson & Johnson baby powder; correct?

A. Right. It's there. It's number 5.

Q. Oh, I missed it.

And then also Shower to Shower, is that a product that you believe Ms. Moore used that contributed to her mesothelioma?

A. I'd have to go back and -- I know -- I think that's also a Johnson & Johnson product, but I'd have to go back and look. I don't remember what her times of use was specific to Johnson & Johnson, off the top of my head. I'd have to go back and review it.

Q. Okay. Are there any other names that are actually not on Exhibit 6, names of finished products, not raw talcs but finished products, that you understand Ms. Moore encountered in her life, whether she used it or it was used on her or somebody used it in her presence that you believe was a significant contributing factor to the development of her mesothelioma?

MS. DEAN: Overbroad, compound.

THE DEPONENT: I believe that's been

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discussed in detail in my declaration. I mean, if I'm understanding you correctly -- so, like, for example, you know -- and I've already been asked questions about Chanel or questions about Avon --
BY MR. BERKES:
Q. I'm not talking about that.
A. Okay.
Q. I'm not talking about Avon, Revlon, Chanel or Colgate.
A. Okay. Then I'm misunderstanding your question.
Q. I'm talking about names that don't appear on Exhibit 6, either product names or company names of companies who made products that you understand Ms. Moore used that we have not discussed in this deposition and that are not on your list on Exhibit 6 that you believe contributed to her mesothelioma?
MS. DEAN: Objection. Overly broad.
(Reporter clarification.)
THE DEPONENT: So if I'm understanding you correctly, is that -- so, like, in Exhibit 6, my notes, I list Avon, and I discuss -- in my declaration I list some of the products that she listed, but that all gets counted as --

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BY MR. BERKES:
Q. I now understand your confusion and -- or the weakness of my question. I understand where you're going.
A. Okay.
Q. I'm trying to get the universe of products or exposures that you understand Ms. Moore had that you believe were significant contributing factors. We have the list from Exhibit 6. We have your declaration. And leaving Avon products aside, setting those products aside, are there any other products that we have not spoken about in this deposition that you believe constituted an exposure Ms. Moore had that was a significant contributing factor to the development of her mesothelioma?
MS. DEAN: Same objections.
THE DEPONENT: But that does not count in either the company name or if it's a specific product name -- so like Chanel, any of the Chanel products would be considered under that number 2 --
BY MR. BERKES:
Q. Right.
A. -- and what's in my declaration. So -- and I am -- as far as I know, I'm not aware of anything else and this would also be, you know,

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based on her deposition testimony, and I'd have to go back and look, but I think I don't remember anyone else except to the fact of, you know, there's a -- under 10, which is Whittaker, Clark & Daniel, who was a supplier to a lot of different people, just in case I'm not -- I'm misremembering, but I think that was -- it still encompasses the same list, but I'm not a hundred percent sure, but I don't remember anyone else, off the top of my head, that I would add to this list.
Q. Okay. Those are all my questions. Thank you, sir, and have a happy Thanksgiving.
A. You too, sir.
THE DEPONENT: Are we ready to take just a brief break? I'm sure Paige wants one. She's nodding.
MS. DEAN: Okay. Mitchell, you're on mute. I can guess you're saying you only have a few minutes.
THE DEPONENT: Are we off the record?
MR. CHARCHALIS: I'm sorry. I was going to say -- this can be off real quick.
(Whereupon, a recess was held from 2:42 p.m. to 3:03 p.m.)
MR. CHARCHALIS: All right. Let's go back

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on the record.

EXAMINATION
BY MR. CHARCHALIS:
Q. Dr. Haber, my name's Mitch Charchalis. I believe I may have met you in another matter, but I am going to be brief.
I represent Lucky Stores in this matter. Okay?
A. Okay.
Q. If I say Lucky, agree with me that you'll understand that's Lucky Stores; correct?
A. Okay.
Q. All right. I know that you, you know, provided numerous opinions during this deposition, but specifically with regard to Lucky, do you have any opinions as to Lucky?
A. No.
Q. Have you been asked to consider any hypotheticals as to Lucky?
A. As of yet, no.
Q. Have you reviewed any Lucky documents in preparation to provide your opinions in this case?
A. Nothing comes to mind, no.
Q. You don't consider yourself an expert in

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the standard of care for retailers; correct?
A. Correct.
Q. And you will not be offering an opinion as to what Lucky should or should not have done?
A. I can't imagine doing that.
Q. Thank you for your time, Doctor.
A. You're welcome.
MS. DEAN: This is Jessica Dean. I have a brief -- hopefully brief redirect.

EXAMINATION

BY MS. DEAN:
Q. Can you hear me okay, Doctor?
A. Yes, I can.
Q. Okay. You were asked some questions about transmission electron microscopes earlier today. Do you recall that?
A. Yes.
Q. I'm paraphrasing, but do you recall saying something that you don't and you wouldn't want anybody to have you be the person operating a TEM machine in order to determine its results? Do you recall that?
A. Yes, I do.
Q. Very different question. As a medical

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doctor, have you, ever over the course of decades, relied on TEM results in order to give asbestos opinions, both in -- as a litigation expert and in your practice as a doctor?
A. Yes.
MR. SLAUGHTER: Objection. Vague.
MR. MASSENBURG: Objection. Vague.
BY MS. DEAN:
Q. Have you relied on, first, in this case, the testing results of others, whether it uses TEM or some other method, to analyze asbestos in bulk analysis?
A. Yes.
Q. Have you relied on, in this case, the testing done by others in order to examine things like air samples to determine how much asbestos may be in the air when using a product?
A. Yes, I have.
Q. Is this the type of information that, before using it, you considered the known strengths and limits of those tests?
A. Of course.
MR. SLAUGHTER: Objection --
MR. MASSENBURG: Objection. Vague.
///

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BY MS. DEAN:
Q. Is this information that you have routinely relied on as a medical expert?
A. Yes.
Q. Is this information that those in your field routinely rely on?
A. Yes.
Q. Even if we consider outside of the context of litigation, is relying on testing of this nature in order to consider its strengths and limitations before making causation opinions -- and when I say testing, I mean testing where you're not the operator, but you just get the results -- something you routinely do?
A. Yes.
MR. MASSENBURG: Objection. Vague, compound.
BY MS. DEAN:
Q. Going back to the context of situations where you're hired by lawyers on either side to give opinions in the context of litigation, is reliance on different tests that evaluate either in a bulk sample or in the air the asbestos in the air something that you only do in cosmetics or industrial talc cases?

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A. No.
MR. ULLOA: Vague and overbroad.
BY MS. DEAN:
Q. With the objection, I didn't get your answer, if you answered.
A. No.
Q. Okay. For instance, in cases where you're evaluating products like a gasket or brakes, have you relied on testing information whether by transmission electron microscope or PLM in order to evaluate the amount and types of asbestos in the air?
A. Of course.
Q. The Chanel lawyer asked you, for some time, about short fibers and there were questions about 5 microns and 4 microns. Do you recall that?
A. Yes, I do.
Q. Okay. Even using the example that the defense lawyer brought up, is your ability to analyze fiber lengths, something that you told us relates to carcinogenicity directly related to understanding and relying on the test methods used and the limitations of that test?
A. Yes, absolutely.
MR. MASSENBURG: Objection. Vague.

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MS. BURGE: Objection. Vague, compound.
BY MS. DEAN:
Q. In terms of more specific, the testing documents that you reference in your declaration and reference materials, have you included things that you believe are reliable, although with the limitations and strengths identified, and that those in your field would routinely rely on?
A. Yes.
Q. Next subject I want to ask you about is latency. You were asked by the lawyer for Chanel to look at your paper where you were an author in 2011 and identified the shortest latency; I think it's 15 years. Do you recall that?
A. Yes, I do.
Q. In terms of your broader opinions about latency, do you rely on just that study or the broader scientific literature on kind of the expected range for latency?
A. The broader scientific literature, of course.
MS. BURGE: Objection. Vague. Sorry.
BY MS. DEAN:
Q. And to put it differently, if someone tried to suggest that that discrete question about

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your one paper represented your opinions about the shortest latency you could expect, would that be accurate?
A. No.
Q. Okay. You were asked some question about the concept of no safe level for quite some time earlier today. Do you recall that?
A. Yes, I do.
Q. First, in the context of radiation, you were asked some hypotheticals about radiation. In any of those questions, do you recall being given information about whether the radiation was even to the same site as the tumor that later developed?
A. I do not.
Q. Okay. In terms of talking about the concept of no safe levels and risk, specifically talking about asbestos exposures and the disease mesothelioma, you discussed kind of the inability to find a known safe exposure level. Do you recall that earlier today?
A. Yes.
Q. Have there been multiple efforts to find low levels and see if they are safe that have been unable to document a safe level?
A. Yes.

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MR. MASSENBURG: Objection. Vague, leading.
BY MS. DEAN:
Q. More broadly, when we talk about your causation opinions -- and I'm just going to, by way of example, use the ones that you talked about in this declaration for some of the companies' summary judgments. When you indicated something was a significant cause, did you consider frequency, regularity, proximity, duration, and intensity?
A. Yes, I did.
Q. If anyone suggested that you merely said there's no safe level; therefore, this is significant, was that your thought process at all?
A. No.
Q. Okay.
MR. MASSENBURG: Objection. Leading.
BY MS. DEAN:
Q. If we want to know how you approached this, you at least gave some indications of that in the declaration that you signed; right?
A. I did.
Q. Okay. Were the exposures that you identified in the declaration close calls, in your estimation as an expert, in terms of determining

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whether they were significant or not?
A. No, there was not a close call.
MR. MASSENBURG: Objection. Vague.
BY MS. DEAN:
Q. Now, in the declaration you looked at some specific exposures including exposures to Jean Nate, Cashmere Bouquet, Avon and others. Do you recall that?
A. Yes, I do.
Q. One company I just want to be very clear about that was not in there is Whittaker, Clark & Daniels. Do you have opinions about Whittaker, Clark & Daniels despite them not being addressed in this disclosure -- I mean this declaration that you filed about specific companies?
A. Yes.
Q. Were you prepared to discuss those opinions today?
A. Yes.
Q. Do you believe that Mae Moore's exposures from Whittaker, Clark & Daniels were substantial and significant?
A. Yes.
MR. BERKES: Objection. No foundation, calls for speculation.

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BY MS. DEAN:
Q. You were asked a very broad question at the beginning of, I think, day one of your multi-day deposition about what your opinions were in this case. Do you broadly recall that?
A. I do.
Q. Did anybody ask you, to your memory -- and I know we're going into two days' worth questions -- but about re-entrainment?
A. No.
Q. Is that something you're ready to discuss?
A. Sure.
Q. Did anybody ask you opinions about potency, the potency differences between fiber types?
A. I don't think so.
Q. Is that something you're ready to discuss?
A. Sure.
Q. Did anybody ask you about many of the materials that are outlined in your Exhibit B or C?
A. No.
Q. If they wanted to get into specifics, one of the things I offered is that we could pull that and look at that beforehand; I'm not sure if you knew that.

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But let me ask you this: Just, were you willing to discuss any of those materials and how they -- what they meant to you in relation to Ms. Moore's case?
MR. AMEELE: Leading, foundation.
MR. MASSENBURG: Objection to the -- yeah, objection to the colloquy of counsel and the repeated efforts by Ms. Dean to instill time limitations and complain about the length of any questions by counsel and then now saying that others should have asked questions about the thousands of references from the list.
BY MS. DEAN:
Q. You can go ahead and answer.
A. Yes.
Q. Now, you've been asked about many of these topics in other cases in the past; right?
A. Yes, I have.
Q. Okay. Avon asked you some questions on day one about specific products that related to Avon and then asked you some questions about Night Magic. Do you broadly remember that? I know that was over a week ago.
A. I do.
Q. In addition to the Night Magic testing

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that you were asked about, you have information from Lewin's testing back in the 1970s on your list. Do you broadly recall that?
A. Yes.
Q. Also to understand your opinions for Avon or any other company, if there is information about the talc they used, the source of the talc containing asbestos, is that something you rely on?
A. Yes.
Q. Have you seen information about whether it is feasible to fully remove asbestos from talc ore?
MR. MASSENBURG: Leading.
THE DEPONENT: I've seen the information that it's not feasible to remove it. In fact, experts including Pooley have said you can't do it.
BY MS. DEAN:
Q. Do you rely on information finding -- looking at testing for the presence of asbestos in talc from the processed talc?
A. Yes.
Q. And then finally, do you also consider information in terms of testing about the end product as it relates to any end product that has the same grade of talc?
A. Yes.

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Q. And I always have a little bit of trouble articulating that, so I want to give an example, just to make sure I'm clear.
If somebody's using Val Chisone Italian-grade talc, whether it's put into a bottle of Johnson baby powder or Shower to Shower or Chanel or an Avon product or Cashmere Bouquet or Coty, if you have testing that specifically relates to an end product that contains that same source talc, is that something you would consider if it's on your reference list?
A. Yes.
MR. MASSENBURG: Objection. Vague.
BY MS. DEAN:
Q. Are there published peer-reviewed studies specifically looking at Italian-grade talc that you rely on in your opinions about products that used Italian talc?
A. Yes.
Q. You were asked questions about fiber length and whether -- there was a hypothetical about whether something was all under 5 microns, whether you would find within a reasonable degree of medical or scientific certainty if that was causative. Do you broadly remember those

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questions?
A. I do.
Q. And in a situation where -- I want to ask you a different hypothetical but related.
In a situation where you had an exposure where some fibers were greater than that 5-micron length and some were less, within a reasonable degree of scientific and medical certainty, do you believe it is reasonable not to consider the fibers that are under 4 microns in terms of their ability to cause the disease mesothelioma?
A. No.
MR. MASSENBURG: Objection. Vague, incomplete and improper hypothetical, assumes facts, calls for speculation.
BY MS. DEAN:
Q. Sorry. You can go ahead.
A. I didn't -- yeah, my answer was no.
Q. Okay. And then the last subject I want to ask about is you were asked both on day one and day two whether you've done a dose reconstruction. Do you recall that?
A. I do.
Q. Without a dosimeter, is it possible to, with precision, identify what a person's exposure

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was to any asbestos product?
A. I'm not aware of any --
MR. MASSENBURG: Objection. Vague --
MR. SLAUGHTER: Objection. Vague, calls for speculation, calls for an expert conclusion --
(Simultaneous speaking interrupted by the reporter.)
MR. SLAUGHTER: Go ahead.
MR. MASSENBURG: Vague and speculation, I believe, but also calls for conclusion outside the area of this expert's expertise.
MR. SLAUGHTER: Join. I don't know why I felt like I had to join. I'm going back to mute.
BY MS. DEAN:
Q. I missed your answer. I'm sorry, sir.
THE DEPONENT: I'm not aware of any, no.
BY MS. DEAN:
Q. Okay. Do you have sufficient information, whether it be from qualitative or semiquantitative information to determine whether Mae Moore's exposure from Avon products were substantial and significant?
A. Yes.
MR. AMEELE: Objection. Leading, foundation.

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BY MS. DEAN:
Q. Were they?
A. Yes.
Q. Same question -- well, let me ask you a slightly different question.
If there is a hypothetical question that is different than Ms. Moore where she had the exposures she discussed to Avon but no other exposures --
Are you with me so far?
A. I am.
Q. Okay. In that scenario, was her exposures to Avon sufficient to cause the disease mesothelioma?
MR. AMEELE: Vague, assumes facts, foundation, incomplete hypothetical.
THE DEPONENT: In my opinion, yes.
BY MS. DEAN:
Q. Okay. Same two questions for Jean Nate that I asked about Avon. Do you have sufficient information, from both qualitative and semiquantitative analysis, to determine whether her exposures to Jean Nate were substantial and significant in causing her mesothelioma?
A. I do.

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Q. Were they?
MR. ULLOA: Objection. Vague, overbroad, misleading. 352. I'm sorry. Go ahead.
THE DEPONENT: In my opinion, yes.
BY MS. DEAN:
Q. Okay. And if they were alone, would they be the cause of her disease?
A. Yes.
MR. ULLOA: Same objections.
BY MS. DEAN:
Q. As it relates to Cashmere Bouquet, would your answers be the same if I substituted out Jean Nate for Cashmere Bouquet for Mae Moore's exposures?
MR. SLAUGHTER: Objection. Assumes facts not in evidence, vague, misleading.
THE DEPONENT: I don't know if you heard my answer, but it was, yes.
BY MS. DEAN:
Q. I hadn't. Thank you.
Same questions if I asked you that as it relates to -- it's been a long week. Sorry -- Chanel. How can I forget? I will just reask because there was an awkward pause there.
Do you have sufficient qualitative and

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semiquantitative information to give an opinion about whether to Mae Moore's exposures to Chanel were substantial and significant in the development of her disease, mesothelioma?

MR. MASSENBURG: Objection --

MS. BURGE: Objection. Vague, overbroad, assumes facts.

THE DEPONENT: Yes.

BY MS. DEAN:

Q. Okay. Was it?

A. Yes.

MR. MASSENBURG: Same objections.

MS. BURGE: Same objections.

BY MS. DEAN:

Q. And in a situation where I asked you to assume that her only exposures were to Chanel products, would that have been the cause of her mesothelioma and likely death?

A. Yes.

MS. BURGE: Objection. Vague.

MR. MASSENBURG: Calls for speculation, calls for a legal conclusion, improper foundation, calls for speculation.

BY MS. DEAN:

Q. And if I -- and if I asked those same

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questions but related to the exposures that are, in your opinion, related to Whittaker Clark & Daniels, would your answers be the same?

MR. BERKES: Objection. No foundation, calls for speculation, assumes facts, improper hypothetical.

THE DEPONENT: Yes. Yes.

BY MS. DEAN:

Q. And in terms of what exposures you attribute to Whittaker, Clark & Daniels, is that something you were prepared to discuss today?

A. Yes.

Q. The only other thing is we were -- between day one and day two got you some additional medical records. Do any of those medical records change any of the opinions that you gave either in your declaration or when you were asked questions over the course of these two days?

A. No.

Q. Okay. Thank you. That's all I have.

MR. MASSENBURG: If we have follow-ups -- I'm on the phone, though, guys, so anybody else want to go before me?

MR. SLAUGHTER: I don't have anything.

MR. BERKES: Go ahead.

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MR. MASSENBURG: Okay.

FURTHER EXAMINATION

BY MR. MASSENBURG:

Q. Dr. Haber, you started, when Ms. Dean was asking you questions, about what you've reviewed to inform your opinion as to whether or not any potential asbestos inclusion in Italian talc could be separated from the finished talc that was sold. You recall those questions from her?

A. Yes.

Q. You cited Pooley, but you said -- I think you said experts including Dr. Pooley. What other experts have said that it is impossible to separate any potential asbestos inclusion from any of the Italian talc through the beneficiation process before it's sold?

MS. DEAN: Objection. Form, overly broad.

THE DEPONENT: I'm just looking at my declaration.

BY MR. MASSENBURG:

Q. Any luck?

A. I'm just -- unfortunately, I was -- because I know I discussed that in my declaration. I can't find it just quickly going through it here.

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My recollection is that there were -- there were -- I've seen reports from various companies including, I believe, Johnson & Johnson and Avon that have reported their inability to remove the asbestos from various beneficiation techniques, and, again, I believe that this is in my declaration and has additional citations, I'm pretty sure, in addition to those and Pooley.

Q. Okay. I will tell you that from my recollection, your declaration does have a citation to Pooley, but that's all I saw in that paragraph regarding that portion of what Ms. Dean was asking as to that area of that opinion.

Other than identifying generally company documents from Johnson & Johnson and Avon, as we sit here now and you're looking at your declaration, can you identify anything besides what you just told me, documents and Johnson & Johnson and Avon and the one document from Dr. Pooley in the early '70s, that says that it is impossible to separate any asbestos involvement from Italian talc through the beneficiation process?

MS. DEAN: Objection. Misstates testimony, to some extent, asked and answered.

THE DEPONENT: I would have to go back and

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look at it. I'm sure that the documents would be within Exhibit B as far as the efficacy of -- or lack of efficacy of trying to remove asbestos from talc.

BY MR. MASSENBURG:

Q. Can you describe for me what the beneficiation process is, how the talc is milled before it's sold?

MS. DEAN: Objection. Both -- two parts of the question, and the first being overly broad and vague.

THE DEPONENT: My understanding is there were different ways of -- whether trying to float it out or using different materials to try to purify or clean out the asbestos. As far as how that has to do with milling, I'm not -- I don't see how -- I'm not sure how this relates to it.

BY MR. MASSENBURG:

Q. Describe for me what the beneficiation process is for talc is, as you understand it.

MS. DEAN: Objection. Vague as to time, overly broad, and compound. To some extent asked and answered.

THE DEPONENT: I'm not going to be able to provide any more than what I just said as far as

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various ways of either using floating or other materials to try to clean the asbestos out of the -- out of the talc, how they --

(Simultaneous speaking interrupted by the reporter.)

MR. MASSENBURG: And then I asked what is floating, and he said I don't know.

THE DEPONENT: And then I --

BY MR. MASSENBURG:

Q. At the end of the --

Yes, sir. Go ahead.

A. I wasn't finished, that's why. I said that I don't know exactly the technique, but this is something that is reported within the documents listed in Exhibit B of my declaration, that one of the techniques for beneficiation was this floating, how precisely that a company goes about doing that, that, I don't know.

Q. In your Exhibit B, I believe I have a combined document that has your declaration with all of the attachments, it's 1736 pages. On page 81 of 1736 there's a citation including the Iwatsubo article in 1998.

Do I need to give you the name of that document in order for you to be able to tell me

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whether you're familiar with that and that you rely on it? It is referenced by you.

MS. DEAN: Objection. Vague.

THE DEPONENT: Okay. So I'm just trying to understand what you're asking.

BY MR. MASSENBURG:

Q. I'm asking if you rely on the article from Iwatsubo in 1998 that is listed in your Exhibit B of your reliance list, the name of the article is "Pleural Mesothelioma: Dose Response Relation At Low Levels of Asbestos Exposure in a French Population-Based Case-Control study." It was --

A. Right. It's in my reference list.

Q. It was published in the -- got it.

(Simultaneous speaking interrupted by the reporter.)

THE DEPONENT: I said it is in my reference list, yes.

BY MR. MASSENBURG:

Q. And that's also true for the Rodelsperger article, 2001, R-o-d-e-l-s-p-e-r-g-e-r, published 2001 "Asbestos and Manmade Vitreous Fibers as Risk Factors for Diffuse Malignant Mesothelioma: Results from a German Hospital-Based Case-Control Study," published in the "American Journal of

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Industrial Medicine"?

A. Yes, it is in my reference list. These are both articles relating to development of mesothelioma and dose -- industrial hygiene dose reconstruction data.

Q. And you answered in response to a hypothetical from Ms. Dean -- I think it was on multiple different companies, but you said you have a semiquantitative and a qualitative -- enough semiquantitative and qualitative data to offer opinions as to whether or not individual products expose -- or use of talc for individual talc was a significant exposure and enough to cause mesothelioma in and of itself. Do you remember those questions, generally?

A. Yes.

Q. What semiquantitative data do you have to form your opinion as to Chanel?

MS. DEAN: Objection. Form, been asked and answered.

THE DEPONENT: Well, with regard to Chanel, we have the exposure data that we're talking about as far as, you know, this is Italian so, for example, the Gordon paper would apply, and this is, you know, exposures in that 1 to 4 fiber

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per cc range -- Gordon was, actually, even a little higher than that -- and with regard to Chanel -- you've got to let me get the exact timing on it here -- but Ms. Moore was using -- for about 30 or so years two to three times per week, so you've got decades of use, multiple times per week using the Chanel products in an indoor situation repeatedly. It's a powdered form. It's respirable. You've got adequate latency since onset is in 1960. This was a regular and frequent occurrence, and putting all those together

BY MR. MASSENBURG:

Q. How long did it take her to use the Chanel powder product every time she used it?

MS. DEAN: Objection. Form, compound, vague as to time.

THE DEPONENT: Well, again, so -- and I think I mentioned this earlier -- number one is you've got the actual putting on of powder, but data from NIOSH and others, you've got re-entrainment, you've got the dust that's in the air, and then you've also got re-entrainment after that dust has settled. So the exposure is more than just however long, whether it's -- whether it's half a minute or a minute or a minute and a

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half, whatever the time was of actually using the product, there's additional exposures after that.

BY MR. MASSENBURG:

Q. Okay. What was the time of actually putting it on as to Chanel?

A. I can't answer that for you. I don't know.

Q. How long --

MS. DEAN: Same --

(Simultaneous speaking interrupted by the reporter.)

MS. DEAN: Chris, I know you're on the phone, but please allow me to make my objections. Same objections as to the prior question, and to some extent, asked and answered.

BY MR. MASSENBURG:

Q. How long did she stand in the Chanel powder after she put it on?

MS. DEAN: Same objections.

THE DEPONENT: I don't recall what she said in her deposition.

BY MR. MASSENBURG:

Q. Did she clean up any of the Chanel powder after she put it on?

MS. DEAN: Objection. Same objections, vague as to time, compound.

THE DEPONENT: I don't recall what she testified to.

BY MR. MASSENBURG:

Q. What did she use to clean it up, if she did?

MS. DEAN: Same objections.

THE DEPONENT: I don't recall whether she said a broom or what she used.

BY MR. MASSENBURG:

Q. You mentioned that you considered several factors including frequency and duration in doing your -- in coming to your conclusions. Do you recall that questioning from Ms. Dean?

A. Yes.

Q. What's the duration of the exposure that Ms. Moore had to Chanel talc powder products other than 2 to 3 times a week over a period of 30 years?

MS. DEAN: Objection. Absolutely unclear.

BY MR. MASSENBURG:

Q. And for --

(Simultaneous speaking interrupted by the reporter.)

MS. DEAN: I'm going to object to unclear. And then counsel said that's a frequency,

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not duration, when he gave frequency and duration. This has been asked and answered. The current question is compound and confusing. This was in a declaration. We talked about it on day one.

MR. MASSENBURG: Object to speaking objections.

MS. DEAN: Come on.

THE DEPONENT: Can I answer?

MS. DEAN: Please.

THE DEPONENT: Are we ready for an answer?

MS. DEAN: Sure.

BY MR. MASSENBURG:

Q. We are.

A. Yeah, you already said, you know, the duration would be 30 years -- well, 31, actually, 1960 to 1990 would be 31 years.

BY MR. MASSENBURG:

Q. What is a duration at a period of time, each use? You don't know, do you?

MS. DEAN: Objection. Form, to some extent, asked and answered, vague and ambiguous, also unclear as to what time you're asking for, given the question.

THE DEPONENT: I don't understand what you're asking.

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BY MR. MASSENBURG:
Q. I'm asking about the duration of the use, not the cumulative total number of years, Dr. Haber. I'm asking about how much -- how long it took her to use a Chanel powder product when she used it.
MS. DEAN: That's a question that has been asked and answered. One more duplicative question, and I'm going to shut it down for Chanel. You've asked three times.
THE DEPONENT: I've already testified that I don't remember how long it took her to put on the Chanel product.
BY MR. MASSENBURG:
Q. And you have not seen any published or unpublished studies showing the fiber release from the use of or handling of any Chanel powder -- talc powder products; correct?
MS. DEAN: Objection. Compound, also vague and ambiguous.
THE DEPONENT: I have seen them related to Italian talc but not -- I don't believe specific to Chanel's Italian talc.
BY MR. MASSENBURG:
Q. You mentioned re-entrainment. What

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studies do you specifically rely on for your opinions as to re-entrainment of asbestos in the home from the use of talcum powder products contaminated with asbestos?
MS. DEAN: Objection. Form, overly broad, vague.
THE DEPONENT: Well, if by -- first off, by contaminated with asbestos you mean talcum powder that contains asbestos, the issue of re-entrainment is not particular to talc; it's particular to asbestos.
Although, I can tell you it probably is particular to -- it applies just to just the talc. But when you have fibers that are light like asbestos -- and there are studies, and I can't cite them for you; they're in my reference list for sure -- but there are plenty of studies that show that as you either sit down or walk through or touch up against or brush up against asbestos fibers that have settled onto a surface, that they're going to become re-entrained into the air and therefore become respirable. Again, and can stay airborne for hours, if not days.
BY MR. MASSENBURG:
Q. What studies do you rely on and cite that

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say fibers are re-entrained and stay respirable for hours or days specifically? I've never read such a study.
MS. DEAN: Objection. Form, and also objection to the commentary. To some extent, asked and answered, vague and confusing.
THE DEPONENT: Right. It is not just one study, but there are studies that show that asbestos can stay airborne for hours to days. I can't cite them for you. They're in my reference list. And, again, with related to the ability for them to get back into the air, there's also studies looking at that, you know, whether it's by -- you know, whether someone's doing an action like sweeping or just brushing up or sitting on sofas, there's studies looking at home exposures, take-home exposures that have looked at this issue.
There's studies of dealing with people who were doing laundry of asbestos-contaminated clothing that looked at how long the asbestos stays in the air after the clothing has been shaken out or handled. Those, again, would be within my reference list.
BY MR. MASSENBURG:
Q. You're counting folks shaking out laundry

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as re-entrainment, in your opinion?
A. No. That was talking about the issue of studies looking at how long asbestos can stay in the air in home environments or environments without, you know, active ventilation systems or what have you. But there are also studies looking at where asbestos is in the home and being re-entrained by people either walking by or it's on their clothing or gets on their shoes and they're bringing it into other rooms or they're brushing it or trying to clean it or trying to sweep it up.
Q. Why can't you cite me in your reliance list -- unless a section, Dr. Haber, that has -- to re-entrainment and these are your studies that you rely on are re-entrainment, why can't you cite to me from your reference list what studies you rely on for your opinions as you've expressed them regarding re-entrainment?
MS. DEAN: Objection to form. Vague and ambiguous. Again, I offered multiple times, if there was some issue you wanted us to identify, you would. You're being asked at 5:41 at the end of day two to identify those documents. I want the record and the timing to be clear. I'm not sure if your timestamp request will do that, but in case it

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doesn't.
MR. MASSENBURG: Oh, it will. But understand this came up when you started asking your redirect questions.
MS. DEAN: I don't believe that for a minute, that you didn't know that re-entrainment is something this doctor talks about until that question.
MR. MASSENBURG: Doesn't matter what you believe. Doesn't matter what you believe.
MS. DEAN: Credibility --
(Simultaneous speaking interrupted by the reporter.)
BY MR. MASSENBURG:
Q. Can you cite to me, please, within your list -- and why can't you, if you're saying you can't -- why can't you cite me to your list, the articles you're relying on for your opinions as you've expressed them for re-entrainment?
A. So the reason why is I've been deposed on this issue many times. I've given the specific citations. We are now -- it's almost 6 clock on a -- going to be on a holiday here. I didn't anticipate anyone even asking about that, and I've been questioned about entrainment many times in the

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past, and I did not think that this was going to be an issue at this particular deposition, and I don't remember the names. There's so many articles that I've read over the years, I can't cite them for you specifically, as I'm sitting here today. That's why.
MS. DEAN: And I continue to be willing to work with counsel when they make a reasonable request to identify things. I don't think it's reasonable to ask at this time, but if you want to work and meet and confer with me, I'm happy to work with you.
MR. MASSENBURG: And I appreciate the hour as well, Dr. Haber. This is my opportunity. But the transcripts I've reviewed of yours, I haven't seen anyone question you about your reliance on re-entrainment and I've read about six of your depositions. That being said, obviously you've been deposed more than that.
Understanding the lateness of the hour, I'll meet and confer with Ms. Dean on this one specific issue as to Chanel. Hopefully we can come to a reasonable compromise.
I appreciate your time, Dr. Haber. I wish you a Happy Thanksgiving, and I apologize to you if

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at any point in time, any of my questions or even the tone of them, sounded a little offensive to you. I really didn't mean to.
THE DEPONENT: Fair enough.
Anybody else?
MS. DEAN: I've got one quick question.
THE DEPONENT: Yes, ma'am.
MS. DEAN: Somebody else need to jump in first?
MR. BERKES: Yeah, ask can I --
MS. DEAN: Bob, go ahead. Sorry.
MR. BERKES: I didn't turn my video on.

FURTHER EXAMINATION
BY MR. BERKES:
Q. Doctor, do you have information as to how Ms. Moore is doing today? By today I mean, like, this week --
A. No.
Q. -- her physical -- okay.
A. Other than based on from what I've seen of her medical records leading up to, but I've not heard anything in this past week.
Q. Okay. That's all. Thank you.
MS. DEAN: I admittedly was jumping in

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because I want to be done, but I didn't mean to cut anybody else off. Did anybody else have follow-up?
(No audible response from counsel.)
MS. DEAN: Okay. I have one question.

FURTHER EXAMINATION
BY MS. DEAN:
Q. This is your declaration, which has been attached as an exhibit. It's page 13. It says declaration of Dr. Steven Haber.
Do you see that?
A. Yes, I do.
Q. Do you see where I'm at that, paragraph 32?
A. Yes.
Q. Okay. I want to just read this.
It has been reported that asbestos found in talc ore is impossible to fully remove from talc. Talc-containing asbestos fibers is carcinogenic to humans and cause malignant mesothelioma. Companies made efforts to use citric acids to burn asbestos out of talc, float the asbestos out of talc, or otherwise remove asbestos from talc through reagents, ultrasonic grinding, and beneficiation.

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Do you see where I'm at?
A. Yes.
Q. And if we look to the citation for 4, there was a suggestion from Chanel's counsel that his memory was the only thing that you cited for this was the Pooley citation. Do you remember that being stated to you just a few moments ago?
A. Yes.
Q. Now, under Footnote 6, you do specifically cite to Dr. Pooley a geologist and consultant to cosmetic talc companies; correct?
A. Yes.
Q. Under Footnotes 4 and 5, you have a host of the other citations?
A. Yes, I do.
Q. And you also have that information in that you've organized in Exhibit B; correct?
A. Yes.
Q. And you also give specific citations to what you mentioned, for instance, Avon records, in this declaration that we provided to defense counsel on November 5th. Do you see that as Footnote 7?
A. I do.
MS. DEAN: Okay. That's all I wanted to

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ask.
DEPOSITION OFFICER: Anything else before we go off the record?
(No audible response from counsel.)
DEPOSITION OFFICER: Going off the record.

(Whereupon, at the hour of 3:46 p.m., the proceedings were concluded.)
-o0o-

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DECLARATION UNDER PENALTY OF PERJURY

I, STEVEN HABER, M.D., do hereby certify under penalty of perjury that I have read the foregoing transcript of my deposition taken on Wednesday, November 24, 2021; that I have made such corrections as appear noted herein in ink, initialed by me; that my testimony as contained herein, as corrected, is true and correct.

DATED this _____ day of _____, 2021, at _____, _____.

_____
STEVEN HABER, M.D.

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STATE OF CALIFORNIA)
)
COUNTY OF LOS ANGELES)

I, PAIGE I. HUTCHINSON, Certified Court Reporter, Certificate No. 13459, for the State of California, hereby certify:
I am the deposition officer who Stenographically recorded the foregoing deposition;
Written Notice Pursuant to Code of Civil Procedure, Section 2025.520, having been sent to the deponent, the deponent:
( ) IN PERSON MADE THE CHANGES SET FORTH IN THE FOREGOING TRANSCRIPT;
( ) APPROVED THE TRANSCRIPT BY SIGNING IT;
( ) FAILED OR REFUSED TO SIGN THE TRANSCRIPT BY NOT SIGNING IT;
( ) BY SIGNED LETTER ATTACHED HERETO, MADE THE CHANGES SET FORTH THEREIN AND APPROVED, OR REFUSED TO APPROVE, THE TRANSCRIPT;
( ) FAILED TO CONTACT THE DEPOSITION OFFICER WITHIN THE ALLOTTED TIME PERIOD.

DATED: _____

_____
(DEPOSITION OFFICER)

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STATE OF CALIFORNIA)
)
COUNTY OF LOS ANGELES)

I, Paige I. Hutchinson, Certified Shorthand Reporter, No. 13459, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth;

That said deposition was taken before me remotely via videoconference; and thereafter reduced to print by means of computer-aided transcription; and the same is a true, correct, and complete transcript of said proceedings taken at that time, to the best of my ability.

I further certify that I am not interested in the outcome of the action.

Witness my hand this, Tuesday, November 30, 2021.



Paige I. Hutchinson, CA CSR No. 13459,
TX CSR No. 11222, WA No. 3336

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CORRECTION LIST

Page/Line	From	To

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EXHIBIT 14

mccrone environmental services, inc.
850 PASQUINELLI DRIVE
WESTMONT, ILLINOIS 60559 • 312-887-7100

404-368-9600

18 December 1987

Mr. Walter Luckewicz
Sr. Analytical Chemist
Avon Products, Inc.
Division Street
Suffern, New York 10901

James Millette PH D

Dear Mr. Luckewicz:

We have completed analysis of your talc samples using the CTFA J4-1 methodology. The samples are designated as 13A and 13B.

Results of this analysis are given in the attached data sheets and the x-ray diffraction patterns.

Thank you for consulting McCrone Environmental Services and if you should have any questions concerning these results, please contact us.

Yours sincerely,

Ralph J. Hinch, Jr.
Research Chemist

RJH:fe
encl.
ref: ME-4578

Hi Luckewicz

Bryan Clark

EXHIBIT
34
12/7/18

Confidential

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LOWEST LIMIT → (0.5%)

Date 12-17-87

Client AMON ME Project

Sample Description TALC 13 A (5A-68R)

LOT 621113

PERSON TO CALL IS BRYAN CLARK.

X-RAY DIFFRACTION

Serpentine: Detected ____ Not Detected ✓

Amphibole: Detected ____ Not Detected ✓

Other Phases Present: Chlorite ✓ a-SiO2 ____

Dolomite ____ Calcite ____ Magnesite ____ Mica ____

Other: ____

Comments: ____

COST $500.00 PER Sample by ↓ TRANSMISSION ELECTRON MICROSCOPY

RJ Kinsey for

LIGHT MICROSCOPY 0.003% LOWEST LIMIT OF DETECTION

Chrysotile ____ % a-SiO2 ____ %

Tremolite-Actinolite ____ total % ____ % fibrous

Nonfibrous Serpentine ____

Others: ____

Comments: ____

mccrone environmental services, inc.

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Date 12-17-87

Client AVON ME Project

Sample Description TALC 13 B (SIJA-68R)
LOT 621114

X-RAY DIFFRACTION

Serpentine: Detected ____ Not Detected ✓

Amphibole: Detected ____ Not Detected ✓

Other Phases Present: Chlorite ✓ a-SiO2 ____

Dolomite ____ Calcite ____ Magnesite ____ Mica ____

Other: ____

Comments: ____

Rjf Kinsey, Jr

LIGHT MICROSCOPY

Chrysotile ____% a-SiO2 ____%

Tremolite-Actinolite ____ total % ____% fibrous

Nonfibrous Serpentine ____

Others: ____

Comments: ____

mccrone environmental services, inc.

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EXHIBIT 15

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WL Y for your RFA file. Please return TPC

REPORT OF CTFA TALC SUBCOMMITTEE ON METHOD TO DETECT CHRYSOTILE AND TREMOLITE IN TALC.

December 10, 1973

The Scientific Advisory Committee of the Cosmetic, Toiletry & Fragrance Association, 1625 Eye Street, N.W., Washington, D.C. 20006 at a meeting held on September 2, 1973, designated that a subcommittee be set up to study the optical microscopic method proposed by the Food and Drug Administration. This method was published in the Federal Register of September 28, 1973. The present membership of the CTFA Talc Subcommittee is shown on an attached sheet.

At the first meeting of the Subcommittee, it was agreed to submit several samples of talc to members who volunteered to apply the FDA proposed optical microscopic method. The following talc samples were distributed without identification - except for randomly applied and non-duplicated code numbers:

Italian Talc	
Montana Talc	
Montana Talc	Source I
Vermont Talc	Source II
Alabama Talc	
No. Carolina Talc	

In addition, a sample of Italian Talc spiked w/w with 1% chrysotile and 0.15% tremolite was sent to each participant. The participants were aware that the sample was spiked, but did not know the percentage of spiking.

The attached table summarizes all reports submitted:

Final Report

AV_STD_001888

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Mrs. Lucy McCrone, McCrone Associates for Chesebrough			
Spiked (WITH CHRYSOTILE)	320	16	Passes
Italian	120	0	Passes
Montana- I	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No.Carolina	0	0	Passes
Montana- II	0	0	Passes
Mr. Harold Stanley of Pfizer			
Italian	~100	>100	Fails Chrysotile Passes tremolite
Montana- I	~100	>100	Fails Chrysotile Passes tremolite
Montana- II	~100	>100	Fails Chrysotile Passes tremolite
Alabama	~100	>100	Fails Chrysotile Passes tremolite
Vermont	~100	>100	Fails Chrysotile Passes tremolite
No. Carolina	~100	>100	Fails Chrysotile Passes tremolite
Spiked	<1000	>100	Fails Chrysotile Passes tremolite
Mr. David Hamer of Johnson & Johnson			
Italian	0	0	Passes
Montana- I	1	0	Passes
Montana- II	25	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	0	0	Passes
Dr. John A. Reffner (U. of Conn.) for Avon			
Spiked	632	12,930	Fails Chrysotile Passes Tremolite
Italian	220	1,114	Fails Chrysotile Passes Tremolite

AV_STD_001889

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Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Dr. John A. Reffner (U. of Conn.) for Avon Cont'd			
Montana-I	0	5,844	Fails chrysotile Passes tremolite
Montana-II	13	9,281	Fails chrysotile Passes tremolite
Alabama	26	15,125	Fails chrysotile Passes tremolite
Vermont	41	165	Fails chrysotile Passes tremolite
No. Carolina	14	11,852	Fails chrysotile Passes tremolite
Dr. Tryggve Baak of United Sierra			
Spiked	3,000	2,000	Fails
Italian	1,000	0	Passes
Montana-I	0	0	Passes
Montana-II	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	500	0	Passes
Richard E. Stevens of Ernest F. Fullam, Inc. for Whittaker C&D			
Italian	8,250	1,350	Fails chrysotile & tremolite
Montana-I	18,000	450	Fails chrysotile & tremolite
Montana-II	29,250	5,200	Fails chrysotile & tremolite
Alabama	21,825	6,075	Fails chrysotile & tremolite
Vermont	3,225	675	Fails chrysotile & tremolite
No. Carolina	20,850	6,000	Fails chrysotile & tremolite

Spiked sample was not run.

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Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Mrs. Lucy McCrone of McCrone Associates for Kolmar			
Italian	53	0	Passes
Montana-I	0	0	Passes
Montana-II	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
*No. Carolina	0	0	Passes
Spiked Sample	488	16	Passes

*Sample noted to contain some fiber bundles which are rolled up talc plus some non-fibrous tremolite

The following participants examined their samples but were unable conscientiously to count particles with confidence, therefore, did not report numbers:

Miss Marie Jones for Dr. G. Cohen - Bristol-Myers Products Research Labs.
Mr. Salvatore DiBianca - The Mennen Company
Liberty Mutual Insurance Co., Research Center - for Kolmar Laboratories
Mr. John Facq - The Colgate Palmolive Company, Research Center

The table reveals strong inconsistency between results obtained by the different scientists applying the method to the same group of coded talc samples. This inconsistency is the result of problems encountered in the methodology.

1. The alpha refractive index of talc - one of the two indices exhibited by talc plates standing on edge - varies in value between 1.539 and 1.550[1]. This in combination with item 2, below, may easily result in the mis-classification of such plates as "fibrous, less than 1.574" and therefore chrysotile.

   Dr. Reffner of the University of Connecticut, in his report to Avon, admits that this factor is paramount - "counts for chrysotile are high since (talc) edges will often be mistaken for fibrous particles".

2. The immersion method for the determination of relative refractive index becomes unreliable when applied to extremely small (ca. 1 μm) particles. This is due in part to the fact that particles around 1 μm in width approach the limit of resolution of the human eye when both size and contrast are considered, especially when applying the Becke line technique prescribed. This will

AV_STD_001891

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2. cause eye fatigue and resulting errors. Thus, a fine talc shard or plate on edge may be easily mistaken for an asbestos fiber. This applies to both the chrysotile and amphibole portions of the test.

3. It is quite likely that chlorite - a mineral of varied composition commonly found in pharmaceutical grade talc - would be incorrectly identified as tremolite. Refractive indices for chlorite vary in the range 1.57-1.66[2].

4. The examination of a sample of one milligram dispersed on a single microscope slide presents the investigator with a preparation which is too dense for a petrographic study.

5. The method is laborious and time consuming. Dr. Reffner quotes an analysis time of about five hours per sample and at JOHNSON & JOHNSON the investigator (D. H. Hamer) estimated at least two or three hours.

6. Dr. Walter C. McCrone in an earlier letter to the FDA suggested that there were relatively few scientists in the country who could use the method effectively. Scientists at Bristol-Myers, The Mennen Company, Liberty Mutual and Colgate-Palmolive had great difficulty in following the method to conclusion.

7. The proposed FDA method implies that all fibrous particles in talc having optical properties similar to those of asbestos minerals are in fact asbestos. This is probably an unwarranted assumption.

REFERENCES:

1. Deer, W.A., Howie, R.A., and Zussman, J., Rock-Forming Minerals, Vol. 3, p. 121 (1962).

2. Ibid, p. 131.

****

We have concluded that the method published in the Federal Register does not provide a truly reliable means for the detection of asbestos in talc. It results in both false-positive and false-negative findings. It is also tedious and may consume as much as one half day per sample.

The subcommittee urges that the Food and Drug Administration defer finalizing the proposed optical microscopic method and proceed into a Phase II program which would combine FDA and Industry in a strong effort to develop a truly reliable method for measuring chrysotile content in talc. We are confident that the detection and estimation of fibrous tremolite can also be done, if necessary, as a fringe benefit, at the same time.

AV_STD_001892

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We estimate that a satisfactory method will take at least six months to a year to develop. We suggest a close liaison between FDA and industry in this all-out effort with updating reviews to take place as frequently as necessary.

Review of Alternate Methods

The CTFA Talc Subcommittee has reviewed several methods to detect chrysotile and tremolite in talc, including modifications of the optical microscopic method. These are listed with comments.

1. Optical Microscopic Method - may be used with some modification. Possibly better selection of R.I. liquids and reduction of sample size per slide.

2. X-ray Step Scanning - A good method for detecting tremolite if we could accept about 0.2% as the threshold of detection. It does not distinguish fibrous from non-fibrous tremolite. The simultaneous detection of chlorite makes method impractical for chrysotile.

3. X-Ray Step Scanning + Optical Microscopy - Acceptable as in #2 above but the optical method continues to present the dilemma in reliable identification of chrysotile. However, this does not rule out a major revision of the optical method to do the chrysotile identification and counting.

4. X-Ray Scanning - The problem of chlorite interference in the detection of chrysotile is present in all x-ray procedures thus far available. It is reliable for the detection of 1% tremolite (both fibrous and non-fibrous).

5. Differential Thermal Analysis - This procedure is capable of detecting chrysotile at the 1% level, however, it will not detect tremolite.

6. Scanning Electron Microscopy - This procedure is not capable of identifying asbestos. Even with energy dispersive analysis, completely satisfactory identification is not possible.

7. Transmission Electron Microscopy + Electron Diffraction - This appears to offer the best, most reliable method and is probably capable of detecting chrysotile and tremolite (fibrous), both at a level of 0.1%. It is estimated that an installation would cost about $130M +, and is obviously prohibitive for the small manufacturer who uses talc. The amount of talc sample examined by this procedure is miniscule.

AV_STD_001893

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Summary

The CTFA Talc Subcommittee has completed its review of the Optical Microscopic Method for the Estimation of Chrysotile and Fibrous Tremolite in Talc, which appeared in the Federal Register, vol. 38 (No. 188),(p. 27076, September 28, 1973). It recommends postponement of the finalization of the proposed regulation on talc. In addition, a collaborative effort between FDA & industry to resolve a satisfactory method of estimating chrysotile and tremolite in talc, is recommended, with periodic liaison reviews to monitor the project status. A task force of industry experts has been designated to pursue alternate methods. We invite FDA to participate in collaboration with the task force.

George W. Sandland
Chairman CTFA Talc Subcommittee

GWS:dd

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AV_STD_001894

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EXHIBIT 16

National Bureau of Standards Special Publication 506. Proceedings of the Workshop on Asbestos: Definitions and Measurement Methods held at NBS, Gaithersburg, MD, July 18-20, 1977. (Issued November 1978)

NOTE: This manuscript was not presented at the Workshop but was submitted for inclusion in the Proceedings.

PRACTICAL ASPECTS OF TALC AND ASBESTOS

C. J. Parmentier and G. J. Gill

Cyprus Industrial Minerals Company
Talc Division
Los Angeles, California 90071

Abstract

The present day controversy and misunderstanding regarding talc and asbestos has existed for many years. This paper reviews some of the reasons for the widespread public misconception that all talcs contain asbestos.

The experiences of a major talc producer are discussed in relation to occurrences of talc and asbestos, and the analytical techniques required to substantiate a talc-asbestos relationship are reviewed.

Key Words: Asbestos; scanning electron microscopy; talc; transmission electron microscopy.

Introduction

Numerous environmental, occupational safety, and health agencies have recognized the medical hazards associated with asbestos minerals and have issued regulations for their use. However, during the past five years an increasing amount of controversy has been encountered regarding terms, definitions, and measurement methods.

Due to the ambiguities in these criteria and various misconceptions regarding the mineralogy of talc, disagreements also exist between industry, medical researchers, state and federal regulatory agencies concerning talc and asbestos.

This controversy affects a variety of industries, ranging from the talc producers themselves to the industrial consumers, their insurance carriers, and even the household consumer of the numerous products containing talc.

This presentation will highlight some observations and experiences of a major talc producer, in relation to occurrences of talc and asbestos. Analytical techniques used for identification of asbestos minerals and fibers in a talc matrix are also discussed.

Definitions

Asbestos:

As used in this presentation, the term "asbestos" pertains to fibrous forms of actinolite, tremolite, anthophyllite, and chrysotile. All of the six recognized asbestos minerals are not included in this review as the above mineral types are the only asbestos minerals this laboratory has found to occur in talcs to date.

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The terms acicular, lath, bladed, cleavage fragments, rods, needle, and columnar are often used as synonyms for the term fiber or asbestiform. It is the term "fiber" which appears in need of a uniform definition. As used in this presentation, a fiber is described as a particle with a length to width ratio of 10:1 or greater. The present OSHA definition [1][1] allows a length to width ratio of 5 or more to 1, with a maximum diameter of 3 μm. Figure 1 illustrates and compares the simulated appearance of particles with the aforementioned ratios. The 5:1 length to width ratio allows blocky particles to be classified as fibers, illustrating the need for more realistic definitions and size criteria of a fiber.

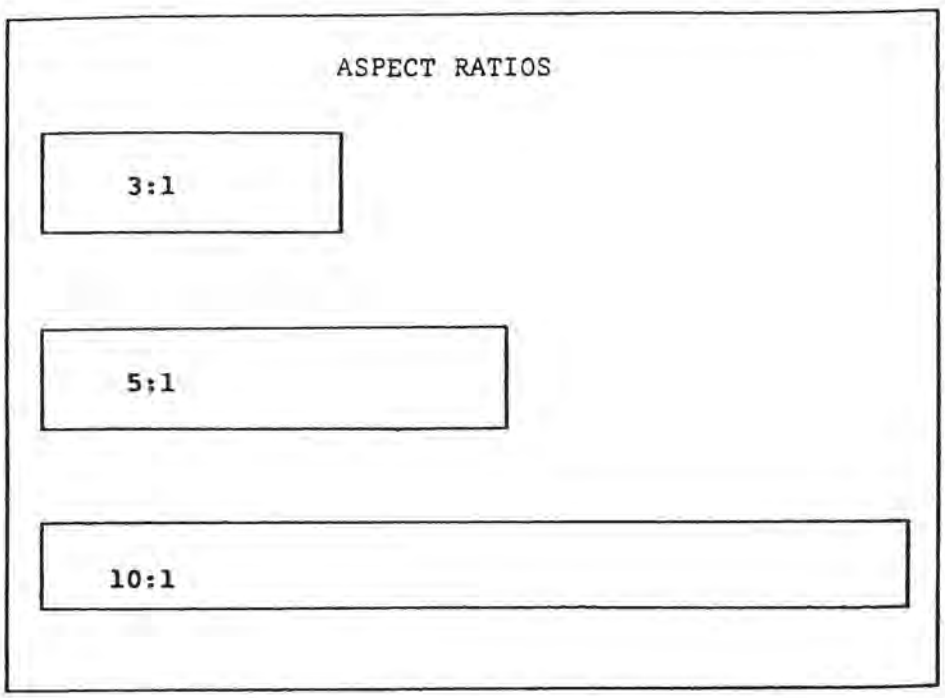


Figure 1. Illustrated by the above drawing are the geometric shapes which have been defined as fibers. The Asbestos Regulation CFR 1910.100L stipulates that a particle with an aspect ratio of 2:1 or greater is a fiber. However, these criteria were further modified by OSHA field information memorandum #74-92, November 21, 1974. The OSHA modification changed the criteria for a fiber from a 3:1 aspect ratio to a 5:1 length-to-width ratio with a maximum diameter of 3 μm.

The 10:1 aspect ratio is used at the Cyprus Industrial Minerals laboratory.

Talc

The term "talc" has also been misused in published studies and requires definition. Talc refers to a specific mineral with a hydrated magnesium silicate composition of laminar or sheet structure. The natural platelet diameter of a talc varies, depending on deposit location and geological condition. Both the size and orientation of the laminar plates, with respect to each other, determine the characteristic form of the talc, e.g., massive or steatite talc versus foliated or micaceous talc. It is this characteristic talc structure which most often determines end use applications. The large micaceous or foliated talcs are ideal for cosmetic applications; while the finer particle size, massive or steatite type talcs are most often used in filler and extender applications. The purity and locations of the talc deposit, in addition to the degree of benefication, also have a significant effect upon the end use application.

[1]Figures in brackets indicate the literature references at the end of this paper.

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Talc and Asbestos

Many misconceptions and misunderstandings of talc have existed due to improper use of terms such as tremolite talc, asbestiform talc, and fibrous talc. The majority of these improper terms were used to describe talc from the New York State talc district. In many earlier medical studies, which indicated a high incidence of talcosis, pneumoconiosis and mesothelioma among talc miners and millers from St. Lawrence County, New York, the supposition is made that talc dust was the cause. Kleinfeld and workers in 1967 [2] compared the mortality among talc miners and millers in New York State to findings among asbestos workers and noted similar pathological findings, to quote, "Rather characteristic was the presence of elongated, terminally clubbed bodies indistinguishable from asbestos bodies as seen in asbestosis." The talc dust exposure consisted predominantly of talc admixed with other silicates such as serpentine and tremolite, carbonates and a small amount of free silica, according to Dr. Kleinfeld. Additionally, Dr. Kleinfeld cites numerous other publications in which medical studies were performed on workers engaged in the milling or mining of the "fibrous variety of talc" [3-6]. However, none of these studies have differentiated between the mineral talc and the asbestiform variety of tremolite.

In a later publication [7], studies of New York State talc deposits and their asbestos contents were carried out. Mineralogical analyses of these materials indicated that all samples were predominantly asbestos.

The amount of asbestos impurities encountered in commercial talc ranges from <0.1 percent to over 50 percent. The majority of commercial talc samples analyzed have asbestos contents ranging from <0.2 percent to a maximum of 2 percent. Commercial production talc samples from New York State show a range of 20 percent to over 50 percent asbestos. A few additional commercial talcs have an asbestos content of 5 to 15 percent.

Figures 2 and 3 illustrate the asbestos contents of typical New York commercial talcs.

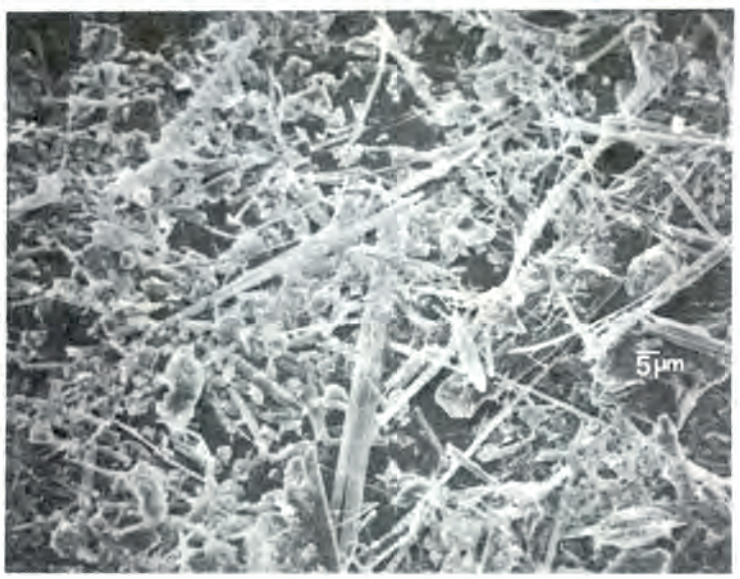


Figure 2. Talc-Fiber No. 1 from International Talc Co. Analyzed as asbestiform tremolite with minor talc content.

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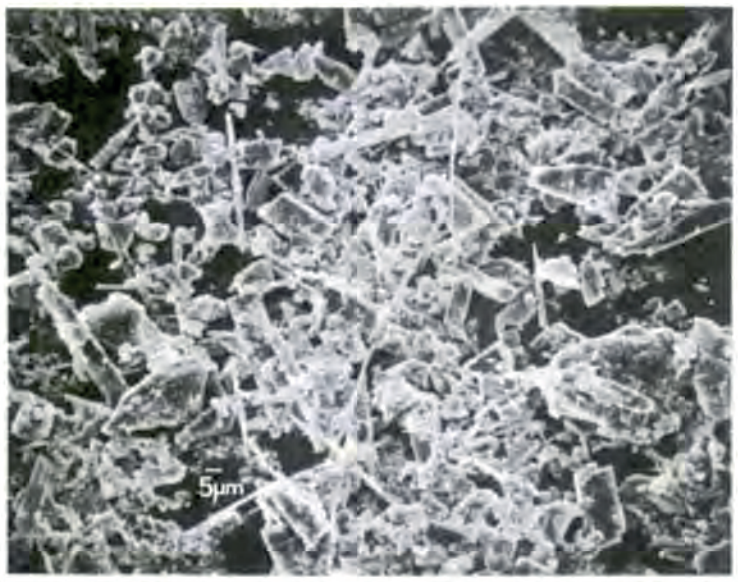


Figure 3. New York talc product used in the paint industry. Actual talc content is less than 40 percent. Majority of fibers are asbestos-tremolite, identified by TEM/SAED.

Cyprus Industrial Minerals Co. is one of the largest talc producers in the world. We have a continuing exploration program and over the past ten years have characterized talc deposits worldwide, in addition to analyzing numerous commercial talc samples. With this background and experience we feel justified in stating that not all talcs contain, or are associated with, asbestos. We also feel confident in stating that our ultra-fine grind Montana talc is the standard of talc purity throughout the world. Although high-purity talc deposits such as the Montana talcs are rare, asbestos-free talcs are not uncommon.

Based on our experience and bank of analytical data, we are aware that some talcs on the market do contain varying amounts of asbestos minerals. The most commonly encountered asbestos impurities in talc are tremolite and anthophyllite. There have been occurrences in which chrysotile asbestos has been found in selected talc samples. However, these occurrences are considered unusual but not unlikely.

Analytical Techniques

The methodology used for the analysis of asbestos fibers in talcs is a subject of considerable controversy. Following is a summarized description of the techniques used by the Cyprus laboratory and the reasons for their use.

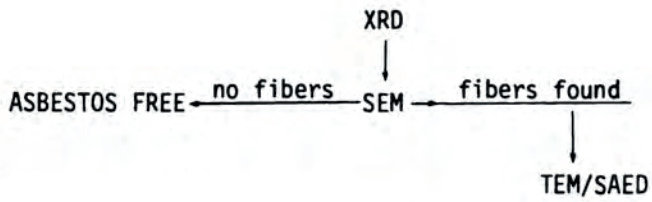
Illustrated in Table 1 is the typical test procedure used to analyze talc for possible asbestos contamination. Although x-ray diffraction is shown as the initial method of analysis, it must be remembered that the primary function of the Cyprus Industrial Minerals laboratory is the characterization of talcs. If we were concerned with analyzing talcs for the presence of asbestos only, we would consider scanning electron microscopy as the most applicable technique to initiate analyses by screening samples for the presence of fibers.

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Table 1. Analytical procedure flow sheet



Scanning Electron Microscopy (SEM) has two very unique advantages compared to optical microscopy techniques. First is the capability to accurately identify a fiber by tilting the specimen, thus viewing a particle from various angles. Additionally, the added depth of focus characteristic of SEM allows the complete particle to be studied at the same time. Figure 4 is included to illustrate this advantage, and shows the typical curled edge of a talc platelet. If a similar talc platelet was observed by optical microscopy, the limiting depth of focus would dictate that only the curled edge was in focus and would appear as a fiber, or the plate would be in focus and appear as a separate particle.

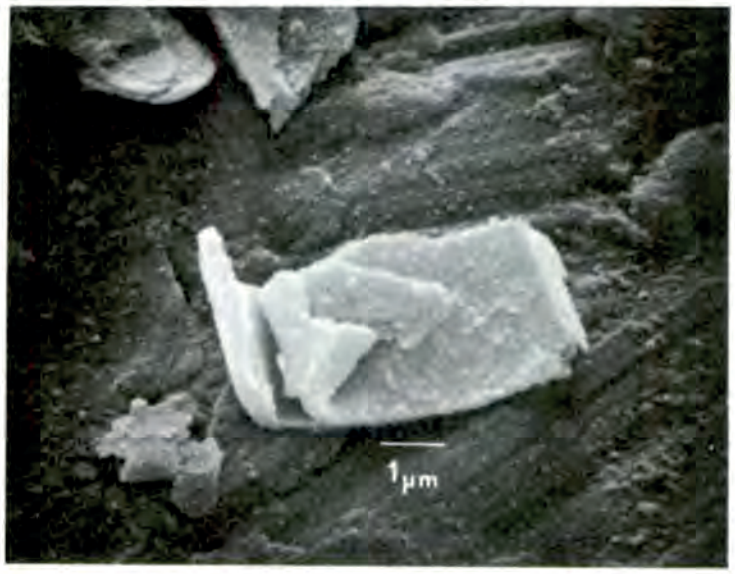


Figure 4. This micrograph illustrates the morphology of a typical curved talc platelet. The problems associated with attempting to define a fibrous structure by optical microscopy and it limited depth of focus can be seen. The optical microscope would make the above particle appear to be two separate particles, one of which would appear as a fiber and the other as a platelet.

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The second advantage of SEM is the easily varied magnification capabilities with sufficient resolution to distinguish the presence of very fine fibers. In contrast, optical microscopy techniques can allow a large number of very fine fibers such as chrysotile to go undetected. Langer, Selikoff, et al., state "Many particles found in lung tissue are submicroscopic, measuring as little as 200 Å (0.02 microns) in diameter, therefore requiring electron microscopy" [1]). Suzuki and Churg also stated the preponderance of submicroscopic asbestos fibers observed in the successive steps in the development of the asbestos body were less than 1 μm in length, necessitating the use of the electron microscope [14].

Figures 5 and 6 are included to illustrate the SEM capabilities by revealing numerous chrysotile fibers present in a talc sample spiked with 1.5 percent chrysotile. Many of these fibers can be observed in figure 6 with sizes approaching single fiber diameters of ~20 nm (200 Å), well below the theoretical resolution limit of optical microscopy.

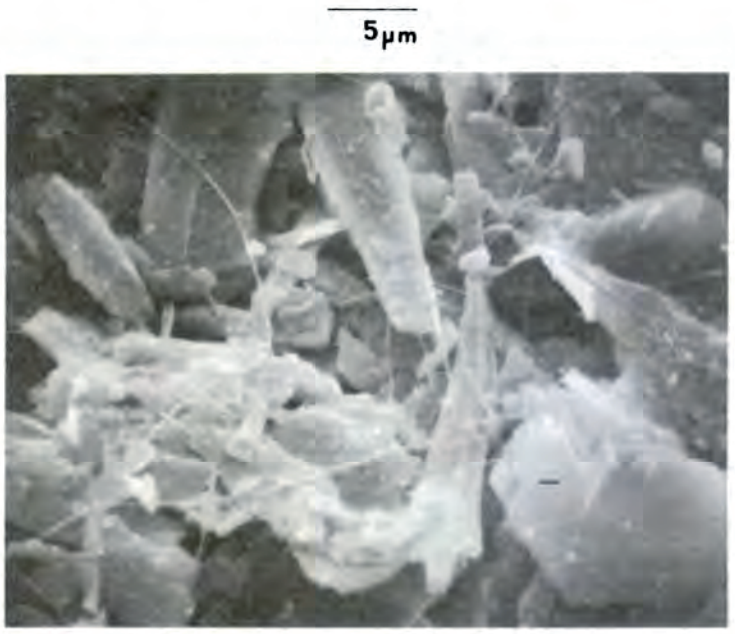


Figure 5. CTFA spiked talc by SEM. 1.5% chrysotile, 0.5% tremolite x 2800 at 40°.

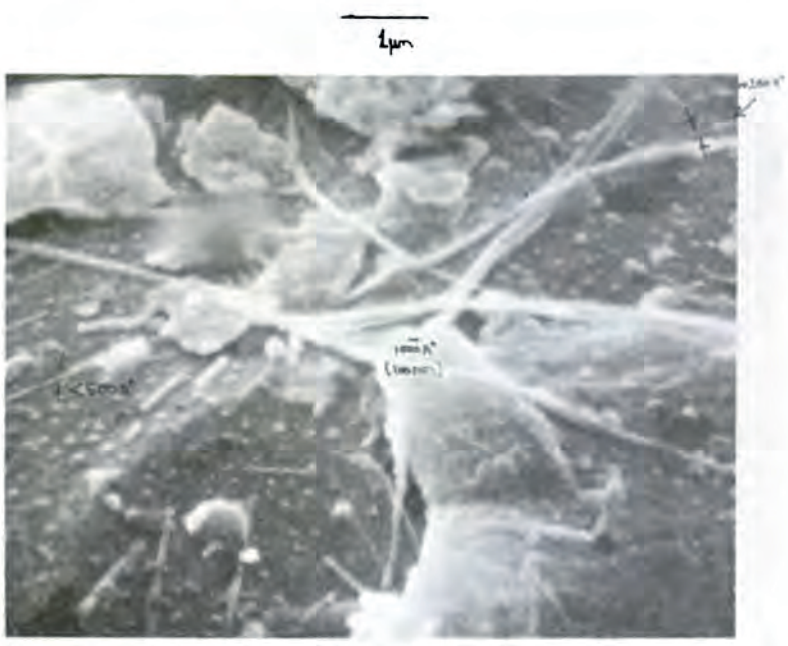


Figure 6. Spiked talc by SEM. 1.5% chrysotile x 13,5000 at 35°.

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Scanning electron microscopy for initial sample screening also has advantages compared to transmission electron microscopy methods. The sample preparation is considered easier and less time-consuming than TEM, which requires preparation of filmed specimen grids for sample mounting. Additionally, and most significant is the fact that by SEM screening of talc samples for fiber presence, the amount of sample examined is approximately an order of magnitude greater than TEM methods (0.1 mg vs. <0.01 mg). This difference becomes a major factor when investigating talc samples for trace fiber content (<1000 ppm.).

Transmission Electron Microscopy and Selected-Area Electron Diffraction

This powerful analytical technique is capable of furnishing a combination of morphological and crystal structure data of small single fibers which can result in very conclusive identification. However, this method requires a good deal of operator expertise and accuracy of data. We feel that fiber analysis via electron diffraction, supplemented with morphological data, provides a positive identification. We have observed, however, many cases where workers have identified minerals through using only partial diffraction patterns; that is to say, only the high angle reflections (low numerical spacings). These spacings are very similar between silicate minerals making absolute identification impossible without the more conclusive low angle reflections (high numerical spacings). Additionally, due to the unique possibilities of unusual mineral occurrences, which are more the expected than the unexpected in mineralogy, the morphology of a fiber does not, and should not indicate asbestos.

Along these lines, some examples of unexpected trace mineral fibers which have been encountered and subsequently identified in specific talc samples or deposits are: zeolite fibers (mordenite), clay mineral fibers (attapulgite-polygorskite), and a rare fibrous variety of antigorite-serpentine known as picrolite [12,15]. These materials are not asbestos by definition.

All of the indicated fibers have similar d-spacings in the high angle reflections (numerically lower than ~5.00 Å), indicating the necessity for using only the numerically high, low angle spacings for positive identification.

Although SAED allows positive and undisputed identification of mineral fibers, only under specific conditions are SAED patterns considered positive identification. The following criteria must be met before an SAED pattern is considered accurate:

1. The camera constant must be determined on the same grid and same sample area as the SAED pattern, using a known standard. Preferred accuracy is obtained by shadowing the specimen preparation with a gold or aluminum metal which allows the camera constant to be calculated directly on the SAED pattern and acts as an internal camera constant.

2. The indexed d-spacings should include the most intense low angle spacings. Any pattern without d-spacings numerically higher than ~5.00 Å (low angle) should be questionable, as many silicate minerals have similar d-spacings in the higher reflection angles.

3. Where applicable, unit cell parameters should also be used to supplement fiber identification.

X-Ray Diffraction

X-ray diffraction (XRD) is a standard mineralogical technique. Within levels of detectability and lack of interfering reflections, it allows the identification and quantitation of asbestos minerals in talc. The major limitations of XRD are the lack of morphological data and the lower levels of sensitivity can allow a large number of asbestos fibers to go undetected.

The information derived from XRD is invaluable for the characterization of a talc, and is of considerable help in the understanding of the mineralogical processes of forma-

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tion and the possible impurities present. The background information of mineral phases present aids and expedites the TEM-SAED interpretation of unknown fibers.

Optical Microscopy

Optical microscopic techniques are considered of minimal value in the analyses of fine-grained complex silicate mineral mixtures, and often result in ambiguous data of questionable value. As previously mentioned, optical microscopy techniques can allow a large number of very fine fibers such as chrysotile to go undetected [7,13]. Due to these findings and the health and economic considerations involved, optical microscopy is not used at the Cyprus laboratory for asbestos in talc analyses or airborne asbestos fiber analyses.

Conclusions

This presentation has reviewed the misunderstandings and widespread misconceptions that all talcs contain, or are associated with, asbestos. Some of the reasons for these misconceptions were shown to be the lack of mineral background in the use of terms and definitions. However, the use of inadequate analytical methods has been shown to be a major cause. The use of ambiguous analytical techniques such as optical microscopy for reasons of expense, lack of experience, or ease of analysis has far-reaching economic and health implications. Only TEM-SAED techniques supplemented by SEM appear to give the necessary degree of accuracy needed for positive results.

The existence of large deposits of high-purity, asbestos-free talc are well documented, and it is hoped that future references to talc will be more clearly defined as to proper mineral content.

In view of the evidence presented from both the medical and mineralogical science fields, it is evident that state and federal regulatory agencies need to redefine terms, definitions, and analytical methods for the assessment of asbestos and talc. This applies to both airborne exposure and bulk samples containing asbestos.

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EXHIBIT 17

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AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 45:229–237 (2004)

Asbestos in Brakes: Exposure and Risk of Disease

Richard A. Lemen, PhD, MSPH*

Asbestos has been incorporated into friction products since the early 1900s. Epidemiological studies have been equivocal in their analysis of the incidence of disease among mechanics servicing brakes. Decomposition of asbestos occurs during the normal usage of the brake due to thermal decomposition into forsterite, although not all asbestos is so converted. Short fibers, below 5 μm in length, are also found in brake products. Several facts are discussed including the toxicity of the remaining asbestos fibers, short asbestos fibers, and the health implications of exposure to forsterite. Control methodologies, when used appropriately, have reduced exposure to asbestos during brake servicing, but have not been able to entirely eliminate exposure to asbestos, thus bring into question the controlled use of asbestos for friction product such as brakes. Even the so called "controlled" use of asbestos containing brakes poses a health risk to workers, users, and their families. Am. J. Ind. Med. 45:229–237, 2004. *© 2004 Wiley-Liss, Inc.*

KEY WORDS: friction products; brakes; chrysotile; forsterite; epidemiology; short asbestos fibers; chrysotile

Historical Aspects of Asbestos Use in Brakes

Woven asbestos friction materials were first used in 1903 in the United States. Molded brake linings were developed in the early 1920s with increasing use until the introduction of the internal brake shoe around 1927. By 1940 virtually every automobile was equipped with molded brake linings [Sheehy et al., 1989]. Disc brakes came into being in 1965 and by 1975 virtually all US cars had such front brakes, however, rear wheel brakes remained mainly of the drum variety. Chrysotile asbestos was used almost exclusively, as the amphibole asbestos type tended to be too harsh and tended to score the brake drums, making them wear much faster. The chrysotile made up from 40 to 50% of the brake lining [Sheehy et al., 1989].

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Decomposition of Asbestos Fibers in Brakes

The US Public Health Service reported a study by Lynch [1968] of decomposition products from brake linings. It found that a small fraction of asbestos fibers survived intact after normal brake use. While this study indicated a small fraction of actual asbestos fiber is released during normal wear into the urban atmosphere, it did not address the actual release of asbestos fiber during servicing and repair of the actual brakes [Lynch, 1968]. One of the first evaluations of worker exposure to asbestos, from brake servicing, found that the British Standard for asbestos of 2 fibers per cc was not exceeded in the general atmosphere but that personal exposures in the vicinity of the operation did exceed the standard on occasion [Hickish and Knight, 1970]. The chemical composition of asbestos materials is changed by the high heat generated during the braking process. Asbestos can begin to change at temperatures around 600°C into its decomposition product, due to a loss of water, into a form of iron magnesium silicate material, the end form which is known as forsterite, a non-fibrous material. During this decomposition of asbestos into forsterite not all fibers are changed and some remain as true asbestos fibers capable of causing disease. Studies conducted by General Motors'

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researchers of brake wear debris demonstrate that 90,000 asbestos fibers per ng remain in that dust [Williams and Muhlbaier, 1980]. Fibers less than 5 μm in length outnumber fibers greater than 5 μm in length by a ratio of 300:1. This translates to approximately 300 billion asbestos fibers greater than 5 μm per g of wear debris and 90 trillion asbestos fibers less than 5 μm.

The role of forsterite in relation to health effects has not been well documented, but what little is known come from limited animal studies, that show the production of small granulomas with little fibrosis, from injection studies [Davis and Coniam, 1973]. Animal studies were not able to assess the possibility of long latent effects or associations with the production of mesothelioma, as the tests were terminated after 1 year. Although little fibrosis has been shown, the studies tend to support a more cytotoxic role for both heated chrysotile and brake lining dust, which is far more toxic than normal chrysotile. Further study is needed to assess the acute and chronic toxicity of forsterite [Davis and Coniam, 1973]. It has also been reported that during this decomposition process the majority of fibers that remain are of small diameter as well as below 5 μm in length [Rohl et al., 1976; Sheehy et al., 1989; Yeung et al., 1999] and thus are less harmful [Hatch, 1970].

Toxicity of Short Asbestos Fibers

Any assumption that short fibers, less than 5 μm in length, are not hazardous cannot be justified based on the available science. Because the analytical method of choice, for regulatory purposes, has been the phase contrast method (PCM) which counts only fibers greater than 5 μm in length, epidemiology studies that have been forced to compare doses in their cohorts to fibers greater than 5 μm in length. It must be noted that the PCM analytical method was chosen based on its ability to count fibers only and not on a health effect basis. While PCM has been the international regulatory method for analysis it is not able to detect thin diameter fibers (<0.2 μm in diameter), and because of this, it is suggested that transmission electron microscopy (TEM) should be an adjunct to PCM, since the evidence suggests that PCM may underestimate exposures and the health risks as found in the analysis of brake residue [Yeung et al., 1999].

Stanton and Wrench [1972] and Stanton et al. [1981] found that the longer, thinner fibers were more carcinogenic, but could not identify a precise fiber length that did not demonstrate biological activity. It must be kept in mind that Dr. Stanton has never said long fibers are bad and short fibers are good. In fact he appreciated that a large number of short fibers, individually of low tumorogenic probability might be more hazardous than fewer long fibers, individually of high probability [Greenberg, 1984]. It has been shown that it is not just the size and shape of the various asbestos fibers that are important in its ability to produce disease but other factors may play a role in the carcinogenicity of the mineral fiber [Wagner, 1980; Wylie et al., 1987]. Studies have also found that the majority of asbestos fibers in lung and mesothelial tissues were shorter than 5 μm in length, thus indicating the ability of the shorter fibers to reach the tumor site, remain there, and, therefore, their role in the etiology of disease is implicated [Dodson et al., 2001; Suzuki and Yuen, 2002]. National Institute for Occupational Safety and Health (NIOSH) research has found that in typical occupational environments fibers shorter than 5 μm in length outnumber the longer fibers by a factor of 10 or more [Dement and Wallingford, 1990]. Shorter fibers must be studied in more depth and they should not be disregarded especially when clearance is retarded [Oberdorster, 2001]. That chrysotile fibers tend to spit longitudinally as well as partially dissolve, resulting in shorter fibers within the lung, was reported in a review of several articles [Dement and Brown, 1993]. Additionally, Fubini [2001] argues that, because all asbestos appears to be nearly equally potent, length and fiber form does not appear to be the only influential aspect on the outcome of disease. He makes this conclusion based on the work of Boffetta [1998] which concludes that the specific type of asbestos is not correlated with lung cancer risk but that industry specific exposure appears to fit the linear slope best, a finding also supported by Dement and Brown [1993]. For mesothelioma, induction was related to the time since first exposure and potency with both industry type and asbestos type [Boffetta, 1998].

The Agency for Toxic Substances and Disease Registry (ATSDR), in response to concerns of short asbestos fibers resulting from the collapse of the World Trade Towers, asked a contractor to convene a panel of seven experts to evaluate the role of short fibers with human disease potential [ATSDR, 2003]. As to non-carcinogenic lung diseases associated with short asbestos fibers the report concludes that "... short fibers may be pathogenic for pulmonary fibrosis, and further research is needed to clarify this issue." The panel concluded that for carcinogenic effects of short fibers the current weight of the evidence is that short fibers less than 5 μm "... are unlikely to cause cancer in humans." While these conclusions were found in the executive summary of the report, a more in-depth review of the body of the report points to a less conclusive assessment for the role of short fibers in the etiology of cancer. In fact, in panel discussions it was noted that no epidemiologic studies have examined populations exposed only to short asbestos fibers. One epidemiology study that may have the ability to address this issue suffered from short latency to evaluate the development of cancer [Higgins et al., 1983]. Another study of workers having exposure for at least 5 years, in a gold mine with 94% of the asbestos fibers being less than 5 μm in length, found an increased mortality from respiratory cancers [10 obs. vs. 2.7 exp.: SMR 3.7; 95% CI = 1.78–6.81] and non-malignant respiratory diseases [8 obs. vs. 3.2 exp.: SMR 2.5; 95%

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CI = 1.08–4.93; Gillam et al., 1976]. A subsequent study [McDonald et al., 1978], looking at the same mine reported above, of miners with 21 or more years underground experience, did not find such an increase for respiratory cancers but did for non-malignant respiratory disease. However, when analyzing the data in the previous study, for only those with 20 years or greater years of employment, both respiratory cancers [7 obs. vs. 2.18 exp.: SMR 3.2; 95% CI = 1.29–6.62] and non-malignant respiratory diseases [8 obs. vs 2.56 exp.: SMR 3.1; 95% CI = 1.35–6.16] were still significantly increased. Two other studies of miners, where 38% of the asbestos fibers were shorter than 5 μm in length also found excess mortality from lung cancer, mesothelioma as well as non-malignant respiratory disease and that the mortality patterns for mesothelioma were significant because they were much greater than that of crocidolite miners in South Africa and Australia [McDonald et al., 1986, 2002].

Animal studies can be misleading when looking at short fibers, especially as rodents clear short fibers from their lungs at a rate approximately 10-times faster than do humans [ATSDR, 2003]. Experimental models are limited also, due to the fact that only fibers of very limited length distributions have been tested [Dodson et al., 2003]. Further, when appropriate analytical techniques have been used the overwhelming majority of the asbestos fibers in the tissues have been found to be less than 5 μm in length [Dodson et al., 2003]. Only two of the seven ATSDR panelists felt there was a reasonable certainty of no harm from short fibers while the other five remained concerned about the ability of short fibers to cause harm [ATSDR, 2003]. In fact, tremolite asbestos fibers were found to produce the highest average fibrosis grades when exposures were to average tremolite fibers less than 5 μm in length [Nayebzadeh et al., 2001].

NIOSH Recommended Worker Protections for Brake Servicing Procedures

In 1975, the NIOSH convened a meeting with other government agencies, university scientists, industry representatives, and labor union officials. It was reported that average peak asbestos air concentrations for specific brake servicing operations, including blow-out, grinding, and beveling of new truck brake linings resulted in average peak asbestos air concentrations, within 10 feet of the operator of 10.5, 3.75, and 37.3 fibers/cc (>5 μm in length). Even when an analysis of the asbestos fibers was done it was found that overall almost all were shorter than 0.4 μm in length. These findings led NIOSH to conclude that enough asbestos is preserved to produce significant exposures during certain brake servicing procedures [Lloyd, 1975]. At that time NIOSH specifically recommended posting warning signs at all areas where brake repair work was to be done.

The sign should read:

Asbestos
Dust Hazard
Avoid Breathing Dust
Wear Assigned Protective Equipment
Do Not Remain in Area Unless Your Work Requires It
Breathing Asbestos Dust May Cause Asbestosis and Cancer

In addition to the warning signs, the Current Intelligence Bulletin (CIB) no. 5 [Lloyd, 1975] also gave very specific recommendations for protecting the worker.

Exposure Assessment of Asbestos in Brakes

A study of fiber release from brake pads of overhead industrial cranes found very small releases of asbestos fibers all well below the current OSHA standard [Spencer et al., 1999]. Such a finding is not surprising, as the normal use of brakes have not generally been shown to produce high fiber release to the general environment [Williams and Muhlbaier, 1982]. The greatest concern, however, lies with exposure to the person removing brakes or installing new brakes or through the manipulation of the pads with compressed air blow-out, wire brushing, or other such methods which can release airborne asbestos. Exposures during brake wear are also higher from vehicles using disc brakes than drum brakes (due to the smaller friction surface area of disc, allowing faster wear) and during high deceleration [Williams and Muhlbaier, 1982]. When evaluating what this means to persons near areas where such decelerations may occur the authors evaluated the amount of asbestos released into the environment in such an area. They chose to look at tollbooths in Connecticut where they concluded that a significant fraction of the ambient asbestos concentrations of 25 ng/m^3 could arise from braking. While this exposure appears low on a one time basis, continued exposures over a working lifetime to tollbooths operators would add to their total body burden of accumulated asbestos fibers and place them at higher risk of developing asbestos-related cancers. Bruckman et al. [1977] did report a case of mesothelioma in a tollbooth operator. These findings could also be important to other persons residing in areas where high decelerations take place, such as along high volume traffic areas, where residential housing is often located.

Rohl et al. [1976] reported that chrysotile asbestos was found in all dust samples taken from car brake drums, with 2–15% in each sample in both fiber and fibril forms, with average concentrations from blowing the dust of 16 fibers/ml of air and that measurable concentrations were also found up to 75 feet from the actual worksite some 15 min after blowing out ceased. Also, Lorimer et al. [1976] found mean fiber concentrations of 3.8 fibers/ml among New York brake repair workers, which is similar to other studies that

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show intact chrysotile fibers may be released from brake materials.

Grinding of the brake linings produced the most asbestos fiber release, some as high as 125 fibers/cm^3, during brake maintenance of truck and buses in a study by Kauppinen and Korhonen [1987]. Up to 8.2 f/cm^3 was found during cleaning of the drum brakes of passenger cars using a compressed air jet to remove the brake dust. Overall the average concentrations were between 0.1 and 0.2 f/cm^3 for an 8 hr TWA for truck and bus repair, and under 0.05 f/cm^3 for passenger car repair. This study clearly demonstrated that while average concentrations can average much lower, excursion levels can reach much higher concentrations during certain operations of the brake maintenance and repair process exceeding the OSHA excursion limits and the 8 hr TWA for asbestos. NIOSH researchers found that when looking at the fibers from the brake repair area 30% were chrysotile, 20% forsterite, and 50% were unknown, leading the researchers to conclude that excessive exposure to asbestos fibers occurs during brake servicing [Roberts and Zumwalde, 1982]. EPA reported that millions of asbestos fibers can be released during brake and clutch servicing and that such asbestos can linger around the garage long after brake jobs are done and can be breathed in by everyone inside the garage which can present a hazard for months or years. Grinding of used brake block linings has been shown to release up to 7 f/cm^3 and beveling new linings up to 72 f/cm^3 and even light grinding of the new linings up to 4.8 f/cm^3 [USEPA, 1986].

Control methods have been shown effective in reducing the concentrations of asbestos fibers in the air in areas where brake repair takes place, however, when such reductions have occurred, the risk of asbestosis is probably eliminated but the risks of cancer are not [Sheehy et al., 1987]. Both Kelly and Cheng [1986] and Rodelsperger et al. [1986], found asbestos concentrations during brake repair to have average exposures that reach 0.28 and 0.1 f/cc, respectively, one above and the other at the current OSHA PEL for asbestos. A study of asbestos exposure during brake inspection and replacement of light-duty vehicles found fiber counts, when not using compressed air blow down, that range from 0.05 to 0.2 f/cc and when using compressed air the average when up to 0.9 f/cc which remained elevated for 15 min after blow out. While this is below the OSHA 30 min excursion limit of 1 f/cc (OSHA, 29 CFR Asbestos, 1910–1001) it does indicate the release of asbestos fibers during brake pad manipulation, and in inspection and replacement [Weir and Meraz, 2001]. In a study that looked at both brake and clutch repair workers in Knoxville and Knox County Tennessee it was found, that when using the worst asbestos control techniques, that those working up to 7.25 hr per day would reach and exceed the current OSHA standard of 0.1 f/cc during brake repair. Citing Anderson et al. [1973] concentrations of asbestos reached as high as 29 f/cc at distances of 5 feet from the brake drums and 4.8 f/cc at distances as far away as 20 feet. Peak concentrations of asbestos fibers in the breathing zone of brake mechanics were reported to be as high as 15 f/cc when using dry brushing, wet brushing, or compressed air during brake repair and 0.2 f/cm^3 as an 8 hr TWA.

Laboratory simulated studies while not always showing similar results may not tell the entire story of actual brake work, as in the case of drilling and grinding simulated by Weir and Meraz [2001]. They report "... that the majority of fibers collected on filters from the air stream have resin deposits attached." They state correctly that the aerodynamic behavior of such fibers is different from the "clean" fibers in their inhalation into the respiratory system. They also say that "... to a great extent, (fibers) remain bound to the matrix of the underlying brake material." The real question is what happens to the remainder of those fibers not included in the "great extent, remain bound ..." which the authors fail to address. And what happens to the nominally bound fibers once trapped in the lung tissues, where fibers may be released. The EPA evaluated the release of fibers from three commercial products (asbestos cement sheet, millboard, and brakes). They found that grinding brakes produced a release of asbestos fibers and other asbestos containing structure types. Asbestos fibers accounted for 46.0% of the asbestos structure types released and when evaluated by fibers/cc/g of asbestos milled were as high as 486.1. This study shows that fibers are indeed released when asbestos containing brakes are ground; that many of the released asbestos structures are indeed fibers and not just bound into bundles, clusters, or matrices; and that sufficient amounts exceed the then 1985 OSHA 15-min ceiling of 10 f/cc and the current excursion limit of 1 f/cc over a 30 min time period [Faigout, 1985]. A more recent study by Blake et al. [2003] has also found higher concentrations of asbestos fibers released during arc grinding but were not above the current OSHA 8 hr TWA PEL. Chrysotile fibers were the only fiber type found in this study of six brake shoe changes and one cleaning test. While this study does not indicate, under the conditions of the study, a high concentration of asbestos fiber concentration over the 8 hr TWA, it does re-iterate that encapsulated fibers of asbestos are released as the brakes are manipulated. Other, so-called encapsulated products, similar to brakes, such as gaskets have also been shown to release respirable asbestos fibers exceeding both the earlier 15 min and the current 30 min excursion limits of the OSHA PEL and in some cases the OSHA 8 hr TWAs [Longo et al., 2002].

Fiber release studies of actual brake repair and replacement and the laboratory simulation studies both demonstrate the ability of encapsulated asbestos containing brake products, to release respirable asbestos fibers at concentrations capable of causing asbestos related disease. But another aspect, generally overlooked when evaluating the ability of asbestos to cause disease in auto mechanics,

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is the adequacy of floor cleaning methods to remove the residual asbestos containing dusts. One study [Phillips and Hamilton, 1994] evaluated this process and found 23% of the businesses allowed employees to dump wheel dram dust directly on the shop floor and that 29% of the firms used dry sweeping instead of wet methods for clean-up, thus reintroducing the aerosolized asbestos fibers into the air for workers to breathe. For these workers, overall exposures would have been greater because of the additive nature of these additional exposures, from clean-up, to those already encountered while servicing the brakes during the repair or replacement process.

Evidence of Disease in Persons Exposed to Asbestos From Brakes

The National Safety Council reported that asbestos used in brakes was potentially harmful [Castrop, 1948]. Mesothelioma has been reported among brake mechanics [McDonald et al., 1970], their wives [Ziem, 1984], and children [Environmental Protection Agency, 1986]. Mesothelioma has been described among a variety of asbestos exposed persons. Huncharek et al. [1989] describes a 47-year-old lifetime non-smoking man whose only known exposure to asbestos occurred while he was a brake mechanic from age 30 to 41, giving him a latency of 17 years. Langer and McCaughey [1982] reported only chrysotile fibrils in the lung parenchyma tissue of a 55-year-old brake repair worker of which 10% were longer than 10 μm. They further describe that ". . . besides this submicroscopic chrysotile fibre in brake drum housing there is a more significant source of free, unaltered fibre in the bevelling, refurbishing, and refitting of brake pads. There is thus ample opportunity, during brake maintenance and repair, for contact with chrysotile fibre both in drum debris (where it will usually be in a transformed state) and as long and predominantly unaltered fibers liberated by machining." Langer and McCaughey [1982] also reported that pathological diagnosis of asbestos-related diseases in people exposed to chrysotile is complicated because asbestos-bodies do not form readily. Vianna and Polan [1978] reported two mesotheliomas in women whose husbands had exposure to brake linings, and one woman who was a textile worker and whose husband was a brake lining worker. Godwin and Jagatic [1968] reported two cases of mesothelioma, one in a 43-year-old woman, with peritoneal mesothelioma, who had spent 3 years weaving brake linings made of chrysotile asbestos and the second in a 50-year-old man who worked 5 years in a Canadian asbestos mine who gave X-ray diffraction evidence of only chrysotile present in his body.

Mesotheliomas have also been observed in pets. In one study of 18 dogs diagnosed with mesothelioma, the owners for 16 were identified and 12 were able to identify possible sources of asbestos exposure. The owners of two of the dogs were car and truck mechanics, respectively [Glickman et al., 1983].

Epidemiological studies have been equivocal. For example Rushton et al. [1983] concluded that their study, while negative, suffered from small numbers of men and that further follow up time would be required to determine any definite causal mortality patterns. Teta et al. [1983] reported a relative risk of 0.65 for automobile repair and related service when they observed a single case of mesothelioma among auto repair workers in their 220 cases reported in the Connecticut Tumor Registry from 1955 to 1977. They concluded that difficulties in ascertaining occupational histories, in their study population thus indicated a better need for record keeping as well as a lack of detailed information regarding the residual cases could obscure the true number of occupationally exposed cases. Teta et al. [1983] also found three case of mesothelioma, one definite peritoneal, one probable pleural, and one possible pleural, in worker at the Raybestos brake manufacturing facility in Connecticut. Robinson et al. [1979] also found among the deaths observed in a friction production plant 17 were the result of mesotheliomas, representing 4.3% of the deaths.

Rodelsperger et al. [1986], report that approximately 300,000 mechanics in the automotive service stations in Germany are exposed to asbestos. In their clinic they have observed four cases of mesothelioma which is clearly not representative of the overall incidence of mesothelioma among brake mechanics, but an indication of the disease occurring in such workers. Wong [1992] reports that the three cases (actually four) observed by Rodelsperger et al. [1986] are not over the background rate. Given that there might exist a background level of mesothelioma occurring in the absence of exposure to asbestos, even though there is no proof of this, this "natural level" is probably much lower than the 1–2/million/year which has often been cited [Hillerdal, 1999], therefore, three or four cases may well be more significant than attributed to by Wong. Jarvholm and Brisman [1988] reported no excess of mesothelioma but a slight increase in lung cancer among car mechanics. In their cancer linkage study of using Swedish census and death register data they found a case of mesothelioma, but concluded that because other exposures could not be ruled out that such a study methodology can not answer the question concerning cancers among car mechanics. Hansen [1989] discovered a case of mesothelioma which she attributed to asbestos exposure in her study of Danish auto mechanics. Spirtas et al. [1994] reports 33 cases of mesothelioma in persons having stated as part of their occupational history brake repair work. One of the confounding factors preventing Spirtas et al. [1994] from calculating a relative risk was that an overwhelming majority of those workers had also been exposed as insulators or shipbuilders.

In a study of mesothelioma among car mechanics in Germany, the authors found no evidence of an increased risk

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of mesothelioma. They concluded, however, that if there was a mesothelioma risk it could not be detected by their methodology. Further they stated that the absence of chrysotile fibers in the lung tissue of one of the cases did not exclude the possibility that, decades before, chrysotile fibers were active at the target cells [Woitowitz and Rodelsperger, 1994].

An additional limitation of the Woitowitz and Rodelsperger [1994] study is that the authors looked only at lung tissue and not pleural tissues. The authors also excluded a number of cases because the workers had other asbestos exposures in addition to their brake work. This exclusion is significant because both asbestos exposures at brake work and during other employments add to an individual's overall body burden of asbestos intake, thus, the role of exposures during brake work can not be discounted in considering an individual's overall risk of developing asbestos-related diseases. Another limitation was the use of hospital controls that had contracted lung cancer which might implicate exposures to asbestos. A recent evaluation of the German mesothelioma registry records 48 cases of mesothelioma in the automobile sector [Neumann, 2001].

Teschke et al. [1997] who found 6 mesothelioma cases in vehicle mechanics among 51 cases of mesothelioma did not find an excess of this disease in this occupation. The authors concluded that most of their cases of mesothelioma were explainable by exposure to asbestos and acknowledge their findings were based on small numbers of cases and any judgments about any causal associations would be speculative.

In a dose-response study to low levels of asbestos exposure, in a French-based case-control study 82% of motor vehicle mechanics had frequent exposure. The authors found a clear dose-response relation between cumulative exposures and pleural mesothelioma and that a significant excess of the mesothelioma was observed at levels that were probably below the limits adopted in most industrial countries [Iwatsubo et al., 1998]. Anderson et al. [1973] reports that 58 mesotheliomas were reported among Australian brake mechanics having no other exposures to asbestos and that only a small fraction of the total 82,827 mechanics in Australia worked with brake blocks or brake linings. He concludes that these 58 cases represent 1,062,946 person-years. If one rounds off the total mechanics to 100,000 mechanics this represents 45 mesotheliomas per million person-years and that if one doubles this number to 200,000 mechanics to include retirees and workers who moved to other occupations then the mesothelioma rate becomes 22.6 per million person-years, a rate substantially above the upper limit of the estimated background rate of 1–2 mesotheliomas per million person-years or around a 10-fold excess. The Australian mesothelioma tumor registry has reported that when analyzing their data for the years 1945 through 2002 that the overall lifetime risk of mesothelioma for vehicle mechanics was 0.7% which is much higher than the background lifetime risk for Australia of 0.007% (70 per million). When analyzing the mesothelioma cases between 1986 and 2001 there were 78 cases with a history of asbestos exposures during either brake lining repair or manufacturing work. Broken down it was reported that 73 were among brake lining repair workers, 5 from manufacturing workers, and that in 43 brake lining repair was their only source of asbestos exposure. When looking at 1980–1985, eight more cases were reported with only brake lining work as their source of exposure. The most recent data for the years 2002–2003 report another eight cases, three of which reported only brake lining work as their only source of asbestos exposure. One of the authors, Dr. James Leigh, reports that when using only the data from 1986 to 2001 (43 cases of vehicle mechanics with no other exposures) and statistics on the number of mechanics in the country that the resulting rate of 32.5 per million person-years represents over 30-times the commonly accepted ''background'' mesothelioma rate of 1 per million person-year. When equating this to the lifetime risk, calculated by the author of 0.38%, this amounts to approximately 55-times the background lifetime risk of 70 per million (0.007%) [Leigh, 2003; Leigh and Driscoll, 2003].

Conclusions Concerning Asbestos and Brakes

A review of the published peer reviewed literature reveals at least 165 cases of mesothelioma in end-product users of friction products. Additional government studies have reported other cases. These numbers can not be attributed ambient air exposure or to chance alone [Newhouse and Thompson, 1965: 1; Godwin and Jagatic, 1968: 1; McDonald et al., 1970: 2; Oels et al., 1971: 1; Greenberg and Davies, 1974: 1; Castleman et al., 1975: 1; Vianna and Polan, 1978: 2; McDonald and McDonald, 1980: 11; Kagan and Jacobson, 1983: 1; Guillon, 1984: 1; Huncharek, 1987: 3; Woitowitz and Rodelsperger, 1994: 16; Teschke et al., 1997: 6; Agudo et al., 2000: 3; Neumann, 2001: 48; Roggli et al., 2002: 24 = 165; and Leigh and Driscoll, 2003: 43]. Milham and Ossiander [2001] of the Washington State Department of Health report: 7; the Environmental Protection Agency, 1986: 6 cases].

The results of the exposure studies, experimental studies, case reports, and findings from the equivocal epidemiological studies by no means exonerate the brake mechanic from being susceptible to a causal relationship between asbestos exposure and mesothelioma. In conclusion several facts remain evident:

- encapsulated asbestos containing brakes do release asbestos fibers when the brakes are both used and manipulated and at concentrations capable of causing disease;

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- short asbestos fibers (<5 μm in length), often found in brakes and brake residue, have been shown to pose a risk of disease;
- the application of control methodologies has resulted in the reduced exposures to asbestos, but have not been able to entirely eliminate exposures;
- additional asbestos exposures, beyond those encountered directly from work with brakes, occur from faulty work practices and clean-up methods which are not appropriate;
- OSHA has stated that their current standard for asbestos [0.1 f/cc] will not eliminate the risk of asbestos-induced cancers [OSHA, 1986], and;
- the International Program for Chemical Safety has concluded that no threshold has been identified for carcinogenic risks for chrysotile asbestos, the principle fiber type used in asbestos-containing brakes [IPCS, 1998].

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EXHIBIT 18

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CONSUMER TALCUMS AND POWDERS: MINERAL AND CHEMICAL CHARACTERIZATION

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Representative consumer talcums and powders, including 20 body powders, baby powders, facial talcums, and also one pharmaceutical talc, were analyzed to determine their mineralogical and chemical composition. Where known, all were formulated prior to 1973. Of the 20 products 10 contained detectable amounts of tremolite and anthophyllite, principally asbestiform, while some also contained fragmented forms of these minerals. The amounts ranged from tenths of a percent to over 14% by weight; two contained detectable amounts of chrysotile asbestos fiber. Eight contained quartz, seven ranging from 2 to 5%, with one as high as 35%. The analyses showed that the consumer products examined were rarely the pure mineral talc, but rather were mixtures of various minerals; some samples consisted of three to five minerals, only one of which was talc. Other common mineral phases included chlorite, platy serpentine, pyrophyllite, mica, and carbonate minerals. Kaolin additive was identified in two products. The single pharmaceutical talc examined contained only a trace amount of quartz.

The chemical composition of these products, including both major oxide and trace element content, correlated with their mineral components. Four samples contained substantial concentrations of nickel, cobalt, and chromium, suggesting lattice substitution or the presence of trace mineral phases. Geological provenance of the talcs may be ascertained on the basis of chemistry. Possible adverse health effects from intermittent use of these products, especially those that contain asbestiform and fragmented anthophyllite and tremolite, chrysotile, quartz, and trace metals, are presently unknown and warrant evaluation.

INTRODUCTION

Consumer talcums and powders are considered by the general public to be talc, an impression that is conveyed and strengthened by the product

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names and ingredients listed on the container labels. However, knowledge of the geological occurrence and mineralogical character of source materials suggests the nature of talc to be highly variable and complex. Twenty-one consumer talcums and powders (Table 1) were mineralogically and chemically analyzed to determine whether these products are actually talc mineral.

Talc is a defined mineral entity, based on specific chemical, crystalline, and physical properties (Ford, 1957). The empirical chemical formula, $Mg_3Si_4O_{10}(OH)_2$, is seldom observed in nature as a result of cation substitution. For example, magnesium is frequently replaced by iron, nickel, chromium, or manganese in the crystal structure. Talc is a sheet silicate, with a structural unit consisting of three layers; a sheet of octahedrally coordinated magnesium hydroxide groups is sandwiched between two layers of tetrahedrally linked silica layers. The Van der Waals bond between the talc sheets are of low energy accounting for the ease with which talc as well as other sheet silicate minerals (micas, clays) cleave

TABLE 1. Designation of Contents in Brand Name or Label

Sample no.	Date of formulation
Products designated as talcs	
3	Not available
8	Not available
12	Approximately 1972
7	September 1972
17	Not available
6	April 16, 1973
19	May 1973
21	Not available
Products designated as powders (talc on label)	
4	December 1970
18	Not available
20	December 1970
5	February 1973
16	Not available
Products designated as powders (or dust)	
1	Between January 1968 and July 1970
14	October 3, 1970
15	Between October 1970 and March 1973
9	February or March 1973
11	July 1969
13	July 16, 1970
2	Not available
10	Approximately 1972

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or break into platy fragments. This facile cleavage, with resultant high surface area, and its softness, small particle size, and whiteness confer upon talc its usefulness as a cosmetic material.

GEOLOGICAL OCCURRENCE OF TALC

Talc rocks (including those commercially worked) are formed by several complex geological processes reacting upon many possible, chemically diverse preexisting rock types. Hydrothermal alteration of magnesia- and silica-rich ultramafic rocks, under a range of low-to-moderate temperatures and pressures, may produce talc. Thermal metamorphism of silica-rich dolomite [$CaMg(CO_3)_2$] will produce talc as well. These processes, however, also commonly result in the formation of a number of other coexisting mineral phases, predominantly hydrous magnesium silicates. Some of these, for example, anthophyllite, tremolite, and serpentine minerals (including chrysotile), occur as microscopic intergrowths with talc, as macroscopic nodules, or even as discrete zones within or adjacent to talc (Table 2). Talc rock is therefore generally not monominerallic but is often a mixture of minerals that may vary widely with respect to kind and quantity. Phlogopite, a magnesium mica, and chlorite, a group of minerals related to the micas, are also commonly associated with talc. Some of these associated mineral phases are asbestiform amphiboles and chrysotile (see discussion of the terms asbestos and asbestiform in Appendix A). Conversely, talc has been described as a common accessory mineral in commercial asbestos deposits (Hurlbut and Williams, 1935).

Talc deposits may be zoned, with different mineral assemblages physically changing in occurrence and proportions over extremely variable

TABLE 2. Minerals that Commonly Occur in Talc Deposits

Mineral group	Phase	Formula
Carbonates	Calcite	$CaCO_3$
	Dolomite	$CaMg(CO_3)_2$
	Magnesite	$MgCO_3$
Amphiboles	Tremolite[a]	$Ca_2Mg_5Si_8O_{22}(OH)_2$
	Anthophyllite[a]	$(FeMg)_7Si_8O_{22}(OH)_2$
Serpentine	Antigorite	$Mg_3Si_2O_5(OH)_4$
	Chrysotile (uncommon)	$Mg_3Si_2O_5(OH)_4$
	Lizardite (uncommon)	$Mg_3Si_2O_5(OH)_4$
Others	Quartz	SiO_2
	Mica, e.g., phlogopite	$K_2(Mg,Fe)_6[Si_6Al_2O_{20}](OH)_4$
	Chlorite, e.g., penninite	$(Mg,Al,Fe)_{12}[(Si,Al)_8O_{20}](OH)_{16}$
	Pyrophyllite	$Al_4[(Si_8O_{20}](OH)_4$

[a]Occurring as fibrous and nonfibrous forms. Other trace mineral phases are often present but are not included.

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distances, ranging from centimeters to tens of meters. Mineral phases in such deposits may include talc plates and fibers, tremolite and anthophyllite fibers, intergrowths of amphibole and talc, serpentine minerals (which may include chrysotile), and free silica (quartz) (Ross et al., 1968). The fiber intergrowth is often such that even extensive beneficiation may not yield a pure product. Thus, where fine-grained intergrowths of talc and tremolite occur, the processed product will likely contain residual tremolite. Further details concerning the crystal chemistry, structure, synthesis, and geological occurrence of talc are found in Appendix B.

INDUSTRIAL AND COSMETIC GRADE TALCS

It is generally recognized that various commercial grades of talc are marketed in the United States (Appendix C). Hildick-Smith (1976) has stated that a talc suitable for pharmaceutical purposes, used in cosmetic and toiletry products, contains at least 90% talc mineral and no detectable asbestos. Such stated compositional restrictions are not placed on industrial grade talcs. One study demonstrated that a number of industrial talcs contained substantial quantities of tremolite, up to 87% by weight of the sample (Schulz and Williams, 1942).

In 1968, a study (Cralley et al., 1968) of 22 cosmetic talcum products demonstrated fiber contents ranging

> from 8 to 30% by count with an average of 19%. The fibrous material was predominately talc but probably contained minor amounts of tremolite, anthophyllite and chrysotile as these are often present in fibrous talc mineral deposits.
>
> With the exception of 4 of the 22 cosmetic talcum products analyzed, the levels of free silica, cobalt, nickel, chromium, and manganese were generally of a low magnitude and within a narrow range. . . . The levels of silica, chromium, and nickel in these four products are sufficiently high, however, to be of concern in their potential to cause disease.

Thus, as late as 1968 some consumer talcum products marketed in the United States contained asbestiform minerals, free silica, and trace metals.

HUMAN DISEASE ASSOCIATED WITH TALC EXPOSURE

For nearly half a century a number of reports have shown that occupational exposure to talc dust is associated with a fine diffuse interstitial lung scarring known as talcosis. Fibrous talcs appeared to be more pathogenic than platy talcs, producing in addition to talcosis, increased risk of malignant tumors in exposed workers (Kleinfeld and

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Messite, 1960; Kleinfeld et al., 1967). Studies concerning the biological consequences associated with talc dust exposure, including cancer, are referred to in Appendix D.

OBJECTIVES OF THE PRESENT STUDY

Twenty-one samples of consumer talcums and powders, including baby powders, body powders, facial powders, and a pharmaceutical talcum, were obtained at retail stores in the New York City area. These samples were acquired and studied during the period 1971–1975 (Table 1). The major purpose of the study was to determine the mineralogical and chemical composition, with particular emphasis on the quantitative determination of tremolite, anthophyllite, serpentine minerals, and quartz. Another objective was to establish a base line for consumer talcums and powders, based on a sampling of products available during the period 1971–1975. This base line provides an index for evaluating possible changes in subsequent formulations.

METHODOLOGY AND RESULTS OF MINERAL AND CHEMICAL CHARACTERIZATION

The analytical techniques employed for mineral identification and quantification included optical microscopy, transmission electron microscopy with selected area electron diffraction, X-ray diffraction, and scanning electron microscopy with X-ray analysis capabilities. Chemical determinations (bulk chemistry and trace metals) were made with a number of standard instruments and geochemical techniques, including spectrophotometry [SiO_2, TiO_2, Al_2O_3, total Fe (Fe_2O_3 by difference from FeO), P_2O_5]; atomic absorption (MnO, MgO, CaO); flame photometry (Na_2O, K_2O); wet chemical assay (FeO); weight loss, volatiles (H_2O, CO_2, organics). X-ray fluorescence was used for all trace metals (Bowes and Langer, 1974).

Optical Microscopy

Optical microscopy is a conventional technique for the identification of minerals and for the study of mineral relationships. A microscope equipped with bright field illumination and polarized light optics was used to analyze the cosmetic powders. Approximately 0.5 mg of powder was placed on a precleaned glass slide and immersed in index oils of known refractive indices. These were checked on a refractometer. The information obtained on particles with this method included most of the measurable optical properties, including indices of refraction, extinction angles of fibers, general morphology, and size characteristics of mineral phases (Fig. 1). In coarse-grained powders, fibers could be identified (tremolite, anthophyllite, talc). Two samples contained cornstarch, easily recognized

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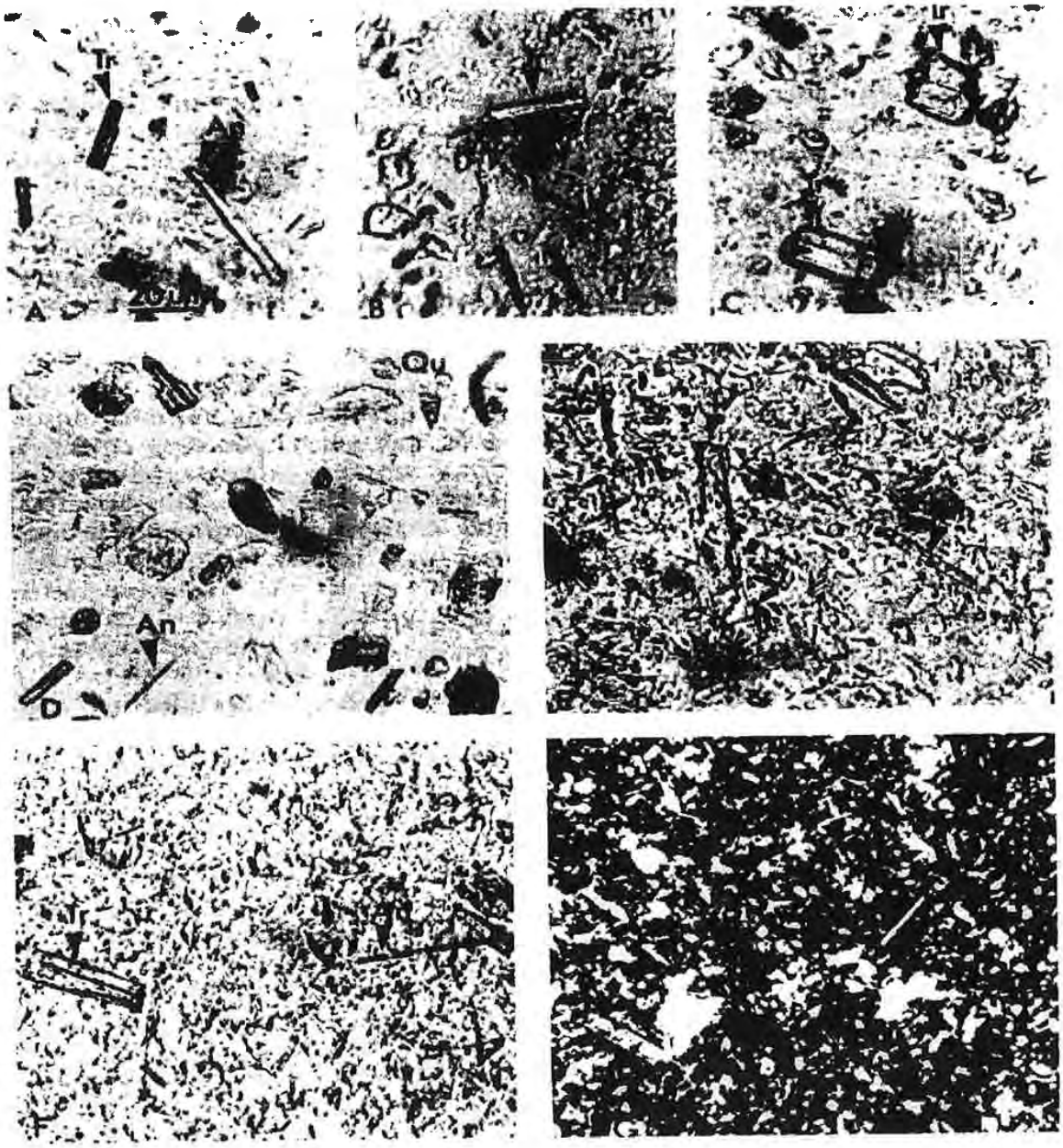


FIGURE 1. Optical photomicrographs of cosmetic talcums and powders grossly contaminated with asbestiform minerals. Photos obtained in plane polarized light (A–F) and between crossed polars (G). Scale in (A) for all photos. Fibers shown have optical properties consistent with tremolite (Tr) and anthophyllite (An). Quartz grains (Qu) and calcite fragments (Ca) are also shown. Most tremolite fibers tend to possess smaller length-to-width ratios than anthophyllite. Tremolite is observed as fragments (C). Photo obtained between crossed polars (G) also demonstrates the presence of fibers in the matrix material. Asbestiform length-to-width ratios measured up to 20:1 (F).

by morphological and optical characteristics. One product consisted entirely of cornstarch.

In most samples, however, the powders were too fine grained, with particle dimensions significantly less than 1.0 μm, for the technique to be useful. The limiting factor for determination of optical constants, and hence for identification of particles, is the resolving power of the microscope. The presence of talc fibers, which may have indices of refraction similar to amphibole (tremolite, anthophyllite) fibers, also confounds analysis. Therefore, although this technique is an excellent diagnostic instrument in some instances these restrictions limited its usefulness.

Other investigators have experienced similar difficulties. For example, in a study of the asbestos content of talc (Stanley and Norwood, 1973), there was difficulty in applying optical microscopy to the problem. The authors concluded that optical microscopy

> while it works well on pure samples of fairly massive fiber length from 3 to 5 microns, our observations by transmission electron microscopy have shown that *naturally occurring asbestiform minerals often lie below the working resolution capabilities of the light microscope* and furthermore while massive fiber bundles can often be observed by either light or electron microscopy the observation of individual fibers smaller than 0.5 by 0.2 micrometers often will require the high resolution capability of the transmission electron microscope (emphasis added).

It is further stated that "light microscopy was helpful only in screening samples with large particles and high concentrations of objectionable fibers."

By comparing the results of optical microscopy with those of quantitative X-ray diffraction and electron microscopy, we observed that large numbers of fibers go undetected. In addition to the restraints of resolution imposed by light microscopy, another major drawback relates to the strong tendency of asbestiform minerals to cleave or break along planes of weakness when they are crushed, producing large numbers of small fibers. For example, light microscopic examination of a talc sample (no. 8), which contains over 7% tremolite (see Table 4), demonstrates the presence of mineral fragments that are primarily not asbestiform (Fig. 1C). However, electron microscopic examination of the same sample demonstrates that many of the submicroscopic tremolite particles are fibrous (see Fig. 3E). The problem involving the determination of the relative proportions of each of these morphological phases in the same sample (mass vs. number) is presently unresolved. Basically, the large fibers are broken during milling yielding a new size distribution in the submicroscopic range.

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X-ray Diffraction

The application of X-ray diffraction analysis in step-scan mode for quantitative determination of asbestos in talc has been described in detail (Rohl and Langer, 1974), including the selection of talc and asbestos reference materials, the preparation of standard dilutions of asbestos minerals in talc to ensure sensitivity and reproducibility, the selection of characteristic X-ray reflections to be scanned, and instrumental technique.

Selection of talc mineral standard. Screening of various types of talcs for use as reference material was made by X-ray diffraction and transmission electron microscopic analysis. A continuous scan was first made to identify the major mineral phases present. Talcs that showed the presence of any serpentine mineral, tremolite, or anthophyllite were eliminated as reference materials. The possibility of false negatives for these minerals was checked by step scanning the diagnostic reflections (Table 3). Further verification of the absence of asbestiform minerals was made by transmission electron microscopy. These techniques permitted the selection of a matrix talc that was completely free of asbestiform minerals.

Chlorite minerals are hydrous iron–magnesium silicates, frequently associated with talcs. Their presence may interfere with the detection of serpentine minerals, both platy (antigorite) and fibrous (chrysotile). This is particularly true if they are present in equal or larger amounts than these latter minerals. Two intense basal reflections at 14.2 Å (001) and 7.1 Å (002) are characteristic of chlorite minerals. The latter reflection occurs close to the (002) reflection of serpentine minerals (7.3 Å). The 3.66 Å (004) reflection of serpentine was selected as diagnostic (Table 3), since the lower intensity (004) reflection of chlorite (3.53 Å) in this region was found not to cause interference.

Selection of the asbestos standard. Reference samples of pure asbestos minerals were obtained from various mineral collections and from the International Association for Research on Cancer (IARC). These were screened for purity and particularly for the presence of interfering contaminants according to the procedures previously described for talc. Two different specimens of chrysotile were used as reference materials: a triple air-jet milled sample from the Jeffrey Mine, Quebec (provided by the Johns-Manville Corp.) and a specimen from Coalinga, California (provided by the Calidria Division, Union Carbide Corp.).

Sample preparation. Among the variables that strongly influence the precision and accuracy of quantitative X-ray diffractometry are particle size, preferred orientation, and surface flatness. Variation due to particle size can be minimized by crushing and screening the asbestos and talc standards to ensure a uniform size distribution, with an effective crystallite dimension on the order of 5 μm or less. The effect of preferred orientation is more difficult to control. The tendency for preferred orientation is largely the function of mineral cleavage properties. Both the talc and the asbestos minerals have excellent cleavages, platy in talc and

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TABLE 3. Calibration Curve Data for the Determination of Asbestiform Minerals and Quartz in Talc by X-ray Analysis[a]

Parameter	Mineral phase			
	Anthophyllite	Chrysotile	Quartz	Tremolite
Miller index of diagnostic reflection	(210)	(004)	(211)[b]	(110)
Corresponding *d*-spacing (A)	8.26	3.66	1.54	8.38
Relative intensity	55	80	15	100
Step-scan interval (2 theta)	10.0–11.0	23.5–25.0	59.5–60.5	10.0–11.0

Percent mineral in talc and corresponding area of reflection

Anthophyllite		Chrysotile		Quartz		Tremolite	
%	in.²[c]	%	in.²	%	in.²	%	in.²
5.0	0.92	0.25	0.01	5.0	2.75	0.1	0.13
10.0	2.35	0.5	0.03	10.0	3.75	0.5	0.30
15.0	3.99	1.0	0.08	20.0	7.11	2.2	0.43
20.0	4.65	2.0	0.22	25.0	9.30	2.7	0.67
25.0	5.12	5.0	0.94	30.0	13.20	4.3	1.25
30.0	7.22	7.0	1.52	40.0	16.90	5.0	1.65
35.0	9.92	8.5	2.21	—	—	7.0	2.08
—	—	8.9	2.34	—	—	10.0	2.80

		Detection limit
Wt % Anthophyllite	= Area (210) = 0.27 (%An) − 0.52 R^2 = 0.95	2.0%
Wt % Chrysotile	= Area (004) = 0.27 (%Ch) − 0.50 R^2 = 0.98	0.7%
Wt % Quartz	= Area (211) = 0.43 (%Q) − 0.60 R^2 = 0.96	1.4%
Wt % Tremolite	= Area (110) = 0.28 (%Tr) − 0.04 R^2 = 0.98	0.1%

[a] Instrumental settings: target/filter, Cu/Ni, 45 kV/20 mA; scintillation counter, 1450 VDC; monochromator, graphite; pulse-time analyzer, 20 V, 5 V (width, level); continuous scan, 1° 2 θ/min; step-scan, 0.02° 2 θ at 2,000 counts fixed.

[b] Rhombohedral index.

[c] Repeated measurements of areas under curves with a polar planimeter indicated average deviation of ± 0.02–0.05 in.².

fibrous in the case of tremolite, anthophyllite, and chrysotile (see Rohl and Langer, 1974, Fig. 2). In attempting to reduce or eliminate the effects of preferred orientation in X-ray analysis, a number of sample preparation and instrumental techniques have been developed (Bragg, 1967; Brindley and Kurtossy, 1961; Cullity, 1956; Klug and Alexander, 1954). In the present study these techniques were tested, but none was found to provide adequate precision (reproducibility). Accordingly, a sample preparation technique was developed that was successfully used, in conjunction with X-ray diffraction in the step-scan mode, to detect diagnostic reflections of these minerals in a talc matrix over a range of concentrations (Table 3).

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The reproducibility of reflection intensities was also greater than other preparation techniques tested.

Binary dilution standards of chrysotile, anthophyllite, and tremolite in talc were prepared gravimetrically. Asbestos fiber concentrations were prepared initially at 5.0, 4.0, 2.0, 1.0, 0.5, 0.2, and 0.1%. Fifty milligrams of the talc–asbestos mixtures were homogenized in 10 ml filtered water utilizing ultrasonic energy. This slurry was poured into a 30 cc syringe and filtered through a 0.22 μm pore size membrane filter. To prevent stratification due to differential particle size and density effects, the syringe is held in a horizontal position, rotated, and shaken during filtration. The residue forms a flat cake of about 0.5 mm uniform thickness on the membrane filter. When dried, the sample is affixed to a glass slide for X-ray diffraction analysis (Rohl and Langer, 1974).

Selection of X-ray reflections. Because of crystal structure similarities in the minerals being studied (i.e., tremolite and anthophyllite), considerable overlapping and interference of X-ray reflections occur. The low symmetry and consequent complex X-ray diffractograms of such minerals as talc, chlorite, and mica, as well as possible interferences from admixed phases such as kaolinite, make it necessary to select a reflection or set of reflections for each mineral component that could be used as an index of the amount of that mineral in a mixture. Such diagnostic reflections were selected by referring to standard X-ray powder diffraction data. These diagnostic reflections were step-scanned at 0.02° 2 theta in a fixed count mode (2×10^3 counts). Precise positions and profiles of the diagnostic reflections were determined. In the fixed count mode, each of the angular intervals selected are scanned with equal accuracy. Thus weak reflections can be determined with equal precision as high intensity reflections. The statistical accuracy depends only on the total number of counts recorded, and the counting rate selected gives a percentage probable error of about 2%. Profiles of the diagnostic reflections, plotted as a function of number of counts vs. 2 theta, are measured with a compensating polar planimeter. The intensity of a reflection is proportional to, but not necessarily a linear function of, its concentration. Other factors that may influence reflection intensities include instrumental conditions, particle size, degree of preferred orientation, sample thickness and flatness, and absorption characteristics (Klug and Alexander, 1954; Rohl and Langer, 1974).

Figure 2 shows calibration curves obtained for chrysotile, anthophyllite, tremolite, and quartz using the step-scan technique. Measured areas of diagnostic reflections are plotted against percent dilution in talc. As indicated in Table 3 tremolite may be determined at levels as low as 0.10% by weight, chrysotile from 0.25 to 0.50%, and anthophyllite, as low as 2% in talc. It is important to note that the limits of detection given in Table 3 are higher and based on a best fit regression analysis. For example, regression analysis indicates that the detection limit for chrysotile is 0.7%, whereas from 0.25 to 0.5% can be actually detected,

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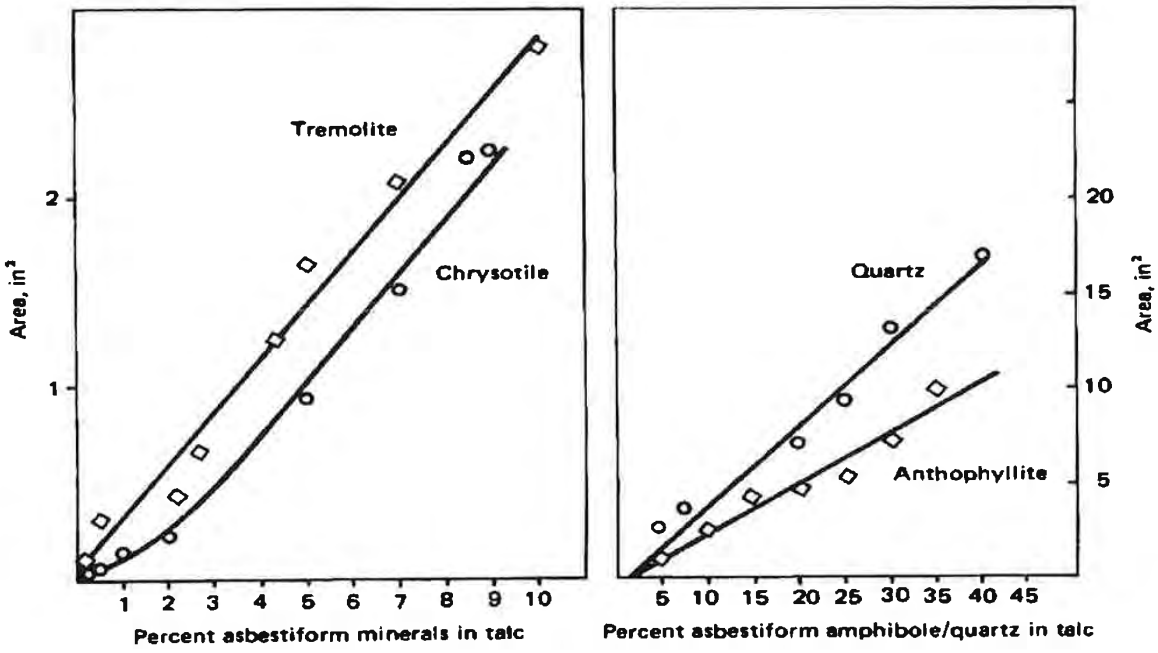


FIGURE 2. Calibration of asbestiform amphiboles and quartz in talc.

depending on particle size, degree of crystallinity, etc. The changes in slope at the lower end of the curves are not reflected so that axial intercepts are exaggerated on the high end of the abscissa.

By using X-ray diffraction in the step-scan mode, Stanley and Norwood (1973) were able to detect a minimum of 0.25% tremolite in talc and a minimum of 0.5% chrysotile and the other asbestiform minerals. However, such low levels of chrysotile were not detected when chlorite was present.

Step scanning. The contents of the containers were thoroughly mixed with a sample splitter to avoid stratification effects. Aliquots of each, weighing 50 mg, were prepared using the identical methodology described for preparation of the dilution standards. The filter-mounted samples were then step scanned over the goniometric intervals diagnostic for the standard asbestiform minerals and quartz. Instrument operating conditions were identical with those used for analyzing the dilution standards. Profiles plotted for the diagnostic intervals and reflection areas after peak stripping were measured by polar planimetry. The weight percents of anthophyllite, tremolite, and quartz contents were estimated by referring to the appropriate regression curve. The quantities of asbestiform materials in the 21 talcums and powders found by this technique are shown in Table 4. The results show that 10 of the 21 samples contain amphibole

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TABLE 4. Summary of Mineralogical Composition of 21 Consumer Talcums and Powders

Minerals	Sample no.																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Talc	M[a]	–	M	M	M	M	M	P	M	M	M	M	M	M	M	M	M	M	M	M	M
Chlorite	P	–	–	P	Tr	P	P	–	P	P	P	P	P	P	P	–	P	P	P	P	P
Phlogopite	–	–	–	–	Tr	–	–	P[b]	–	–	P	P	–	–	–	–	–	–	–	–	–
Calcite	–	–	–	–	–	P	–	Tr	–	P	P	P	P	P	P	–	–	–	–	–	P
Dolomite	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	P	–	–
Quartz	5.5	–	1.6	–	–	1.9	–	35.1	–	–	–	4.0	–	3.0	–	2.0	–	1.6	2.0	–	–
Kaolin	–	–	–	–	–	–	Tr	P	–	–	–	–	–	–	–	–	–	–	–	–	–
Tremolite	2.7	–	–	–	–	0.5	0.4	7.4	–	–	10.3	–	–	–	0.1	3.0	0.1	–	–	–	2.4
Anthophyllite	11.4	–	–	–	–	–	–	4.9	–	–	–	4.6	–	–	2.4	5.2	2.1	–	–	–	6.5
Chrysotile	–	–	–	–	–	–	–	–	–	–	–	<0.50	–	–	<0.50	–	–	–	–	–	–
Pyrophyllite	–	–	–	–	–	–	–	P	–	–	–	P	–	–	–	–	–	–	–	–	–
Rutile	–	–	–	–	–	–	Tr	–	–	–	–	–	–	–	–	–	–	–	–	–	–

[a]M = major; P = present; Tr = trace.
[b]High K_2O and Na_2O suggests that this phase is a mica (muscovite/biotite).

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minerals, ranging in amounts from a few tenths of a percent to over 14%. Tremolite was the most commonly found (9 of the 21), and anthophyllite occurred with tremolite in 6 of the 21. A serpentine mineral phase was indicated in two samples, in amounts at or near the lower limits of detection. Verification of the serpentine phase as chrysotile in the two samples in amounts corresponding to the observed concentrations was made by electron microscopy.

Continuous scanning. In order to study the presence of all mineralogical (and possibly other crystalline) components the samples were scanned from 5° to 70° 2 theta at a scanning rate of 1° 2 theta per minute. This technique, as expected, proved satisfactory for the identification of major components, but it was generally found to be incapable of detecting tremolite, anthophyllite, or serpentine minerals except in cases of gross contamination. The high noise level (low peak-to-background ratio) often prevents the detection of quantities on the order of 4–6% or less and also excludes this technique for quantitative analysis. As a result of high noise level three false positives, as indicated by continuous scanning, were subsequently shown to be negative for amphibole by step scanning and electron microscopy. In addition, continuous scanning may not generally detect serpentine minerals in the presence of chlorite or kaolinite.

Electron Microscopy and Electron Diffraction

The transmission electron microscope has been shown to possess the sensitivity required for fiber identification and for determination of particle size distribution of submicroscopic particles (Langer and Pooley, 1973; Langer et al., 1973).

Accordingly, aliquots of talcum samples were prepared for electron microscopic analysis by a technique that disperses particles in a drop of nitrocellulose solution on a glass slide. A second glass slide is placed on the first and the two are drawn lightly apart, leaving a film. This technique is intended to minimize the alteration of particle size distribution. The film is mounted on electron microscope grids and scanned at magnifications of X20,000.

Morphologically, amphibole minerals are generally quite dissimilar from other silicate minerals. Both anthophyllite and tremolite are rectilinear, often with amphibole-type step cleavage or, infrequently, with prismatic terminations. Tremolite fibers tend to be electron dense and shorter than anthophyllite (Fig. 3), while the latter has a tendency to be electron translucent and to show diffraction contrast figures (Langer and Pooley, 1973). Sheet silicate minerals (talc, chlorite, micas) tend to be equidimensional in shape, often with pseudohexagonal outlines (Fig. 4). Curled talc plates or talc fibers on edge may superficially resemble asbestiform minerals, but selected area electron diffraction patterns easily distinguish between the two (compare Fig. 5A, C, and D).

Electron microscopy, in combination with selected area diffraction,

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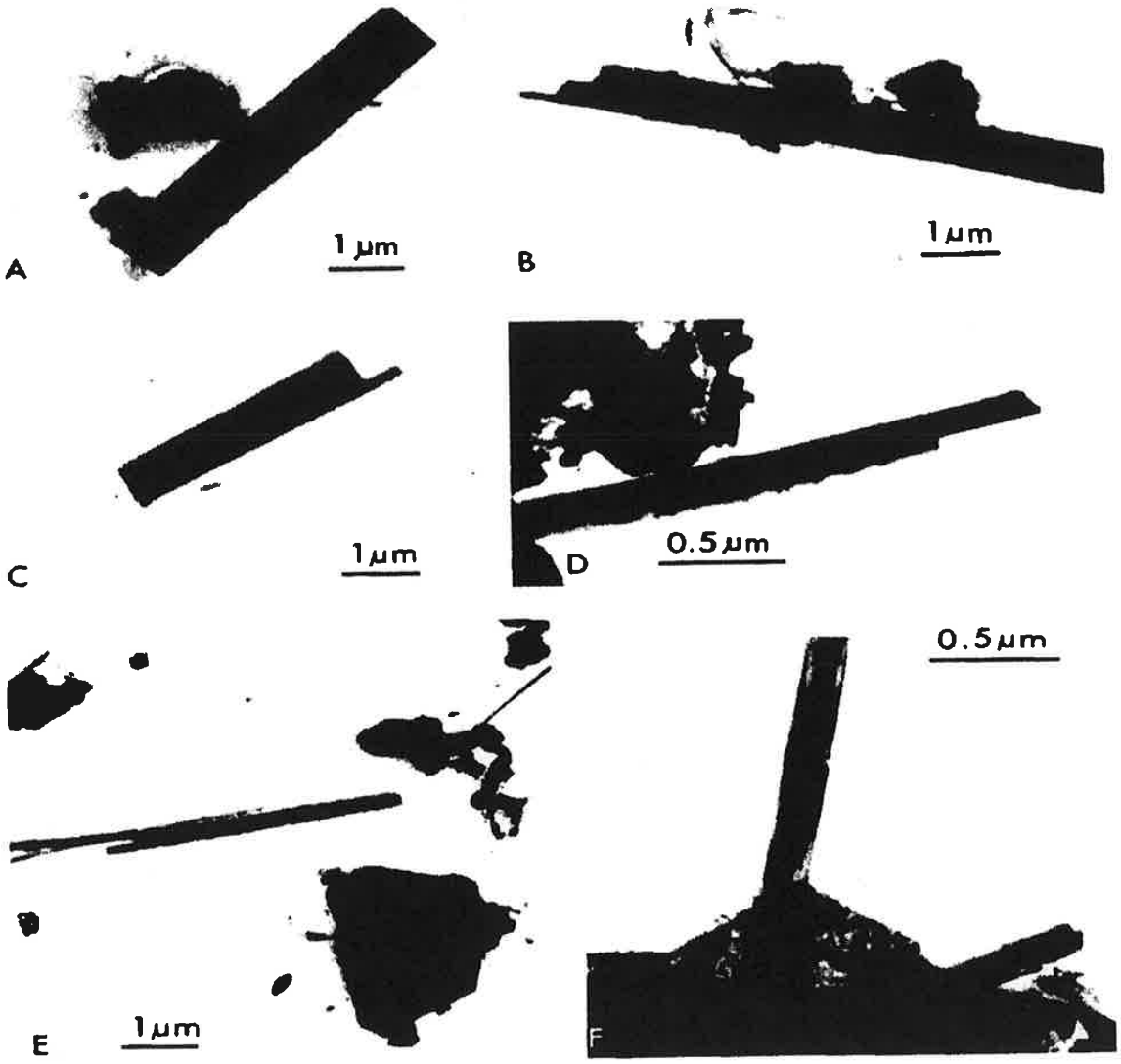


FIGURE 3. Transmission electron micrographs showing range in morphological characteristics of asbestiform tremolite and anthophyllite in talc. The entire range of morphological variations observed for these minerals is observed in the asbestos standards: rectilinear fibers with parallel ends and edges (A); step-cleavage ends (B); unit fibrils protruding from fiber body, (C); curvilinear fiber with amphibole cleavage end (D); high length-to-width ratio fibers (E); fibers protruding from interiors of talc plates (F). All of these morphological variations and forms (A-E) have been described in anthophyllite and tremolite asebestos samples. The amphibole structure was confirmed in all cases by selected area electron diffraction characterization. Scale as marked. Micrographs obtained on a JEOL JEM 120 U with an accelerating voltage at 120 kV.

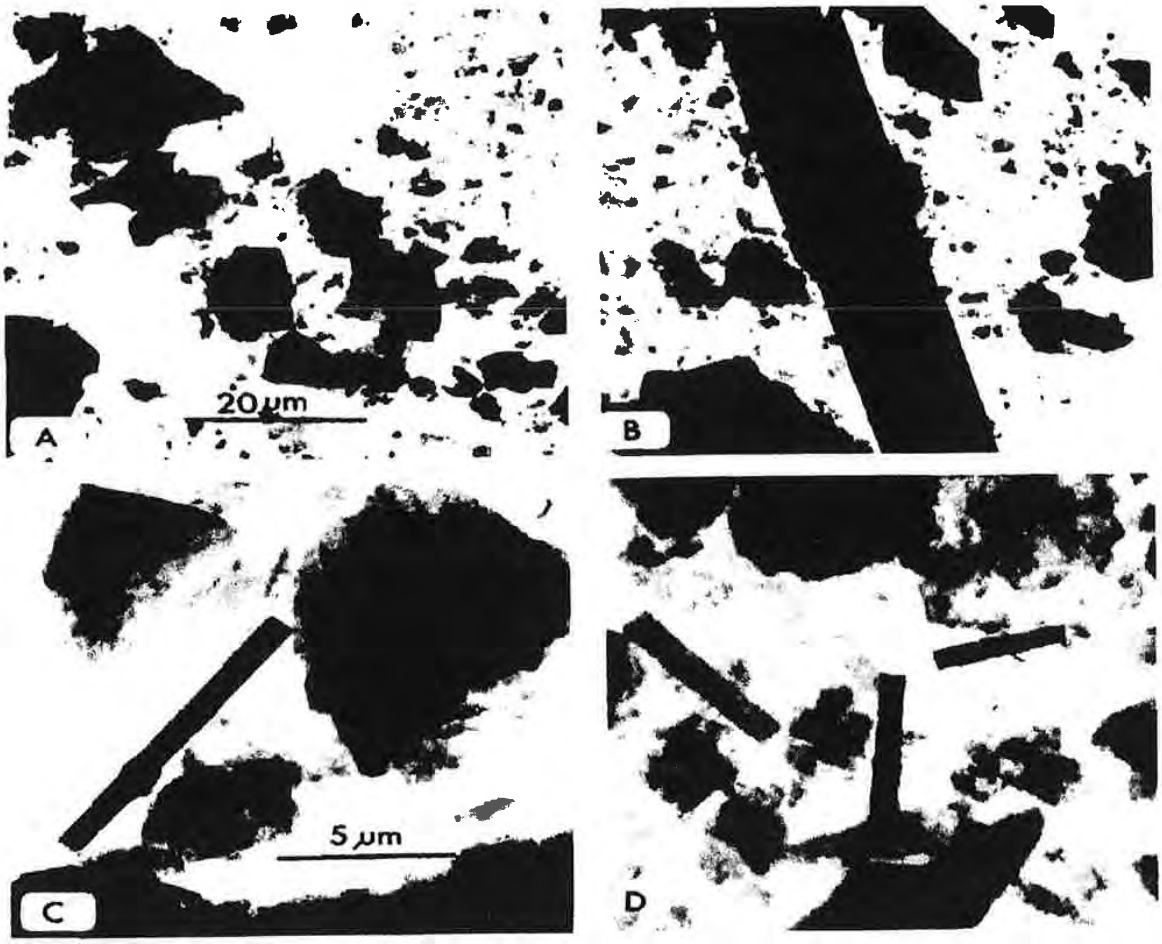


FIGURE 4. Transmission electron micrographs of cosmetic talc samples composed primarily of plates with an occasional large talc fiber (B, C); talc with many talc fibers (D); Scale is the same in (A) and (B) and in (C) and (D). All selected area electron diffraction patterns obtained on fibers yielded those consistent for talc plates (see Fig. 5, A and B). In all talc-containing samples examined by electron microscopy talc grains tended to range from 25 to 0.2 μm in greatest dimension. Micrograph obtained on a JEOL JEM 120 U with an acceleration voltage at 120 kV.

was used to verify the presence of amphibole in the 10 samples shown to be positive by X-ray diffraction. Electron microscopy, while not quantitative, also showed that amphibole fibers were present in relative amounts that corresponded to their percentages as shown by X-ray diffraction.

The presence of traces of chrysotile, rather than platy serpentine, in samples 12 and 15 was verified by electron microscopy (Fig. 6). By

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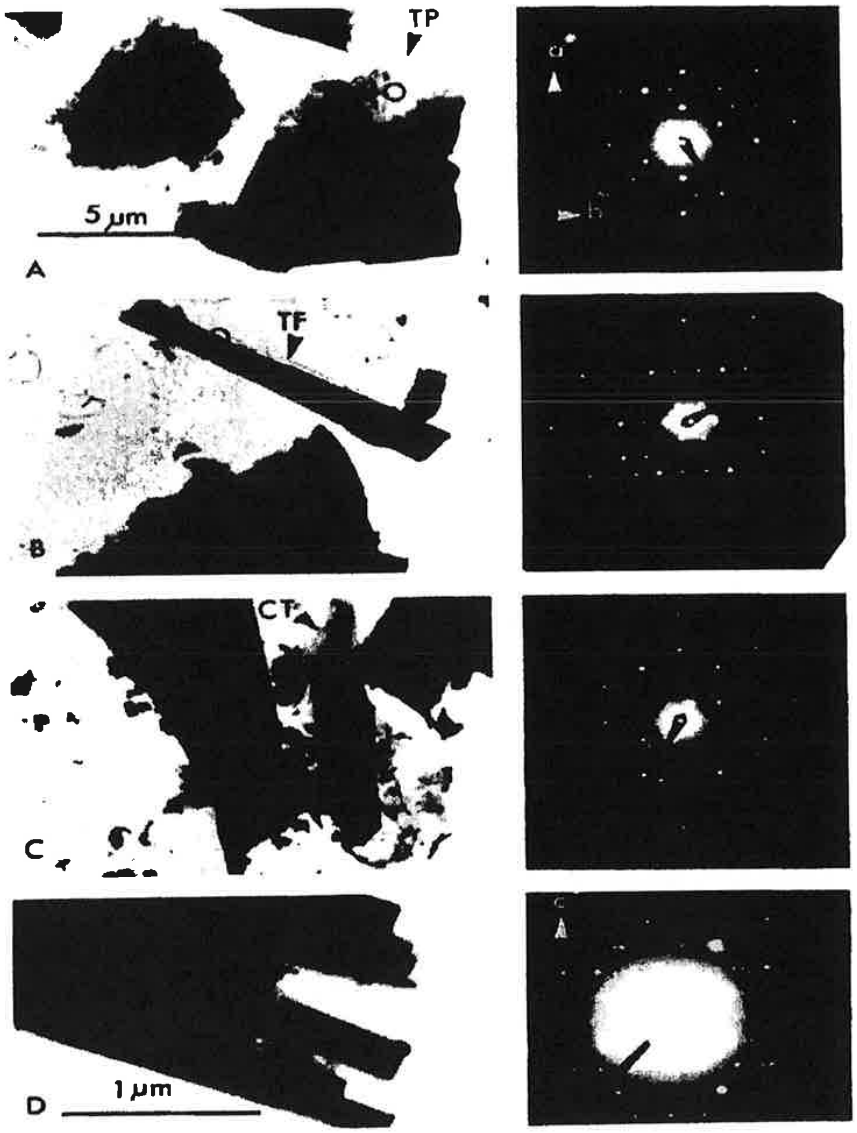


FIGURE 5. Transmission electron micrographs and accompanying selected area electron diffraction (SAED) patterns for cosmetic talc samples. The talc plate (TP) in (A) shows typical polygonal cleavage and diffraction contrast contours for the mineral species. The accompanying SAED pattern displays the characteristic reciprocal ab^* plane pseudohexagonal symmetry for talc. Talc a^* and b^* directions indicated on (A). Measurement of pattern indicates a 5.3 Å repeat along a^* and a 9.1 Å repeat for b^* (measured at [110]). Talc fiber (TF) in (B) displays irregular ends and nonrectilinear edges. The SAED pattern is also pseudohexagonal, but some reflection intensities [e.g., the (060), (0.12.0)] are more pronounced. This may be due to both orientation and structural effects. The curled talc plate (CT) in (C) displays an incipient Debye-Scherrer ring pattern (the effects of both folding over of talc and small associated grains). The amphibole fiber (D) was diffracted only on one of the protruding unit fibrils. The c^* axis is shown, with repeat measured at 5.3 Å. Areas where diffraction patterns were obtained are indicated by location circles; particles were photographed at the SAED magnification ×26,500. Scale is the same in A-C; scale in D as marked. Micrographs obtained on a JEOL JEM 120U with an accelerating voltage at 120 kV.

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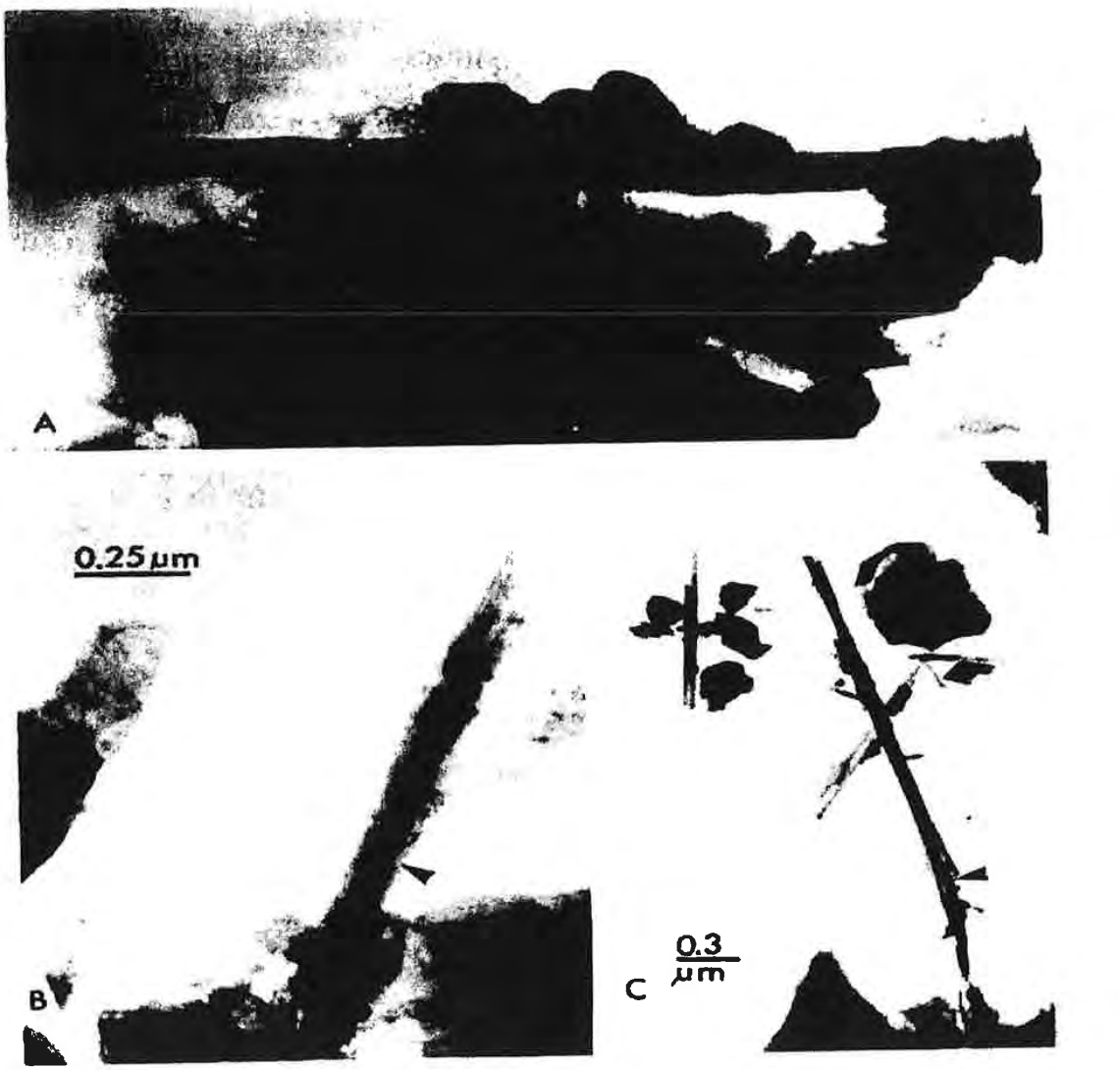


FIGURE 6. Transmission electron micrographs of asbestiform minerals in cosmetic talc, other than amphibole. (A and B) Two chrysotile fibers with morphological characteristics induced by electron beam damage. No diffraction pattern was obtained on either fiber. Arrow markers (A and B) indicate areas where these beam-damaged features are most prominent. Both fiber bundles appear to rest on talc plate substrates. Free chrysotile fibers and fibrils (C) were found in a sample found negative for asbestos by all other techniques. Scale as marked. Micrographs obtained on a JEOL JEM 120 U with an accelerating voltage at 120 kV.

comparison with known dilution levels of chrysotile in talc observed by electron microscopy, the levels of contamination of chrysotile in the two samples correspond to about 0.25–0.5% chrysotile, which was suggested by the X-ray diffraction results. The chrysotile fibers were all shorter than 2 μm and the diameters less than 0.2 μm, explaining why they were not visible by optical microscopy.

Chemistry of Consumer Talcums and Powders

The bulk chemistry (Table 5) and mineral contents (Table 4) of the talcums and powders complement each other in that one data set implies limits for the other. For example, analysis of sample 1 shows the presence of FeO and CaO (Table 5). Recalculation of these oxides into values for the empirical formulas for tremolite and anthophyllite indicates that sufficient quantities are present to account for the presence of these minerals (Table 4). An appreciable decrease in SiO_2, which should normally occur, was not observed, because of the occurrence of over 5% quartz content. The Al_2O_3, Na_2O, and K_2O are reflected by the presence of chlorite (probably the penninite phase). Variations in oxides were also observed in the other samples that contain amphibole minerals (6–8, 11, 12, 15–17, and 21). In these samples, a number of other factors account for the wide variations in oxide percentages: in 6, the presence of chlorite

TABLE 5. Major Oxide Content of 21 Consumer Talcum and Powders[a]

Major oxide	Sample no.										
	1	2[b]	3[c]	4	5	6	7	8	9	10	11
SiO_2	61.99	0.00	62.68	58.72	61.94	52.95	59.67	71.93	58.68	51.65	49.48
TiO_2	0.10	0.00	0.14	0.04	0.03	0.17	1.40	0.19	0.08	0.71	0.22
Al_2O_3	0.82	1.30	0.37	0.24	0.45	1.16	0.87	15.73	0.58	1.45	2.32
Fe_2O_3	0.00	0.00	0.08	0.04	0.03	0.02	0.18	0.10	0.12	0.09	1.23
FeO	1.51	0.00	0.32	3.03	0.51	0.86	0.84	0.34	3.12	0.34	0.07
MnO	0.00	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00
MgO	29.60	0.00	29.83	28.25	30.19	29.02	29.23	2.95	29.23	27.90	25.67
CaO	0.40	0.00	0.04	0.10	0.04	3.46	0.90	2.37	0.17	4.75	1.61
Na_2O	0.07	0.00	0.03	0.03	0.05	0.00	0.05	0.48	0.00	0.03	0.42
K_2O	0.02	0.00	0.02	0.02	0.02	0.05	0.05	1.37	0.00	0.00	0.19
P_2O_5	0.01	0.00	0.03	0.03	0.01	0.13	0.14	0.05	0.00	0.05	0.01
Volatiles[f]	5.36	98.70	4.66	5.38	5.51	10.32	5.64	5.25	5.34	9.72	10.41
Total	99.88	100.00	98.20	95.88	98.79	98.14	98.97	100.76	97.32	96.69	91.63

[a] Weight percent, recalculated as oxides, following standard petrochemical procedures. The bulk analysis of the powders reflects the combined mineral content after additives were extracted using water, dilute HCl, acetone, benzene, and ether.

[b] Analysis of 2: 98.7% = starch + organics and volatiles; 1.3% = Al_2O_3 (aluminum chlorhydrate?).

[c] Standard talc used as matrix for fiber standard dilutions.

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sharply reduces the SiO_2 content and elevates the Al_2O_3 content. The presence of the carbonate mineral calcite increases the expected CaO and volatile contents (the latter includes CO_2); in 7, the high TiO_2 is reflected by the presence of the mineral rutile (TiO_2); in 11, the high CaO, moderately high Al_2O_3, and low SiO_2 contents reflect the presence of calcite, chlorite, and tremolite.

Several of the above samples (numbers 8, 12, and 15) require special evaluation. Sample 8 is extremely high in SiO_2, Al_2O_3, Na_2O, and K_2O and extremely low in MgO content. The chemistry indicates that this material was not derived from a talc rock, but rather from one rich in alumina and silica. The mineralogy reflects this, as do the trace metals (see trace metal section). The amphibole minerals in sample 8 are associated with both pyrophyllite [$Al_4Si_8O_{22}(OH)_4$] and quartz, both present in substantial quantities. The mica phase is not phlogopite, but muscovite, accounting for the presence of substantial quantities of K_2O and Na_2O. A plagioclase feldspar was also detected in the mineral phase. Sample 12 is very high in Al_2O_3 but extremely low in SiO_2, apparently the result of high chlorite content as well as substantial amounts of pyrophyllite. Sample 15 is low in SiO_2 and extremely high in volatile content, reflecting the presence of both carbonate phases and organic additives.

The trace element analyses (Table 6) show distributions that are in accordance with the known behavior of trace elements in minerals. With

TABLE 5 (*continued*) Major Oxide Content of 21 Consumer Talcum and Powders[a]

Sample no.											
12	13	14	15	16	17	18	19	20	21	A[d]	B[e]
47.32	53.83	57.47	44.83	62.26	54.45	59.93	58.54	62.19	56.34	57.34	61.49
0.18	0.11	0.11	0.07	0.06	0.10	0.10	0.18	0.08	0.12	0.21	0.01
9.34	1.74	1.65	0.69	0.45	4.26	0.79	1.11	0.69	1.35	2.30	1.20
0.05	0.03	0.02	0.00	0.18	0.04	0.00	0.00	0.00	0.02	0.11	0.38
1.22	0.70	0.65	0.62	1.04	1.41	0.84	1.38	0.81	1.39	1.05	1.07
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00
29.83	27.14	26.98	23.88	30.00	30.79	30.40	29.83	30.19	27.90	27.44	30.54
0.69	5.49	5.52	3.67	0.13	1.13	0.50	1.13	0.43	1.53	1.69	0.46
0.03	0.07	0.05	0.35	0.09	0.09	0.09	0.00	0.07	0.07	0.10	—
0.05	0.00	0.02	0.07	0.05	0.02	0.02	0.00	0.00	0.00	0.10	—
0.21	0.14	0.13	0.10	0.01	0.04	0.13	0.00	0.13	0.02	0.70	—
10.26	10.81	10.41	21.34	5.92	7.54	5.65	5.94	5.14	9.99	8.03	5.00
99.18	100.06	98.01	95.62	100.19	99.87	98.45	98.21	99.73	98.73	98.20	100.11

[d] Average of 20 talc samples.
[e] Average of 8 talc analyses in Deer et al. (1962).
[f] Volatiles are lost on ignition (total H_2O, CO_2, organics, and other volatiles).

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TABLE 6. Trace Element Content of 21 Consumer Talcum and Powders[a]

Trace metals	Sample no.																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Ba	<10	–	<10	<10	<10	<10	<10	50	<10	990	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Ce	<10	–	<10	<10	<10	<10	<10	10	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Cl	210	–	130	135	185	200	140	130	115	125	115	120	430	435	410	165	140	130	110	120	130
Co	35	–	<3	85	<3	<3	<3	<3	88	<3	<3	<3	<3	<3	<3	21	<3	4	<3	<3	<3
Cr	310	–	28	600	16	23	24	<15	820	25	18	24	38	49	41	340	32	30	28	25	42
Cu	<5	–	<5	<5	8	<5	<5	9	<5	<5	<5	<5	5	8	10	13	6	7	6	6	13
Ga	<1	–	4	<1	<1	1	<1	20	<1	1	3	13	2	1	2	2	7	3	2	3	<1
La	<10	–	<10	<10	<10	<10	<10	40	<10	<10	<10	<10	<10	<10	30	<10	<10	10	<10	<10	<10
Nb	7	–	8	8	11	7	9	14	5	7	6	18	7	7	5	5	9	8	9	9	7
Ni	710	–	17	172	27	13	10	<4	2210	34	4	11	10	17	10	460	14	20	28	19	42
Pb	8	–	8	<5	<5	<5	<5	49	7	<5	17	5	7	12	8	6	9	7	8	5	16
Rb	5	–	5	<5	<5	<5	5	45	<5	<5	<5	<5	<5	5	5	5	<5	5	5	5	<5
S	235	–	130	120	2230	440	150	305	155	425	110	280	485	595	535	320	140	160	105	155	1070
Sr	10	–	10	10	10	20	30	160	<10	25	100	<10	15	20	20	<10	15	10	10	10	15
Th	<5	–	<5	<5	<5	<5	<5	6	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
Zn	➤	–	85	37	18	12	15	20	37	➤	➤	➤	35	11	20	73	27	8	11	3	➤
Tr	<10	–	<10	<10	<10	90	10	190	<10	10	10	30	<10	<10	<10	<10	50	<10	<10	<10	<10

[a]Values in parts per million. The symbol < indicates the limit of detection of the analytical method. The symbol ➤ indicates concentrations of Zn are greater than 1,000 ppm.

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the crystal lattice of a mineral acting as a sorting mechanism for cations, the cations can enter a crystal structure providing they have appropriate size and charge. These phenomena apply to major as well as minor elements. Thus, barium is present in large amounts in sample 8, which has a high K_2O content (1.37%). Since barium and potassium have similar ionic radii, barium is easily admitted into potassium minerals, such as micas and feldspars (both found in 8). Rubidium and strontium are also enriched in sample 8, since these metals also easily substitute for potassium. Gallium is found in large amounts in samples 8, 12, and 17. These samples are also very high in Al_2O_3. Gallium has the same ionic charge and radius as aluminum and, in fact, is found only in aluminum-bearing minerals.

In four samples (1, 4, 9, and 16) there are significantly higher concentrations of cobalt, chromium, and nickel than found in the other samples. These four samples also have high contents of FeO (Table 5). The association of these four transition metals has been observed before in certain geochemical environments, particularly in ultramafic rocks. Since talcs derived from the metamorphism of serpentines and peridotites (ultramafic rocks) are considerably enriched in FeO (Deer et al., 1962), it is likely that the divalent cations are substituting for iron in the brucite layer of the talc.

DISCUSSION AND CONCLUSIONS

Talc used in the United States represents a wide range of mineralogical substances. Industrial grade talcs are obtained from different rock types of highly variable mineral composition with the result that the mineral talc may actually be a minor constituent. However, it has been stated that consumer talcum products should contain at least 90% of the mineral of the same name and no asbestos fiber (Hildick-Smith, 1976). Review of the literature suggests that at least until 1968, materials that were marketed as cosmetic talcum products did not necessarily conform to these criteria.

Talc mineral may occur in a platy form or in a fibrous form. Talc fiber may occur as a small proportion of the mineral desposit or as a major constituent. Intergrowths of talc with other mineral phases are common. These phases may be simply macroscopic zones adjoining talc mineral or may occur as microscopic intergrowths within the talc. Of the many minerals that may coexist with talc, a number of asbestiform phases commonly occur: tremolite, anthophyllite, and chrysotile have been identified in these deposits. In addition, free silica (quartz) is a frequent constituent. The trace metal content may include elevated levels of nickel, chromium, and cobalt.

There is general agreement between the mineral composition and the major and trace element content of the consumer talcum products. On the

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basis of mineral and chemical contents, the type of geological provenance may be ascertained.

Methodology has been developed for quantitative X-ray diffraction determination of anthophyllite, tremolite, serpentine, and quartz in consumer talcums and powders. Important factors in the calibration standard development include selection of talc and reference minerals and the selection of diagnostic X-ray reflections. The sample preparation technique is sensitive and reproducible. Dilution standards are step scanned over diagnostic reflection areas, peak areas are measured, and a set of standard calibration curves is developed by regression analysis. Samples of consumer talcums and powders are prepared and analyzed under identical conditions and compared with the calibration curves, permitting quantitative analysis of these minerals. X-ray diffraction alone cannot distinguish between asbestiform and fragmented forms of anthophyllite and tremolite nor between asbestiform and platy serpentine varieties. Electron microscopic analysis was used to distinguish between these forms.

Mineralogical characterization of 21 consumer talcums and powders showed that 10 contained measurable concentrations of asbestiform tremolite and anthophyllite, and some also contained fragmented forms of these minerals. Two samples contained trace quantities of chrysotile (0.25–0.5%). These observations were confirmed by transmission electron microscopy. The amphibole phases present in these talcum products ranged in amounts from several tenths of a percent to over 14% by weight. Quartz was present in eight consumer talcs in amounts ranging from 1.6 to 35.1% by weight.

Consumer talcum products are for the most part complex mineral assemblages, which confer X-ray sorbing and fluorescing effects that are not equivalent to, and are usually greater than, those of the binary systems used in preparing the dilution standards. In consumer talcum products minerals such as talc, micas, chlorite, calcite, dolomite, and others tend to diminish reflection intensities of asbestiform minerals by sorbing X-rays or by contributing to background noise. Also, repeat runs on some selected specimens have demonstrated greater peak areas due to slight modifications in instrumental settings (e.g., increase in receiving slit width). Therefore, the values for weight percent concentrations given in this report are conservative.

Examination of the same consumer talcum products by both optical and transmission electron microscopy indicates that not all of the materials fall within the definition of fiber or asbestiform. For example, one consumer talcum product that contained more than 7% tremolite was observed to contain both fragmented tremolite grains by optical microscopy and asbestiform fiber with 3:1 or greater length-to-width ratio by transmission electron microscopy. Optical microscopy may provide useful information. However, more complete characterization can be obtained by electron microscopy and selected area electron diffraction. Using electron

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microscopy, for example, several samples of consumer talcum products exhibited both free amphibole fiber, discrete from talc grains, and, in addition, numerous small amphibole fibers were visible, apparently interlayered between talc or chlorite plates (see Fig. 6A).

Preliminary examination of the asbestiform amphiboles by an electron microprobe technique has demonstrated that individual fiber chemistry is identical to those fibers encountered in the IARC Asbestos Standards (Timbrell and Rendall, 1971).

On the basis of the mineralogical and chemical characterization of these products, all formulated prior to June 1973, we conclude that cosmetic grade talc was not used exclusively. The presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc. This standard should be cognizant of talc complexities, mineralogical and chemical in nature, and should provide for adequate analytical protocols to ensure monitoring. We also recommend that evaluation be made to determine possible health hazards associated with the use of these products.

APPENDIX A: DEFINITIONS OF TERMS USED IN TEXT

Asbestos "A name applied to a group of naturally fibrous minerals" (chrysotile, amosite, crocidolite, tremolite, anthophyllite cited by name) (Bureau of Mines, 1968). The term asbestos has also been applied to commercially exploited fibrous clays, including attapulgite and palygorskite (Whittaker, 1968).

Asbestos implies current or possible exploitation, based on the presence of special physical and chemical properties, determined on the bulk sample level. For example, high fiber tensile strength, flexibility, low heat conductivity, high electrical resistance, and chemical inertness are properties of asbestos. Noncommercial varieties of the same mineral may not possess the same qualities on the bulk level. For example, amosite has been considered to be the economically exploited variety of grunerite (Deer et al., 1962). If so, and even this is contested among mineralogists today, large macrocrystals are significantly different physically and structurally. Grunerite fiber is rigid, amosite fiber is flexible; grunerite yields well-defined single X-ray reflections with nonrotational film techniques, amosite yields multiple reflections as if rotated in the X-ray beam; grunerite appears to be a single crystal, amosite splays as if composed of strands. However, when both substances are pulverized, the resultant powder yields submicroscopic fibers, many of which are virtually indistinguishable on the basis of morphology, structure (determined by selected area electron diffraction), and chemistry (determined by an electron probe

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technique). Amosite may be considered as an aggregate of unoriented, discrete, grunerite crystals with only the *c* axis in common alignment.

Comminution of such aggregates produces fibers with characteristics identical to those of single crystals of grunerite that have been similarly pulverized. Some workers have suggested that mechanical size reduction of amosite yields fibers with crystal growth surfaces rather than cleavage surfaces. Since amphibole cleavage tends to parallel prominent crystal face planes, such distinctions on the submicroscopic level may disappear. This appears to be the case for tremolite and anthophyllite as well. However, because no methods exist to distinguish between possible differences in fiber surface, we do not refer to anthophyllite and tremolite fibers in these talcums as asbestos. Instead they are referred to as asbestiform. It should be stressed, however, that evidence does not exist that would indicate that fibers with crystal growth surfaces or cleavage surfaces possess lesser or greater biological potential than fibers from commercial asbestos deposits.

Asbestiform "Formed like or resembling asbestos; fibrous; . . . . (Bureau of Mines, 1968). The term is used herein for amphiboles (anthophyllite and tremolite) seen on both light and submicroscopic examination, which resemble comminuted asbestos varieties, on the basis of morphology. Essentially, when these fibers are derived from commercial deposits we term them "asbestos" and when analytically identical fibers are found as noncommercial intrusions with the mineral talc, we term them "asbestiform." The use of two terms does not imply differences that can be analytically determined.

Fiber "The smallest single strand of asbestos or other fibrous materials" (Bureau of Mines, 1968). We use this term in a broader sense. For example, chrysotile fibers are called fibrils, possessing unit diameters of about 200–400 Å. Coherent bundles of fibrils are also called fibers. Fiber in the present text is used to denote any elongated single mineral unit visible on the light or electron microscopic level. The Occupational Safety and Health Administration has applied a 3:1 length-to-width ratio to distinguish fiber from mineral fragment.

APPENDIX B: CRYSTAL CHEMISTRY, CRYSTAL STRUCTURE, AND GEOLOGICAL OCCURRENCE OF TALC

Chemistry of Talc

The empirical chemical formula of talc is $Mg_3Si_4O_{10}(OH)_2$, but ferrous and ferric oxides, alumina, titania, soda, lime, and oxides of manganese have been reported in quantities up to several percents by

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weight. Titanium and aluminum appear to substitute for silicon, whereas iron, nickel, and manganese substitute for magnesium. Alkali metals are not readily accommodated in the structure and evidently occur as interlayer ions or as components of mineral impurities. For example, excess calcium may reflect the presence of the interlayer mineral phase tremolite (Deer et al., 1962; Stemple and Brindley, 1960). One major talc deposit in the eastern United States contains substantial amounts of nickel, as much as 0.2%. Notwithstanding these minor components, talc is essentially (by weight) 32% MgO, 63% SiO_2, and 5% structurally bound water.

Talc Structure and Crystal Habit

The three-layered crystal structure comprises a sheet of octahedrally coordinated $Mg(OH)_2$ groups (the brucite layer) sandwiched between two planes of tetrahedrally linked SiO_4 groups (silica layers). Apical oxygens of the silica sheets are directed toward the brucite layer and in part replaced by hydroxyl groups, which form a portion of the inner structural unit. Valence balance is accomplished within the structure, so that there is a net zero charge on juxtaposed unit layers at the silica base interfaces.

The basic unit of the talc structure was determined over 40 yr ago (Gruner, 1934; Hendricks, 1938), yet the repeated cell geometry and space group were only recently resolved. X-ray single crystal patterns now indicate talc to be triclinic (Rayner and Brown, 1966; Ross et al., 1968).

In addition to chemical and structural complexities, talc occurs with both plate and fiber habits (Ford, 1957). The development of the fibrous cyrstal form, with an elongated crystallographic *a*-axis, may be a manifestation of ionic substitution since its refractive index is higher than platy talc (Fleischer and Osborn, 1957; Gruner, 1944). Talc that contains substantial amounts of these elongated forms is referred to in the mineralogical literature as fibrous talc. Similar observations with regard to the mineral brucite have been reported (Liebling and Langer, 1972) in which high iron content in the normally platy brucite is associated with the development of a fibrous habit. It is of interest to note that minnesotaite, considered by some to be an iron-rich form of talc, always occurs with a fibrous, or even a needle-like, habit (Gruner, 1944).

Formation of Talc in the Laboratory of Nature

In closely controlled experimental systems, talc has been synthesized (Bowen and Tuttle, 1949; Yoder, 1952). Bulk chemistry, water fugacity, temperature, and pressure parameters are defined within extremely restricted limits and ranges to produce relatively pure crystallization products. However, in laboratory synthesis, just as in nature, coexisting mineral phases are produced if slight variations in any of the parameters are introduced. These phases include anthophyllite, serpentine, and in some instances tremolite.

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Nature of Talc Plates

Electron microscopic examination of talc minerals demonstrates that single talc grains consist of contiguous single crystals, mosaics of disoriented crystallites, and intergrowths with other mineral phases, particularly tremolite (Kleinfeld et al., 1973; Stemple and Brindley, 1960; Wright, 1960). Selected area electron diffraction patterns obtained on these objects display, in order, single crystal arrays, Debye-Scherrer rings, and superimposed complex patterns characteristic of intergrown single crystal phases.

Talc and Mineral Intergrowths

Tremolite is one common intergrowth in talc, and it requires relatively little energy thermodynamically to occur. Replacement of magnesium by calcium in the brucite layer may lead to structural as well as chemical modification (Bragg and Claringbull, 1965). Rotation of unit tetrahedra in talc forms double chains from sheets, readily accomplished by substitution of $Mg(OH)_2$ by $Ca(OH)_2$. The bulk chemistry is thereby changed from $Mg_6Si_8O_{20})(OH)_4$ to $Ca_2Mg_5Si_8O_{22}(OH)_2$. The final structural array is remarkably similar in both materials; the crystallographic *a*-axis of talc is approximately 5.26 Å, which corresponds with the *c*-crystallographic axis of tremolite (approximately 5.24 Å); the *b*-axis for talc is approximately 9.10 Å, which is equal to the *b*/2-axis of tremolite; the *c*-axis of talc, approximately 18.8 Å, is about equal to twice the *a*-dimension of tremolite (approximately 18.2 Å). The monoclinic stacking angles, the beta-angle, are within a few degrees of each other.

Intergrowths may form in which amphibole formation is not complete so that a mixed phase exists, referred to mineralogically as "talcboles." These are not as rare as once believed and may even be common in the more complex talc deposits.

APPENDIX C: INDUSTRIAL AND COSMETIC GRADE TALCS

Studies have demonstrated that industrial talc often consists of a variety of minerals, the utilization of which is based on physical properties rather than mineral composition (Hogue and Mallette, 1949; Schulz and Williams, 1942; Thompson, 1974; Wells, 1965).

Early analyses of cosmetic talc also showed a wide range in mineral composition. Of six such products examined in one study, only 6–47% by weight of the inorganic material that constituted the product was the mineral talc; 14–51%, serpentine minerals; 5–77% carbonate minerals; 0–trace, quartz; 0–trace, tremolite; 3–12%, other minerals (Schulz and Williams, 1942).

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APPENDIX D: BIOLOGICAL HAZARDS ASSOCIATED WITH TALC EXPOSURE

A fine, diffuse, bilateral, progressive fibrosis was observed among miners and millers of tremolite talc in Georgia (Dreessen, 1933; Dreessen and Dalla Valle, 1935). Siegal et al. (1943) studied a population of workers mining and milling tremolite and anthophyllite-bearing talc deposits in New York state. In addition to the bilateral fibrosis, pleural plaques, similar to those encountered in asbestos workers, were observed. Review of postmortem material in this study indicated that asbestos bodies were present in lung tissue. These findings were also reported in cases of severe pneumoconiosis in tremolite millers by Daymon (1946), and by Porro and Levine (1946).

Millman (1947) reported that exposure to cosmetic-grade talc produced nodular fibrosis in workers. No quartz was detected in the dust. The author concluded that talc itself was capable of producing scarring. The observation was supported in studies by Reichman (1944) and by Wyers (1949) and in a study of talc miners and millers in Italy where exposure to pure talc produced a 10% incidence of pneumoconiosis in workers (Parmeggiani, 1948). Excess deaths attributed to pneumoconiosis have been reported among workers in northern Italy mining talc considered to be free of asbestiform fibers (Rubino et al., 1976).

Some investigators have held that fibrous talcs (not differentiated as talc or asbestos fiber) are biologically more hazardous than platy talcs. For example, in a review of the literature by Porro et al. (1942), Gloyne and Gardner are referred to as considering that the clinical, radiological, and pathological disease states of asbestosis and talcosis are very similar. There are several reports of the occurrence of asbestos bodies in the lung tissue of workers exposed to talc (Daymon, 1946; Hobbs, 1950; Kleinfeld et al., 1973; McLaughlin et al., 1949; Porro et al., 1942).

Several studies suggest that fibrous talcs are more dangerous as a result of the included asbestos fiber. For example, McLaughlin et al. (1949) compared fibers in talc with the proportion of fibers recovered from the lung tissue of an exposed worker. A larger concentration of fibers was found in the tissues as compared with the raw talc. Talc pneumoconiosis was reaffirmed by Kleinfeld and Messite (1960) in their study of the New York state talc workers.

In a study by Kleinfeld et al. (1967) it was demonstrated that talc pneumoconiosis accounted for almost 30% of excess deaths among the talc miners and millers. Most of these were due to the complication of pneumoconiosis, cor pulmonale. However, 21% of the 91 deaths recorded were due to malignant tumors: lung carcinoma, pleural fibrosarcoma, and stomach, colon, rectum, and pancreatic cancers. A peritoneal mesothelioma was reported as well. In addition to these tumors, retroperitoneal sarcoma, hepatoma, and leukemia were also found. Statistical evaluation of

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these data indicated that a 3- to 4-fold excess of cancers existed in this group, as compared to a matched control population.

The biological activity of both tremolite and anthophyllite fibers has been known for some time, and both have been cited as asbestos minerals by Merewether (1930) and Noro (1946). Asbestos disease among workers (and others exposed to anthophyllite and tremolite) has been reported (Burilkov and Badajov, 1970; Kiviluoto, 1960; Meurman, 1968; Meurman et al., 1974; Schepers, 1965; Wegelius, 1947; Weiss and Boettner, 1967).

Recent experimental data also indicate that tremolite fibers are biologically active (Graham and Graham, 1967). Some investigators have suggested that inorganic fiber fibrogenicity and carcinogenicity is limited only by its ability to reach the alveolar space (Holt et al., 1965; Pott and Friedrichs, 1972; Pott et al., 1974; Robock and Klosterkötter, 1976; Stanton and Wrench, 1972).

Wagner et al. (1975) reported lung scarring in Wistar rats with pure talc, exposed by inhalation. The severity and extent of the lung scarring was comparable to that produced by chrysotile asbestos under identical experimental conditions. In addition to lung scarring, ingestion of talc was reported to be associated with leiomyosarcoma of the stomach as well as one adenoma and several sarcomas of the uterus. However, the exposure levels were high and the numbers of observed tumors small, so that statistical validation of the carcinogenic potential of pure talc and its relevance to human exposures were not achieved.

There are also extensive data concerning hazards associated with exposure to silica or trace metals, particularly nickel and chromium (National Research Council, 1975). Analytical data are presented here that suggest possible disease potential and the need for investigation in these areas.

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EXHIBIT 19

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COMMERCIAL TALC
ANIMAL AND MINERALOGICAL STUDIES*

R. Z. Schulz[1] and Charles R. Williams[2]

THE possible pathological effects of exposure to talc dust in industry have been discussed to a certain extent in the literature. It is a well-known fact that wherever talc is used as a dusting agent, workers may be exposed to large amounts of talc dust. Dreessen and Dalla-Valle (1) (2) after studying the effects of exposure to dust in talc mines and mills in Georgia and Vermont arrived at the conclusion that talc does not produce a disabling pneumoconiosis, but does result in diffuse fibrosis, which may be seen in roentgenograms. Experimental work by Gardner (3 and 4) indicates that the reaction caused by talc produced some inflammation which showed no tendency to progress in 2 years. There is, however, one important factor which has not been investigated, and that is the effects of variations in composition of commercial talcs. The term "talc" as used industrially generally refers to a substance which meets certain physical requirements rather than one which has a definite chemical composition. The mineral talc, is a specific substance, a hydrous magnesium silicate ($H_2Mg_3(SiO_3)_4$). Several minerals may accompany it as it occurs in nature and some of them may be quantitatively more important than the talc. The most prominent minerals are serpentine, (hydrous magnesium silicate, $H_4Mg_3Si_2O_9$), dolomite (calcium magnesium carbonate), and tremolite (calcium magnesium silicate). Variations in composition of "talcs" used in industry (in cosmetics, as fillers in paper, paints, linoleum, as a dusting agent in the rubber industry, etc.) are extreme (5).

For this reason, the writers deemed it advisable to study the effects on guinea pigs of several different types of so-called "talcs" used industrially.

A series of 7 commercial "talcs" with widely-different mineralogical compositions were used in the experiments. They were picked from the group of 51 analyzed talcs (Table 1) to represent the whole range of composition found. The mineralogical analyses of the experimental samples and the silicate-carbonate ratios are shown in Table 2. These ratios are given since we have assumed in the past that a "talc" with a low proportion of silicates would be safest to use. The numbers, 814-6A; 814-11C, etc., will be used to identify these talcs in subsequent discussions.

Method

The samples were prepared for injection by suspending 5 gm of a given "talc" in 100 cc of physiological saline, autoclaving for 30 minutes at 20 lbs pressure following the technic used by Sayers and Miller (6).

Guinea pigs weighing 250 gm were given a single intraperitoneal injection of 4 cc of the suspension which had the equivalent of 200 mgm of "talc". Each "talc" was injected into a group of 10 animals. One animal from each group which had received one of the above-named "talcs" was sacrificed at intervals ranging from 10 days to 15 months.

Tissues removed were fixed in 10% formalin and sections were cut from paraffin or celloidan blocks. One section from each was mounted unstained in Canada balsam. Others were stained with Hematoxylin-eosin. Special stains were used to bring out connective tissue.

Results

Mineralogical

Unstained sections mounted in Canada balsam were studied petrographically to determine mineralogical changes which had taken place. The results are shown in tables 3 to 9.

"Talc" 814-6A is one which has a high carbonate content (a low silicate ratio). The most notable change which took place was a sharp drop in the amount of carbonate present. This occurred during the first few weeks and then leveled off, although at the end of 15 months there was still a small amount of carbonate left, but mostly as very coarse particles (larger than 20 μ). There is also a tendency for the serpentine to decrease, as indicated by the marked change in the proportions between "talc" and serpentine in the original sample, compared with the samples which had

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TABLE 1

Sample number	wt. % soluble	% less than 10 μ by count	% by count less than 10 μ					Use
			Talc	Serpentine	Carbonate	Quartz	Tremolite	Others
1	49.18	97	4	6	82	—	—	8	Dusting rubber
2	46.14	95	9	5	83	tr.	—	3	Dusting rubber
3	45.53	95	21	33	32	tr.	tr.	14	Dusting rubber
4	43.88	90	12	6	75	—	tr.	7	Dusting rubber
5	43.03	95	14	10	63	—	9	4	Dusting rubber
6	41.73	95	6	5	86	—	—	3	Dusting rubber
7	41.52	95	8	6	70	—	12	4	Dusting rubber
8	39.23	95	5	6	72	—	12	5	Dusting leather
9	38.27	95	15	28	45	tr.	—	12	Dusting rubber
10	36.28	95	10	8	67	tr.	6	9	Filler in felt
11	35.56	90	12	33	45	tr.	tr.	8	Dusting rubber
12	34.18	95	12	5	58	—	16	14	Packaging for redistribution
13	32.44	85	5	13	79	—	—	3	Dusting rubber
14	32.09	90	16	22	57	—	—	5	Dusting rubber
15	29.86	95	15	9	68	—	3	5	Dusting rubber
16	28.78	95	16	12	64	tr.	—	8	Dusting rubber
17	27.94	95	14	12	67	—	tr.	7	Dusting rubber
18	26.65	85	16	11	58	—	9	6	Talc mill (Ga.)
19	25.27	90	6	8	82	—	—	4	Dusting rubber
20	24.19	90	4	3	88	—	—	5	Dusting rubber
21	24.78	96	6	14	77	—	tr.	3	Talcum powder
22	24.43	95	14	11	67	tr.	—	8	Dusting asphalt
23	24.08	95	17	10	68	—	—	5	Dusting rubber
24	23.54	90	11	6	78	—	—	5	Lubricated mechanical packing
25	22.94	90	16	26	47	tr.	—	11	Dusting rubber
26	22.83	90	4	6	80	3	—	7	Dusting rubber
27	22.14	97	47	29	12	—	—	12	Talcum powder
28	20.94	95	11	14	66	tr.	5	4	Dusting rubber
29	20.09	75	24	35	4	—	11*	6	Dusting rubber
30	19.98	90	14	38	21	tr.	24	3	Filler in soap
31	19.14	70	20	46	26	tr.	—	8	Dusting rubber
32	17.22	90	29	7	34	tr.	21	9	Dusting rubber
33	14.68	90	24	30	32	tr.	8	6	Dusting in shoe industry
34	12.52	90	3	3	8	—	82	4	Dusting rubber
35	10.20	85	36	33	20	tr.	—	11	Dusting rubber
36	9.96	80	51	27	7	—	—	15	Dusting rubber
37	9.14	75	15	22	17	tr.	31	5	Dusting rubber
38	9.02	65	35	49	12	—	—	4	Talcum powder
39	8.51	90	41	54	tr.	tr.	—	5	Talc mill
40	7.95	90	32	49	9	tr.	tr.	10	Dusting rubber
41	6.00	65	25	51	19	—	—	5	Talcum powder
42	5.38	90	37	52	5	tr.	—	5	Talc mill
43	5.08	80	27	57	9	tr.	1	5	Dusting rubber
44	4.39	85	40	47	5	tr.	—	8	Talcum powder
45	4.20	75	4	6	3	tr.	79	8	Dusting rubber
46	4.02	90	31	13	38	—	—	8	Talcum powder
47	3.83	90	3	5	8	—	80	4	Filler in paper
48	3.56	75	38	50	8	tr.	—	4	Dusting rubber
49	1.85	40	52	34	8	tr.	—	6	Talc mine
50	1.13	50	52	39	—	tr.	—	9	Filler in paper
51	0.93	35	44	53	tr.	tr.	—	4	Talc mine

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1. 814-6A	4
2. 814-11C	3
3. 814-25D	2
4. 814-33	1
5. 814-40B	
6. 814-50	
7. 814-34	

Talc. . .
Serpentine . . .
Carbonate . . .
Others. . . . . .

Max. size in μ
% <10μ. . .

* The lett
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Table 5
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been in the animals for the full period of the experiment. It is also interesting to note that toward the end of the experiment there was a marked parallelism of the "talc" needles. This may be the result of the purely mechanical factor of movement in the abdominal wall of the animal.

This material (814-11C) contained about 50% dolomite when injected. As in the first case, it had disappeared at the end of 15 months. Serpentine, likewise, showed a relative decrease.

TABLE 2

TALC SAMPLES

	WT. % SOLUBLE	TALC	SERP.	CARB.	QTZ.	TREM.	OTHERS	SI:CO₂ RATIOS
	%	%	%	%	%	%	%	
1. 814-6A	41.73	6	5	86	—	—	3	15:85
2. 814-11C	35.56	12	38	45	tr	tr	8	55:45
3. 814-25Q	22.94	16	26	47	tr	tr	11	53:47
4. 814-33	14.68	24	30	32	tr	8	6	68:32
5. 814-40B	7.95	32	49	9	tr	tr	10	91:9
6. 814-30	1.13	52	39	—	—	—	9	100:0
7. 814-34	12.52	3	3	8	tr	82	4	92:8

TABLE 3

814-6A

	RAW MATL.	A*	B	C	D	E
	%	%	%	%	%	%
Talc	6	45	48	55	70	69
Serpentine	5	16	17	15	18	20
Carbonate	86	31	28	22	6	4
Others	3	8	7	8	6	7
Max. size in μ	—	150	100	100	120	80
% < 10μ	—	97	90	90	80	70

* The letters A to E refer to animals killed at times progressing from 10 days to 15 months after injection of "Talc."

Table 5 shows a "talc" which also contains about 50% carbonate. During the first few months there was a marked decrease in the amount of carbonate, which leveled off to a residue of coarse particles persisting throughout the remainder of the experiment. Here again, there was also an apparent loss of serpentine. The "talc" is the one constituent which is unaffected.

In this case (814-33), the same general trend was found, that is, an increase in "talc" with a decrease in carbonate. The outstanding characteristic of this "talc" is its fine grain with 80 μ as the maximum size and 90–95% of the grains below 10 μ.

TABLE 4

814-11C

	RAW MATL.	A	B	C	D	E
	%	%	%	%	%	%
Talc	12	32	34	30	45	49
Serpentine	35	34	30	34	37	42
Carbonate	45	27	28	30	10	tr
Quartz	tr	tr	tr	tr	tr	tr
Tremolite	tr	tr	tr	tr	tr	tr
Others	8	7	8	10	8	9
Max. size in μ	—	80	80	80	75	70
% < 10μ	—	90	90	90	90	85

TABLE 5

814-25Q

	RAW MATL.	A	B	C	D	E
	%	%	%	%	%	%
Talc	16	39	42	46	44	50
Serpentine	26	24	28	30	22	38
Carbonate	47	28	22	24	25	4
Quartz	tr	tr	tr	tr	tr	tr
Tremolite	tr	tr	tr	tr	tr	tr
Others	11	9	8	10	9	8
Max. size in μ	—	60	70	70	80	60
% < 10μ	—	85	85	80	75	80

TABLE 6

814-33

	RAW MATL.	A	B
	%	%	%
Talc	24	32	36
Serpentine	30	40	42
Carbonate	32	15	10
Quartz	tr	tr	tr
Tremolite	8	6	5
Others	6	7	7
Max. size in μ	—	80	80
% < 10μ	—	90	95

This sample (814-40B) contains about 10% dolomite at the start, but this had disappeared at the end of 4 months. As shown in table 7, serpentine also decreased during the course of the experiment.

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This "talc" (814-50) contained no dolomite. It is the nearest to mineralogically-pure talc that was encountered in all of the analyzed samples. It contained about 50% of the mineral talc. There

TABLE 7
814-40B

	RAW MAT'L.	A	B	C	D
	%	%	%	%	%
Talc	32	44	52	61	64
Serpentine	40	45	38	32	26
Carbonate	9	3	2	tr	tr
Quartz	tr	tr	tr	tr	tr
Tremolite	tr	tr	tr	tr	tr
Others	10	8	8	7	9
Max. size in μ	—	80	70	80	80
% < 10μ	—	90	90	90	90

TABLE 8
814-50

	RAW MAT'L.	A	B	C	D
	%	%	%	%	%
Talc	52	54	56	52	62
Serpentine	39	38	36	42	30
Others	9	8	8	6	8
Max. size in μ	—	75	70	80	75
% < 10μ	—	90	90	85	90

TABLE 9
814-34

	RAW MAT'L.	A	B	C	D
	%	%	%	%	%
Talc	3	4	3	3	2
Serpentine	3	3	2	tr	tr
Carbonate	8	—	—	—	—
Quartz	tr	tr	tr	tr	tr
Tremolite	82	88	90	93	92
Others	4	5	5	4	6
Max. size in μ	—	100	100	150	140
% < 10μ	—	95	95	95	95

was very little change in composition throughout the 15 months of the experiment as table 8 shows.

Tremolite is occasionally used as a "talc" where a more brittle type of fiber is required. Such a material is shown in table 9. The composition remained practically the same during the experiment.

From the mineralogical point of view, two facts stand out as a result of these experiments. First, most of the dolomite disappeared in 12 to 15 months with only the coarsest particles remaining; second, in "talcs" which contained carbonate, the serpentine was also removed, but to a lesser degree. As an interesting sidelight, it was also noted that after a period of about 8 to 12 months there was a tendency of the talc needles to align themselves parallel to the abdominal wall of the animal.

Gross Findings

At the time the animals were sacrificed, they appeared to be in good health and nutrition. At post-mortem, the organs appeared to be essentially normal, the talc having accumulated for the most part on the ventral parietal surface of the peritoneum, although smaller nodules were also found on other peritoneal surfaces. The nodules at first were large, of greyish buff color and moderately firm. Even at the end of 12 days, they were not particularly fragile. In the course of time, the lesions became more dense and firm. In talcs 814-6A and 814-11C the nodules at the end of 15 months were smaller than those in animals sacrificed at earlier periods. There was no apparent increase in the size of the nodules, except what could be expected in the variations in the amount of talc locally deposited.

Microscopic Findings

The histological study of tissue changes reveals that the material is mostly taken up and held by macrophages and giant cells. In talcs 814-33 and 814-25Q, the macrophages predominated throughout the entire period of time. In the remaining talcs, large giant cells were more numerous and prominent. These frequently were packed with particles leaving only a rim of cytoplasm containing the nuclei. In all cases, the fibrous tissue was of minimal amount and in no instance was there evidence of a progressive proliferation of the fibrous tissue similar to that found in the silicotic nodule. The histological end results are those of storage of foreign material, primarily in phagocytic cells, with sufficient accompanying fibrous tissue to hold these cells in place, thereby storing the foreign material permanently in such a way that it might well be called a "storage fibrosis".

The greatest amount of fibrous tissue was pro-

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duced by talcs 814-34 and 814-50. In the latter, fibroblastic proliferation was most pronounced during the early phases, although the amount of connective tissue formed was not prominent at the end of the experiment. Because of this tendency to product more fibrous tissue than the others, they should be placed more or less in a class by themselves. The permissible concentration of dust should be kept at a lower level than in the other "talcs" examined. The animals, however, did not attain the fibrosis found in active silica.

Discussion

The organs of the body showed no lesions, with the exception of the places where the "talc" had been deposited. The pathological histology of all of the "talcs" tested had in common the holding of the particles in a local area by phagocytic cells of the macrophage and giant cell type. The kind of cell which would ultimately predominate was in large part determined by the size of the particle. In addition an early slight fibrous tissue formation occurred with "talcs" 814-34, 814-50. The early fibrous tissue proliferation appears to be the result of an acute early reaction which was later lost. Progressive fibrosis, such as produced by crystalline-free silica, did not occur in the talcs studied. The fibrosis which does occur is only enough to hold and limit the space for storing the foreign material. Such localization tends to restrict the zone of possible hazard. While inhalation of this material in large quantities could probably be tolerated without symptomatic effect, the material, the cells in which it is stored, and the fibrous tissue holding these cells and "talc" particles, increase the rigidity of the tissues involved.

The lung, particularly the terminal portions or alveoli, whose very essence of function is that of being stretched and compressed with each respiration, would be impeded in its movement by the accumulation of these particles and the resulting reaction. The degree of this impediment would depend upon the extent of involvement. Fortunately, the reserve capacity of a normal lung is sufficiently great to offset a considerable impairment without affecting the vital requirement. However we wish to emphasize that while the degree of impairment is not great, it cannot be assumed that there is no hazard.

Summary

Petrographic analysis showed that in "talcs" 814-6A, 814-11C, 814-25G, and 814-33 carbonates and serpentine decreased as the experiment progressed. Such "talcs" are to be preferred from the health aspect, inasmuch as a smaller amount of material is more or less permanently stored. The greatest amount of fibrous tissue was developed in the presence of the two "talcs" (814-34, 814-50) which contained the least carbonate. "Talcs" of this type should be avoided wherever possible, but when these are essential, methods of controlling the dust should be employed.

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EXHIBIT 20

Environmental Health Perspectives
Vol. 9, pp. 129–132, 1974

Asbestos in Talc

by Arthur N. Rohl*

Talc deposits include asbestos minerals such as chrysotile and amphiboles that may be carried over into consumer products. Optical microscopy and x-ray diffraction analyses may not reveal their presence. Examples are given of electron microscopy procedures that permit detection and measurement.

The mineral talc is a hydrous magnesium sheet silicate that occurs in both platy and fibrous crystal forms. Talc tends to occur in rock masses coexisting with a number of other hydrous magnesium silicate minerals. Typically, talc deposits consists of fine-grained, intergrown mixtures of minerals which may contain considerable amounts of asbestos. In addition, talc deposits often show complex mineral zonation, which adds to the difficulty of selective mining. For example, in the talc deposits of the Gouveneur District of New York State, talc occurs with the asbestos minerals chrysotile, tremolite, and anthophyllite in addition to other silicate minerals.

Since the mining of talc rock almost invariably includes the mining of asbestos as well, the asbestos contaminant may be carried over into the consumer product and thus introduce the risk of asbestos disease. This possibility leads to an important public health question: is asbestos present in consumer talcs, and if present, which mineral fibers and in what concentrations?

Among the standard mineralogical techniques which may be used for identification and quantitation of asbestos in talc are optical microscopy, x-ray diffraction, and electron microscopy (EM).

Optical microscopy, employing polarized light optics, is useful for determining the optical properties of particles. However, in the instance of talc, the extremely fine grained intergrowths of different minerals and the extensive overlapping and similarities of their optical properities limit this technique to a preliminary or screening function. Since large numbers of fibers may go undetected, optical microscopy would not be capable of quantitative analysis.

X-ray powder diffraction is a routine technique for analyzing crystalline materials. It is relatively simple in principle, but the results may be difficult to interpret. The limitations of precision and accuracy must be given careful consideration.

The identification and quantitation of asbestos fibers in talc by x-ray diffraction may be achieved by comparison of known dilutions (fiber type and quantity) of asbestos in a talc matrix with unknowns. The preparation of standard dilutions of asbestos minerals in talc for quantitative analysis requires: (1) a talc matrix completely free of contaminating asbestos minerals, (2) pure asbestos fiber as the sought adventitious phase, (3) a preparation method for insuring homogeneity and reproducibility of the standard dilution material, and (4) selection of x-ray reflections with no superimposed interferences. Condition (1) requires the selection of pure talc matrix material. In the first stage of screening, material was first scanned by x-ray diffraction to identify the major mineral phases rapidly, especially asbestos minerals. If no asbestos phases were detected, the material was

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re-examined in a more sensitive mode of x-ray diffraction called step scanning, and finally by electron microscopy. In this way a pure talc was selected (pure with respect to asbestos; small amounts of chlorite and phlogopite mica were tolerated).

In a similar way, pure samples of anthophyllite, tremolite, and chrysotile were screened and selected for use in preparing the talc-asbestos standard dilutions.

In x-ray diffraction the reproducibility of reflection intensities is strongly influenced by the degree of cleavage of crystalline powders. The minerals under investigation exhibit a high degree of platy and fibrous cleavage. A number of preparation techniques have been developed for reducing preferred orientation effects. These were tested, but none were found to give satisfactory reproducibility. Accordingly a technique was developed and employed which gives a high degree of sensitivity for substances present in minute quantities and with a greater level of reproducibility of reflection intensities.

Binary systems of three asbestos minerals in talc were prepared at varying levels of dilution concentrations. Standard weights of these mixtures were dispersed in water with ultrasonic energy to disperse the phases homogeneously. This slurry was filtered through a membrane filter by use of a hypodermic syringe (Fig. 1). The residue forms a flat cake which is mounted for x-ray analysis. This technique has the advantage of uniformly preparing, mounting and measuring the talc-asbestos dilutions under identical conditions.

Because of the structural similarities between some of the minerals, there was considerable overlapping or interference in many reflections, and this made it necessary to select reflections which could be unambiguously used as indices of the amount of each mineral present. These diagnostic reflections were step-scanned at 0.01°2θ, in a fixed-count mode. This permits the weak reflections produced at low dilution levels to be determined with precision. From the fixed-count data a profile of the diagnostic reflection is obtained and the area above background is taken to be proportional to the reflection intensity. The results of these analyses are given in Table 1, which shows that: chrysotile at dilution levels less than 0.25% was not detected, tremolite was detected down to 0.1% dilution level, and anthophyllite was not detected at concentrations below 2.0% (diagnostic reflection is at 8.26 Å; $I/I_1 = 55$).

In order to determine the number of chrysotile fibers present at various dilution levels, aliquots of the various dilutions were prepared for EM scanning. A fairly standard technique called the rubout method was used. For each dilution level, 20 fields from three EM grids are photographed at constant magnification and the number of long unit fibrils per field are counted from printed enlargements (Figs. 2 and 3). These fiber counts show fairly good correlation with levels of chrysotile dilution. By using the fiber count data, it is possible to calculate the number of fibers in a unit weight of sample. Thus, at a 1% dilution level there would be about 40×10^6 fibers/mg. Even at the lowest level of detection by x-ray diffraction, i.e., 0.25%, there would be about 10^9 fibers/mg. Cosmetic talcum powder, for example, which had been step-scanned and chrysotile not found might contain billions of fibers released during dusting with a half-gram dose.

Thus, very large numbers of asbestos fibers may be present in talc end products, yet they remain undetected if only optical microscopy and x-ray diffraction are used. On the other hand, EM can be a very sensitive method for detecting extremely minute amounts of asbestos in talc.

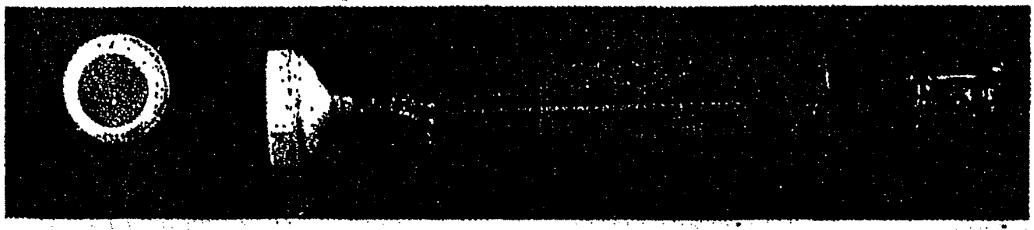


FIGURE 1. Membrane filter holder–hypodermic syringe system of sample preparation.

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Table 1. Comparison of lower limits of detection of asbestos minerals in talc by step scanning and continuous scanning.

Asbestos mineral	Diagnostic reflection, Å	Detection limit concentration, % Step scanning (0.01° 2θ)[a]	Continuous scanning (1° 2θ/min)[b]
Chrysotile	3.66	0.25	1.0
Tremolite	8.38	0.10	2.0
Anthophyllite	8.26	2.0	4.0

[a] Operating conditions: fixed count rate = 2000; 45 kV, 20 mA.
[b] Operating conditions: 500 counts/sec; time constant = 2.0; 45 kV, 20 mA.

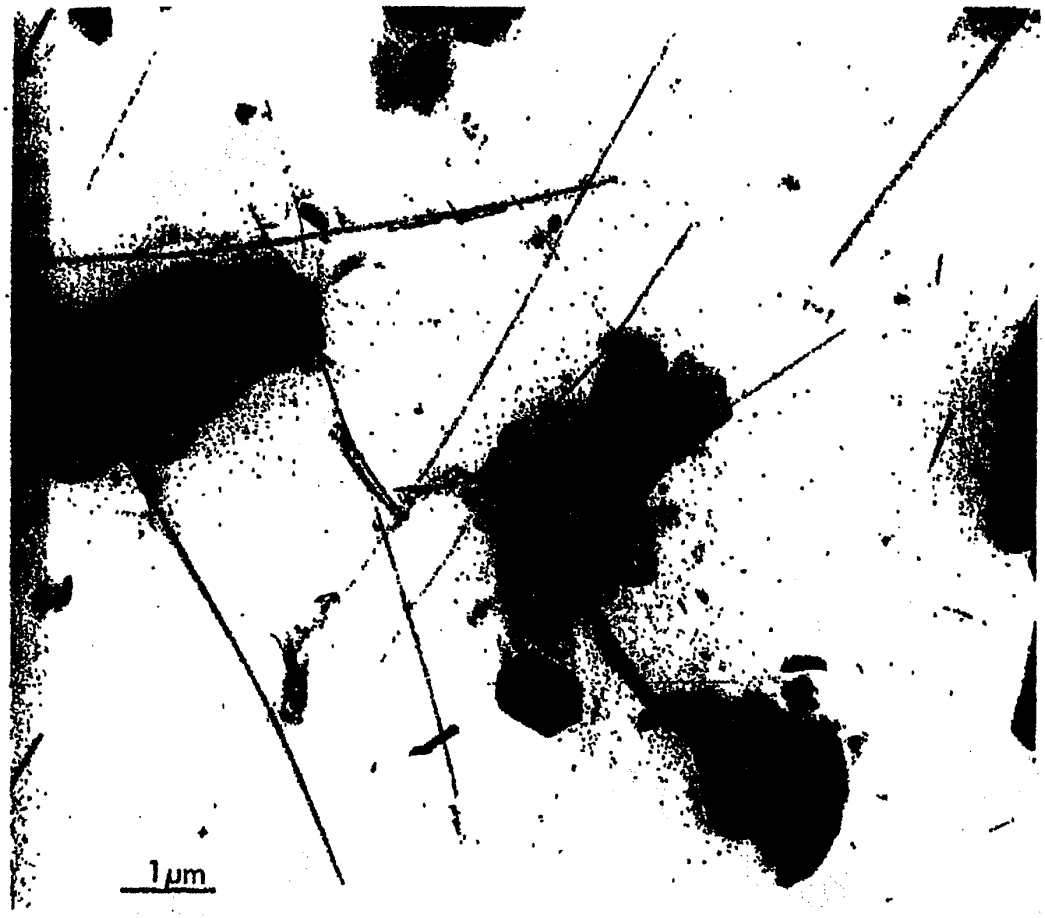


FIGURE 2. Electron photomicrograph of chrysotile–talc (99% talc, 1% chrysotile).

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FIGURE 8. Electron photomicrograph of chrysotile–talc (95% talc, 5% chrysotile).

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EXHIBIT 21

A TEXTBOOK
OF
MINERALOGY

WITH AN EXTENDED TREATISE ON

CRYSTALLOGRAPHY AND PHYSICAL MINERALOGY

BY
EDWARD SALISBURY DANA
Late Professor Emeritus of Physics, Yale University

FOURTH EDITION, REVISED AND ENLARGED

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Professor of Mineralogy and Curator of the Mineral Collections, Sheffield Scientific School of Yale University

F. EYOLF BRONNER

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APPENDIX TO THE MICA DIVISION — VERMICULITES

The Vermiculite Group includes a number of micaceous minerals, all hydrated silicates, in part closely related to the chlorites, but varying somewhat widely in composition. They are alteration-products chiefly of the micas, biotite, phlogopite, etc., and retain more or less perfectly the micaceous cleavage, and often show the negative optical character and small axial angle of the original species. Many of them are of a more or less indefinite chemical nature, and the composition varies with that of the original mineral and with the degree of alteration.

The laminæ in general are soft, pliable, and inelastic; the luster pearly or bronze-like, and the color varies from white to yellow and brown. Heated to 100°–110° or dried over sulphuric acid most of the vermiculites lose considerable water, up to 10 per cent, which is probably hygroscopic; at 300° another portion is often given off; and at a red heat a somewhat larger amount is expelled. Connected with the loss of water upon ignition is the common physical character of exfoliation; some of the kinds especially show this to a marked degree, slowly opening out, when heated gradually, into long worm-like threads. This character has given the name to the group, from the Latin *vermiculari, to breed worms*. The minerals included can hardly rank as distinct species and only their names can be given here: *Jefferisite, vermiculite, culsageeite, kerrite, lennilite, hallite, philadelphite, vaalite, maconite, dudleyite, pyrosclerite.*

III. Serpentine and Talc Division

The leading species belonging here, Serpentine and Talc, are closely related to the Chlorite Group of the Mica Division preceding, as noted beyond. Some other magnesium silicates, in part amorphous, are included with them.

SERPENTINE.

Monoclinic. In distinct crystals, but only as pseudomorphs. Sometimes foliated, folia rarely separable; also delicately fibrous, the fibers often easily separable, and either flexible or brittle. Usually massive, but microscopically finely fibrous and felted, also fine granular to impalpable or cryptocrystalline; slaty. Crystalline in structure but often by compensation nearly isotropic; amorphous.

X-ray analysis of chrysotile shows that it is composed of bundles of parallel fibers, but although the individual fibers are elongated parallel to one crystallographic direction (*c* axis) their orientation otherwise varies. The structure is monoclinic. Four molecules of $H_4Mg_3Si_2O_9$ in the unit cell. Each silicon atom is surrounded by four oxygen atoms arranged at the points of a tetrahedron, a part of the oxygen atoms being shared by neighboring tetrahedral groups. Together these groups form chains extending parallel to the vertical axis. The chains are similar to those of the amphiboles with the composition Si_4O_{11}. The binding forces between these chains are weak thus accounting for the fibrous structure. The arrangement of the Mg and OH groups is similar to that in brucite.

Cleavage *b*(010), sometimes distinct; also prismatic (50°) in chrysotile. Fracture usually conchoidal or splintery. Feel smooth, sometimes greasy. H. = 2·5–4, rarely 5·5. G. = 2·50–2·65; some fibrous varieties 2·2–2·3; retinalite, 2·36–2·55. Luster subresinous to greasy, pearly, earthy; resin-like, or wax-like; usually feeble. Color leek-green, blackish green; oil- and siskin-green; brownish red, brownish yellow; none bright; sometimes nearly white. On exposure, often becoming yellowish gray. Streak white, slightly shining. Translucent to opaque.

Pleochroism feeble. Optically −, perhaps also + in chrysotile. Double refraction weak. Ax. pl. ∥ *a*(100). $X \perp b(010)$ the cleavage surface; $Z \parallel$ elongation of fibers. $2V = 20°$ to 90°. Indices variable, from 1·490–1·571.

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Var. — Many unsustained species have been made out of serpentine, differing in structure (massive, slaty, foliated, fibrous), or, as supposed, in chemical composition; and these now, in part, stand as varieties, along with some others based on variations in texture, etc. Some authors separate the mineral into two modifications: (*a*) *antigorite* (see below) with chemical and optical relations to the Chlorite Group, and (*b*) massive and fibrous *serpentine* and *chrysotile*.

A. In Crystals — Pseudomorphs. The most common have the form of chrysolite. Other kinds are pseudomorphs after pyroxene, amphibole, spinel, chondrodite, garnet, phlogopite, etc. *Bastite* or *Schiller Spar* is enstatite (hypersthene) altered more or less completely to serpentine. See p. 555.

B. Massive. 1. *Ordinary massive.* (*a*) *Precious or Noble Serpentine* is of a rich oil-green color, of pale or dark shades, and translucent even when in thick pieces. (*b*) *Common Serpentine* is of dark shades of color, and subtranslucent. The former has a hardness of 2·5–3; the latter often of 4 or beyond, owing to impurities.

Resinous. Retinalite. — Massive, honey-yellow to light oil-green, waxy or resin-like luster.

Bowenite (Nephrite *Bowen*). — Massive, of very fine granular texture, and much resembles nephrite, and was long so called. It is apple-green or greenish white in color; G. = 2·594–2·787; and it has the unusual hardness 5·5–6. From Smithfield, Rhode Island; also a similar kind from New Zealand, called *tangiwaite* or *tangawaite*.

Rivolite is a banded variety with a fine green color from Mexico.

C. Lamellar. *Antigorite*, thin lamellar in structure, separating into translucent folia. H. = 2·5; G. = 2·622; color brownish green by reflected light; feel smooth, but not greasy. It shows a negative interference figure with *X* normal to cleavage. From Antigorio valley, Piedmont, Italy.

D. Thin Foliated. *Marmolite*, thin foliated; the laminæ brittle but separable. G. = 2·41; colors greenish white, bluish white to pale asparagus-green. From Hoboken, New Jersey.

E. Fibrous. *Chrysotile.* Delicately fibrous, the fibers usually flexible and easily separating; luster silky, or silky metallic; color greenish white, green, olive-green, yellow and brownish; G. = 2·219. Often constitutes seams in serpentine. It includes most of the silky *amianthus* of serpentine rocks and much of what is popularly called *asbestos* (asbestus). Cf. p. 574.

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Picrolite, columnar, but fibers or columns not easily flexible, and often not easily separable, or only affording a splintery fracture; color dark green to mountain-green, gray, brown. The original was from Taberg, Sweden. *Metaxite* is similar. *Baltimorite* is picrolite from Bare Hills, Maryland.

Radiolite is like serpentine except in regard to its solubility and specific gravity. In spherical aggregates of radiating fibers from near Dillenburg, Nassau.

F. Serpentine Rocks. Serpentine often constitutes rock-masses. It frequently occurs mixed with more or less of dolomite, magnesite, or calcite, making a rock of clouded green, sometimes veined with white or pale green, called *verd antique*, *ophiolite*, or *ophicalcite*. Serpentine rock is sometimes mottled with red, or has something of the aspect of a red porphyry; the reddish portions containing an unusual amount of oxide of iron. Any serpentine rock cut into slabs and polished is called *serpentine marble*.

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a, Serpentine derived from chrysolite; *b*, from amphibole; *c*, from pyroxene

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Microscopic examination has established the fact that serpentine in rock-masses has been largely produced by the alteration of chrysolite, and many apparently homogeneous serpentines show more or less of this original mineral. In other cases it has resulted from the alteration of pyroxene or amphibole. Sections of the serpentine derived from chrysolite often show a peculiar structure, like the meshes of a net (Fig. 997); the lines marked by grains of magnetite also follow the original cracks and cleavage directions of the chrysolite (Fig. 998, *a*). The serpentine from amphibole and pyroxene commonly shows an analogous structure; the iron particles following the former cleavage lines. Hence the nature of the original mineral can often be inferred. Cf. Fig. 998, *a*, *b*, *c* (Pirsson).

Comp. — A magnesium silicate, $H_4Mg_3Si_2O_9$ or $3MgO.2SiO_2.2H_2O$ = Silica 44·1, magnesia 43·0, water 12·9 = 100. Iron protoxide often replaces a small part of the magnesium; nickel in small amount is sometimes present. The water is chiefly expelled at a red heat.

For chemical relations to the minerals of the Chlorite Group, see p. 668.

Pyr., etc. — In the closed tube yields water. B.B. fuses on the edges with difficulty, F. = 6. Gives usually an iron reaction. Decomposed by hydrochloric and sulphuric acids. From chrysotile the silica is left in fine fibers.

Diff. — Characterized by softness, absence of cleavage and feeble waxy or oily luster; low specific gravity; by yielding much water B.B.

Micro. — Readily recognized in thin sections by its greenish or yellowish green color, low relief and aggregate polarization due to its fibrous structure. When the fibers are parallel, the interference-colors are not very low, but the confused aggregates may show the "ultra blue" or even be isotropic. The constant association with other magnesia bearing minerals like chrysolite, pyroxene, hornblende, etc., is also characteristic. The presence of lines of iron oxide particles as noted above (Fig. 998) is characteristic.

Obs. — Serpentine is always a secondary mineral resulting, as noted above, from the alteration of non-aluminous silicates containing magnesia, particularly chrysolite, amphibole or pyroxene; more rarely from monticellite, chondrodite, vesuvianite, garnet, talc, etc. It may occur as a replacement of the original mineral, forming a pseudomorph, or it may be deposited elsewhere in the rock openings or as replacing some other mineral. It frequently forms large rock-masses, then being derived from the alteration of peridotites, dunites and other basic rocks of igneous origin; also of amphibolites or other similar metamorphic rocks which may have had a sedimentary origin. In the first case it is usually accompanied by spinel, garnet, chromite and sometimes nickel ores; in the second case by various carbonates such as dolomite, magnesite, breunnerite, etc. Serpentine is a mineral which occurs commonly, though rarely in masses of great size. In the metamorphic rocks it is commonly found as layers, lenticular bodies, etc.

Serpentine is so common a mineral and so widespread in its occurrence that only its most important and interesting localities can be mentioned here. In Saxony, massive ornamental material comes from Zöblitz; and the variety *metaxite* from Schwarzenberg; in Silesia at Reichenstein *picrolite* and *chrysotile*. A variety containing soda from the Zillertal, Tyrol, Austria, is called *nemaphyllite*. In Italy pseudomorphs after monticellite occur in the Val di Fassa, Trentino; the variety *antigorite* was originally described from Valle Antigorio, Piedmont. In Switzerland various types of serpentine are found near Zermatt, in Valais. *Thermophyllite* is found in Finland at Hoposuo. In crystals pseudomorphic after chrysolite from Snarum in Buskerud, Norway. Fine serpentine from the Lizard, Cornwall. Asbestos occurs in the Transvaal in the Barberton district and at various points in Australia.

In the United States fine at Newburyport, Essex Co., Massachusetts. In Rhode Island *bowenite* at Smithfield, Providence Co. In New York from the Tilly Foster mine near Brewster, Putnam Co., pseudomorphic after chondrodite, also in cube-like cleavage forms, presumably pseudomorphous after some unknown mineral; in St. Lawrence Co., at Somerville and elsewhere. In New Jersey *marmolite*, etc., at Hoboken, associated with brucite, magnesite, etc.; at Montville, Morris Co., *chrysotile* and *retinalite* with common serpentine; in Sussex Co., at Vernon and Franklin. In Pennsylvania, at Easton, Northampton Co., pseudomorphous after pyroxene and amphibole; massive, fibrous and foliated of various colors at Texas, Lancaster Co.; at West Chester, Chester Co., *williamsite*; at Bare Hills near Baltimore in Maryland (*baltimorite*). Asbestos is found in Arizona from near Globe, Gila Co., from the Sierra Ancha, and the Grand Canyon.

In Canada abundant among the metamorphic rocks of Quebec between the Vermont boundary and Gaspe Co., at Danville, Richmond Co.; Thetford in Megantic Co.; Brough-

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ton in Beauce Co., etc.; in Ottawa Co., at Templeton. The asbestos often forms seams several inches in thickness in the massive mineral and has been extensively mined.

The names *Serpentine, Ophite, Lapis colubrinus,* allude to the green serpent-like clouding of the serpentine marble. *Retinalite* is from ῥητίνη, *resin; Picrolite,* from πικρός, *bitter,* in allusion to the magnesia (or bittererde) present; *Thermophyllite,* from θέρμη, *heat,* and φύλλον, *leaf,* on account of the exfoliation when heated; *Chrysotile,* from χρυσος, *golden,* and τίλος, *fibrous; Metaxite,* from μέταξα, *silk; Marmolite,* from μαρμαίρω, *to shine,* in allusion to its peculiar luster.

Use. — As an ornamental stone; the fibrous variety furnishes the greater part of the heat insulating material known as asbestos.

Deweylite. — A magnesian silicate near serpentine but with more water. Formula perhaps $4MgO.3SiO_2.6H_2O$. Amorphous, resembling gum arabic, or a resin. Microscopically fibrous. H. = 2–3·5. G. = 2·0–2·2. Color whitish, yellowish, reddish, brownish. Index, 1·55. *Z* parallel to fibers. Deweylite is usually found with serpentine as one of its decomposition products and commonly encloses a carbonate. It occurs as pseudomorphs after talc, etc. It occurs with serpentine at Kuttenberg in Bohemia of Czechoslovakia. From near Kraubat in the Mürstal in Styria, Austria, including the bright red variety called *eisengymnite.* With serpentine from the Val di Fiemme, Trentino, Italy; in granular limestone at Passau, Bavaria. In the United States it occurs at Middlefield, Hampshire Co., Massachusetts; in Pennsylvania at Texas, Lancaster Co., also in Berks, Chester, and Delaware counties. *Gymnite,* named from γυμνός, *naked,* in allusion to the locality at Bare Hills, Maryland, is the same species.

Genthite. Nickel Gymnite. — A gymnite with part of the magnesium replaced by nickel, $2NiO.2MgO.3SiO_2.6H_2O$. Probably should be included as a variety of garnierite. Amorphous, with a delicate stalactitic surface, incrusting. H. = 3–4; sometimes very soft. G. = 2·409. Luster resinous. Color pale apple-green, or yellowish. From Texas, Lancaster Co., Pennsylvania, in thin crusts on chromite. Also reported from near Prägratten in the Austrian Tyrol; from near Malaga, Spain; and on Michipicoten Island in Lake Superior, Ontario.

Garnierite. Noumeite. — An important ore of nickel, consisting essentially of a hydrated silicate of magnesium and nickel, perhaps $H_2(Ni,Mg)SiO_4$ + water, but very variable in composition, particularly as regards the nickel and magnesium; not always homogeneous. Amorphous. Soft and friable. G. = 2·3–2·8. Luster dull. Color bright apple-green, pale green to nearly white. Index, 1·59. In part unctuous; sometimes adheres to the tongue. Occurs in serpentine rock near Noumea, capital of New Caledonia, associated with chromic iron and steatite, where it is extensively mined. A similar ore occurs at Riddle in Douglas County, southern Oregon; also at Webster, Jackson Co., North Carolina. Reported also from the Transvaal in South Africa and from Madagascar. A nickel silicate found in peat in the Ural Mts. has been called *kerzinite.*

Nepouite. $3(Ni,Mg)O.2SiO_2.2H_2O$. Monoclinic. In microscopic crystal plates with hexagonal outline. Good cleavages; ‖ (001) and (010). H. = 2–2·5. G. = 2·5–3·2. Color pale to deep green. Optically −. Ax. pl. ‖ (010). $X \perp$ (001). 2V very small. Indices vary with nickel content; 1·53–1·63. Occurs in the nickel deposits at Nepoui and elsewhere in New Caledonia.

Connarite. — A hydrous nickel silicate, perhaps $H_4Ni_2Si_3O_{10}$. Hexagonal. In small fragile grains. Perfect cleavage (0001). H. = 2·5–3. G. = 2·5. Color yellowish green. Optically −. $\omega = 1{\cdot}59$, $\epsilon = 1{\cdot}56$. From Röttis, north of Plauen in Saxony.

Maufite. Essentially an aluminum, nickel silicate, perhaps $(Mg,Ni,Fe)O.2Al_2O_3.3SiO_2.4H_2O$. In fibrous-like sheaves. Emerald-green color. H. = 3. G. = 2·27. Found in a small seam in serpentine near Umvukwe Geodetic Station, Umvukwe Mts., southern Rhodesia.

TALC.

Orthorhombic or monoclinic. Rarely in tabular crystals, hexagonal or rhombic with prismatic angle of 60°. Usually foliated massive; sometimes in globular and stellated groups; also granular massive, coarse or fine; fibrous (pseudomorphous); also compact or cryptocrystalline.

Cleavage: basal, perfect. Sectile. Flexible in thin laminæ, but not elastic. Percussion-figure a six-rayed star, as with the micas. Feel greasy. H. = 1–1·5. G. = 2·7–2·8. Luster pearly on cleavage surface. Color

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apple-green to white, or silvery white; also greenish gray and dark green, sometimes bright green perpendicular to cleavage surface, and brown and less translucent at right angles to this direction; brownish to blackish green and reddish when impure. Streak usually white; of dark green varieties lighter than the color. Subtransparent to translucent. Optically negative. Ax. pl. $\parallel a(100)$. $X \perp c(001)$. Axial angle small, variable. Indices approx.; $\alpha = 1{\cdot}539$. $\beta = 1{\cdot}589$. $\gamma = 1{\cdot}589$.

Var. — *Foliated, Talc.* Consists of folia, usually easily separated, having a greasy feel, and presenting ordinarily light green, greenish white, and white colors. G. = 2·55–2·78.

Massive, Steatite or *Soapstone.* *a.* Coarse granular, grayish green, and brownish gray in color; H. = 1–2·5. *Pot-stone* is ordinary soapstone, more or less impure. *b.* Fine granular or cryptocrystalline, and soft enough to be used as chalk; as the *French chalk*, which is milk-white with a pearly luster. *c. Indurated talc.* An impure slaty talc, harder than ordinary talc.

Pseudomorphous. *a.* Fibrous, fine to coarse, altered from enstatite and tremolite. *b. Rensselaerite*, having the form of pyroxene from northern New York and Canada.

A peculiar form of clay which swells when wet, found at the Hacienda Santa Lucia near Mexico City, Mexico, and which corresponds in composition to a hydrated talc has been called *lucianite.*

Comp. — An acid metasilicate of magnesium, $H_2Mg_3(SiO_3)_4$ or $H_2O.3MgO.4SiO_2$ = Silica 63·5, magnesia 31·7, water 4·8 = 100. One-half the water is lost below dull red heat; the remainder goes off rapidly at about 900° C. Nickel is sometimes present in small amount.

Talc shows variations in composition, especially in the water content. A part of the water can be driven off by heat without any change in the crystalline or optical characters, suggesting that some of the water present is out of the crystal structure.

Pyr., etc. — In the closed tube B.B., when intensely ignited, most varieties yield water. In the platinum forceps whitens, exfoliates, and fuses with difficulty on the thin edges to a white enamel. Moistened with cobalt solution, assumes on ignition a pale red color. Not decomposed by acids. Rensselaerite is decomposed by concentrated sulphuric acid.

Diff. — Characterised by extreme softness, soapy feel; common foliated structure; pearly luster; it is flexible but inelastic. Yields water only on intense ignition.

Obs. — Talc or steatite is a very common mineral of secondary origin, and in the form of steatite constitutes extensive beds in some regions. It is often associated with serpentine, talcose or chloritic schist, and dolomite, and frequently contains crystals of dolomite, breunnerite, also asbestus, actinolite, tourmaline, magnetite. It has been formed by the alteration of non-aluminous magnesian silicates, like chrysolite, hypersthene, pyroxene, amphibole, etc. It is very common in pseudomorphs; see above.

Only a few of the most important localities for the occurrence of talc are given. Apple-green talc occurs at Mt. Greiner in the Zillertal, Austrian Tyrol; in Switzerland at St. Gotthard in Ticino and at Fiesch, etc., in Valais. Steatite comes from Göpfersgrün near Wunsiedel, Bavaria. From near Lizard Head in Cornwall with serpentine; from the Shetland Islands. In the Transvaal in the Barberton district. Steatite occurs in large amounts in India and China.

In the United States at various points in Vermont, New Hampshire, and Massachusetts. From Smithfield, Providence Co., Rhode Island; in New York at Edwards a fine fibrous talc (*agalite*); and elsewhere in St. Lawrence Co.; the so-called *rensselaerite* is common in northern New York. In Pennsylvania in Chester, Delaware, and Lancaster counties. In Maryland at Cooptown, Harford Co., with green, blue, and rose colors. Steatite occurs in Cherokee Co., North Carolina. In Canada talc and steatite are found in Brome Co., and elsewhere in Quebec and in Hastings Co., etc., in Ontario.

Use. — In the form of soapstone used for wash tubs, sinks, table tops, switchboards, hearth stones, furnace linings, etc.; the tips of gas burners, tailors' chalk, slate pencils, carved ornaments, etc.; in powdered form as filler in papers, as a lubricant, in toilet powders, etc.

Gavite is apparently a variety of talc, differing in the amount of water present and in its solubility in acids. From Gava valley, Italy, occurring as a coating on garnet, chlorite, titanite, etc.

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SEPIOLITE. Meerschaum.

Compact, with a smooth feel, and fine earthy texture, or clay-like. Microscopically is shown to be a mixture of fine fibrous material and an amorphous substance of apparently the same composition. The mixture forms the variety *meerschaum*. The fibrous mineral has been called *α-sepiolite* or *parasepiolite*; the amorphous material has been called *β-sepiolite*. H. = 2–2·5. G. = 2. Impressible by the finger nail. In dry masses floats on water. Color grayish white, white, or with a faint yellowish or reddish tinge, bluish green. Opaque. Biaxial, −. Indices, 1·52–1·53. 2V usually very small. *Parasepiolite* has a lower refraction index ($\beta = 1{\cdot}506$), 2V = 50°.

Comp. — $H_4Mg_2Si_3O_{10}$ or $2H_2O.2MgO.3SiO_2$ = Silica 60·8, magnesia 27·1, water 12·1 = 100. Some analyses show more water, which is probably to be regarded as hygroscopic. Copper and nickel may replace part of the magnesium.

Pyr., etc. — In the closed tube yields first hygroscopic moisture, and at a higher temperature gives much water and a burnt smell. B.B. some varieties blacken, then burn white, and fuse with difficulty on the thin edges. With cobalt solution a pink color on ignition. Decomposed by hydrochloric acid with separation of silica. *Parasepiolite* gelatinizes with acid.

Obs. — Commonly found as a secondary mineral in connection with serpentine; also with magnesite and at times with opal. Occurs in Asia Minor, in masses in stratified earthy or alluvial deposits near Eski Shehr associated with magnesite. It is also found at Thebes in Bœotia, Greece, with opal and derived from serpentine. In Moravia of Czechoslovakia at Hrubschütz on the Iglawa north of Kronau. Formerly obtained from Morocco where it was used in place of soap and known as *Pierre de savon de Maroc*. In Spain at Vallecas southeast of Madrid. Found in the United States in Chester and Delaware counties, Pennsylvania; in New Mexico near Sapella, San Miguel Co., and in Grant Co.

A fibrous mineral, having the composition of sepiolite, occurs in Utah.

The word *meerschaum* is German for *sea-froth*, and alludes to its lightness and color. *Sepiolite* is from *σήπια, cuttlefish*, the bone of which is light and porous.

Spadaite. — Perhaps $MgSiO_3.H_2O$. Massive, amorphous. H. = 2·5. Fusible at 4. Color reddish. Optically −. Indices, 1·51–1·53. 2V small. From Capo di Bove, near Rome, Italy. Noted at Gold Hill, Nevada.

SAPONITE. Piotine.

Monoclinic or orthorhombic. Commonly massive. In nodules, or filling cavities. Soft, like butter or cheese, but brittle on drying. G. = 2·24–2·30. Luster greasy. Color white, yellowish, grayish green, bluish, reddish. Does not adhere to the tongue. Biaxial, −. $X \perp$ to a cleavage; $Z \parallel$ elongation. $\alpha = 1{\cdot}479–1{\cdot}490$, $\beta = 1{\cdot}510–1{\cdot}525$, $\gamma = 1{\cdot}511–1{\cdot}527$. 2V small (optical description of material from Michigan).

Comp. — A hydrous silicate of magnesium and aluminum; the mineral is usually amorphous and impure. Material from Michigan gave: $9MgO.Al_2O_3.10SiO_2.15–16H_2O$.

Pyr., etc. — B.B. gives out water very readily and blackens; thin splinters fuse with difficulty on the edge. Decomposed by sulphuric acid.

Obs. — Saponite characteristically occurs in the amygdaloidal openings of basic eruptive rocks, associated with calcite, zeolites, etc. It is commonly one of the last minerals to crystallize and apparently has been formed through the alteration of some magnesium silicate. Occurs at Lizard Head in Cornwall, in veins in serpentine; at various localities in Scotland; *bowlingite* is from near Bowling in Dumbarton, and *cathkinite* from the Cathkin Hills, near Glasgow. In Sweden at Svärdsjö in Kopparberg northeast of Falun (*piotine* and *saponite*). In the United States it occurs with the copper deposits of Keweenaw Peninsula, Michigan, and in Minnesota in amygdaloid on the north shore of Lake Superior (*thulite*), and in the Thunder Bay district of Ontario, Canada. Also occurs on St. George Island off the north shore of Prince Edward Island.

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Saponite is from *sapo, soap;* and pliotine from πιοτης, *fat.*

Lassallite. Composition perhaps $3MgO.2Al_2O_3.12SiO_2.8H_2O$. In snow-white fibrous masses. G. = 1·5. In France from the antimony mine at Meyssonial en Mercœur in Haute-Loire and at Can Pey near Arles-sur-Tech, Pyrénées-Orientales.

Iddingsite. — $MgO.Fe_2O_3.3SiO_2.4H_2O$. Orthorhombic. Foliated. Three pinacoidal cleavages. H. = 3. G. = 2·5–2·8. Color brown. Optically −, sometimes +. Ax. pl. ‖ (010). $X = a$ axis. Indices very variable, from 1·608 to 1·765. Strong dispersion, $\rho < \upsilon$. Occurs as an alteration product of chrysolite at Carmelo Bay, Monterey Co., California; from a number of localities in Colorado, etc. Minerals identical with or closely resembling iddingsite have been noted as alteration products of chrysolite in the basalts of Traversa and Orosei, Sardinia, and have been given the names *traversite* and *oroseite.*

Celadonite. — A silicate of iron, magnesium and potassium. Earthy or in minute scales. Lamellar or fibrous. Perfect cleavage. Very soft. Color green. Optically −, 2V small. $\beta = 1{\cdot}63$. From cavities in amygdaloid at Mte. Baldo near Verona, Venetia, Italy. Also from the Zillertal, Tyrol, Austria.

Glauconite. — Essentially a hydrous silicate of iron and potassium. Shows a considerable variation in composition and probably occurs in both colloidal and crystalline forms. Usually amorphous, and resembling earthy chlorite. Noted in small crystal grains in a dolomite from near Bonneterre, St. Francis Co., Missouri. Micaceous cleavage. Optically −. X nearly normal to cleavage. Indices, 1·60–1·63. 2V = 0°–20°. Color dull green. Occurs in rocks of nearly all geological ages; abundant in the "green sand," of the Chalk formation, sometimes constituting 75 to 90 per cent of the whole. Found abundantly in ocean sediments near the continental shores. It has been considered to have been formed by the alteration of augite, hornblende, mica, etc. A manganese glauconite from the Marsjat forest, Ural Mts., has been called *marsjatskite. Greenalite* is a green hydrated ferrous silicate found as granules in the cherty rock associated with iron ores of the Mesabi district, Minnesota. Resembles glauconite but contains no potash.

Pholidolite. — Corresponds approximately to $K_2O.12(Fe,Mg)O.Al_2O_3.13SiO_2.5H_2O$. Monoclinic. In minute pseudo-hexagonal crystalline scales. Perfect cleavage (001). H. = 4. G. = 2·408. Color grayish yellow. Optically −. $X \perp$ (001). Indices 1·60–1·545. 2V small. From Taberg in Vermland, Sweden, with garnet, diopside, etc.

IV. KAOLIN DIVISION

KAOLIN MINERALS: KAOLINITE, NACRITE, DICKITE.

Monoclinic; in thin rhombic, rhomboidal or hexagonal scales or plates with angles of 60° and 120°. Usually constituting a clay-like mass, either compact, friable or mealy.

Cleavage: basal, perfect. Flexible, inelastic. H. = 2–2·5. G. = 2·6–2·63. Luster of plates, pearly; of mass, pearly to dull earthy. Color white, grayish white, yellowish, sometimes brownish, bluish or reddish. Scales transparent to translucent; usually unctuous and plastic.

The study of minerals commonly included under the name of kaolin shows three species with different optical characters. The suggested separation is into *nacrite* (from near Freiberg, Saxony), *dickite* (from island of Anglesey, Wales, and Red Mountain, near Ouray, Colorado), and *kaolinite.* All are monoclinic. Optical axial plane, ⊥ (010) and nearly ‖ (100). Indices $\alpha = 1{\cdot}557$–$1{\cdot}561$, $\beta = 1{\cdot}562$–$1{\cdot}565$, $\gamma = 1{\cdot}563$–$1{\cdot}566$. *Nacrite* and *dickite* are nearly or quite transparent and in tabular crystals. *Kaolinite* is translucent to opaque and in crystals elongated parallel to c axis. *Nacrite* is usually optically −, rarely +; *dickite* is +; *kaolinite* −. $Z = b$ axis in all three. The angle between X and the normal to (001) = 10° to 12° in *nacrite*, 15° to 20° in *dickite*, 1° to 3½° in *kaolinite.* Dispersion $\rho > \upsilon$, rarely $\rho < \upsilon$ in *nacrite*; $\rho < \upsilon$ in *dickite*; $\rho > \upsilon$ in *kaolinite. Kaolinite* absorbs dyes readily becoming pleochroic; the other two do not show this. Study by X-rays shows distinctly different molecular spacings in the three cases.

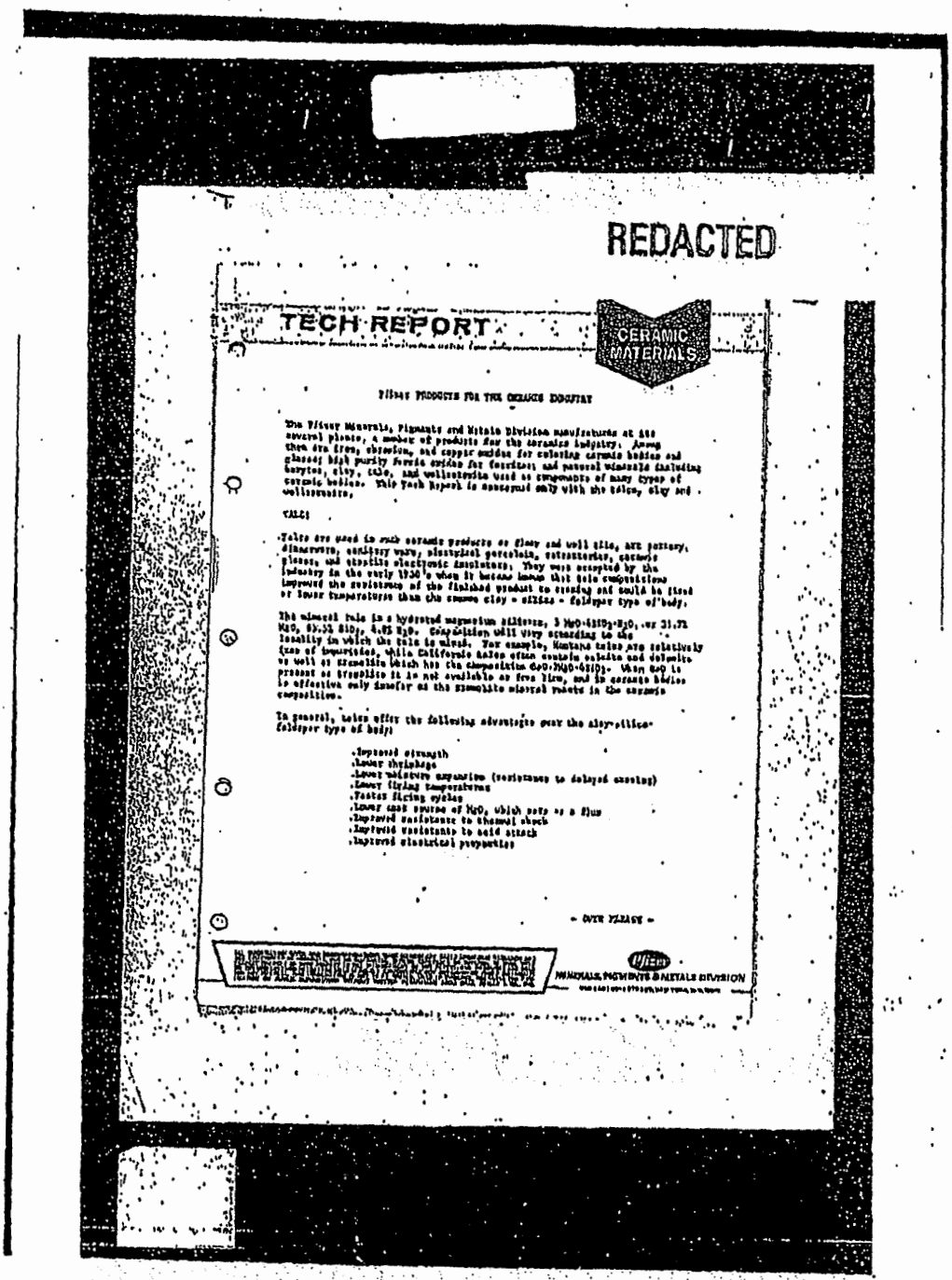
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EXHIBIT 22

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REDACTED

TECH REPORT

CERAMIC MATERIALS

Pfizer PRODUCTS FOR THE CERAMIC INDUSTRY

The Pfizer Minerals, Pigments and Metals Division manufactures at its several plants, a number of products for the ceramics industry. Among them are iron, chromium, and copper oxides for coloring ceramic bodies and glazes; high purity ferric oxide for ferrites; and natural minerals including barytes, clay, talc, and wollastonite used as components of many types of ceramic bodies. This Tech Report is concerned only with the talcs, clay and wollastonite.

TALC:

Talcs are used in such ceramic products as floor and wall tile, art pottery, dinnerware, sanitary ware, electrical porcelain, refractories, ceramic glazes, and steatite electronic insulators. They were accepted by the industry in the early 1930's when it became known that talc compositions improved the resistance of the finished product to crazing and could be fired at lower temperatures than the common clay - silica - feldspar type of body.

The mineral talc is a hydrated magnesium silicate, $3MgO \cdot 4SiO_2 \cdot H_2O$, or 31.72 MgO, 63.33 SiO_2, 4.95 H_2O. Composition will vary according to the locality in which the talc is mined. For example, Montana talcs are relatively free of impurities, while California talcs often contain calcite and dolomite as well as tremolite which has the composition $CaO \cdot 3MgO \cdot 4SiO_2$. When CaO is present as tremolite it is not available as free lime, and is ceramic bodies is effective only insofar as the tremolite mineral reacts in the ceramic composition.

In general, talcs offer the following advantages over the clay-silica-feldspar type of body:

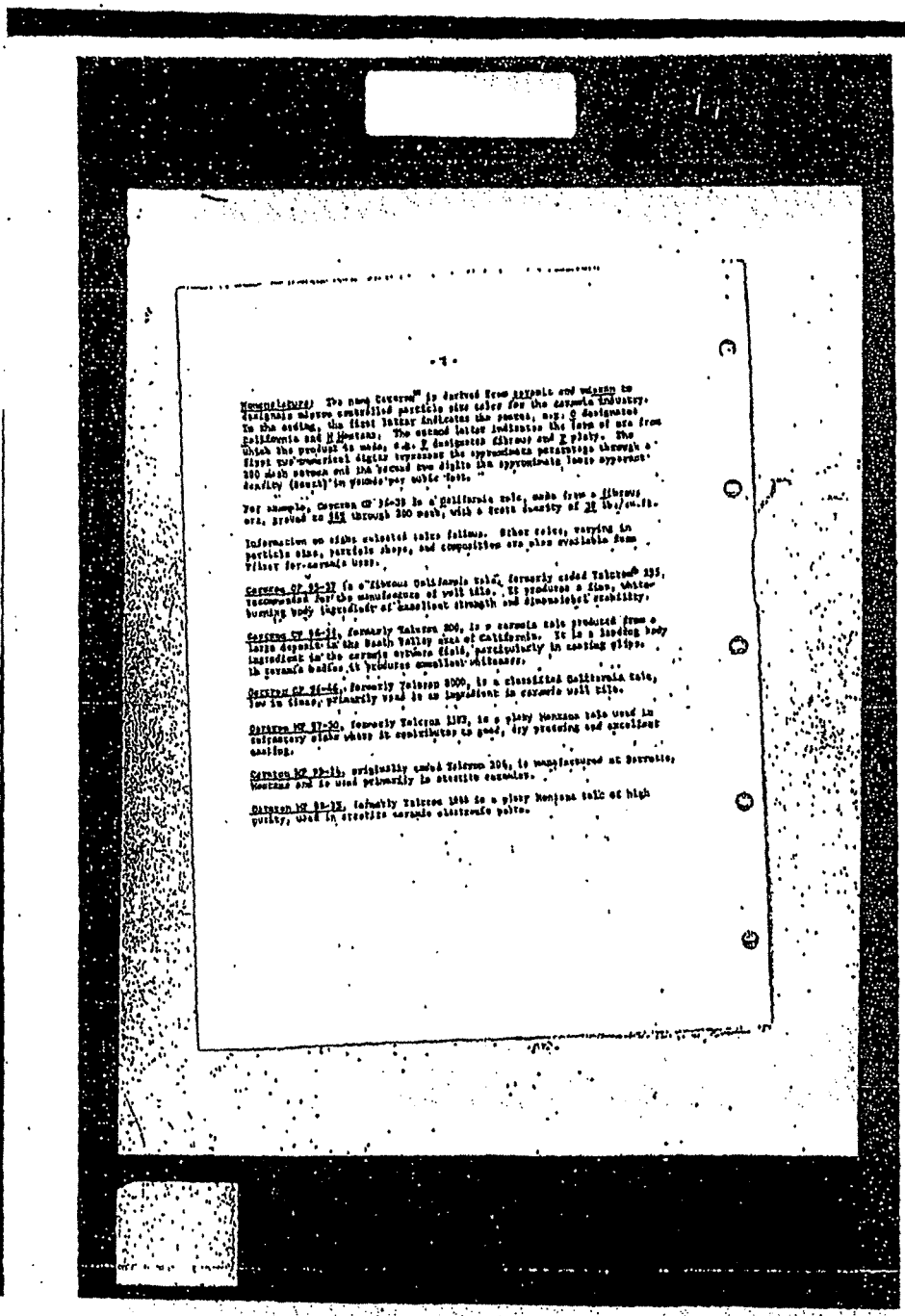
- .Improved strength
- .Lower shrinkage
- .Lower moisture expansion (resistance to delayed crazing)
- .Lower firing temperatures
- .Faster firing cycles
- .Lower cost source of MgO, which acts as a flux
- .Improved resistance to thermal shock
- .Improved resistance to acid attack
- .Improved electrical properties

- OVER PLEASE -

Pfizer MINERALS, PIGMENTS & METALS DIVISION

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- 4 -

Nomenclature: The name Cerocron is derived from zeronia and wollaston to designate a narrow controlled particle size talcs for the ceramic industry. In the coding, the first letter indicates the source, e.g. C designated California and M Montana. The second letter indicates the type of ore from which the product is made, e.g. F designates fibrous and P platy. The first two numerical digits represent the approximate percentage through a 200 mesh screen and the second two digits the approximate loose apparent density (lbs/ft³) in pounds per cubic foot.

For example, Cerocron CF 96-38 is a California talc, made from a fibrous ore, proved to 95% through 200 mesh, with a bulk density of 38 lbs/cu.ft.

Information on other selected talcs follows. Other talcs, varying in particle size, particle shape, and composition are also available from Wilbur Ellis-Ceramic Dept.

Cerocron CF 92-37 is a fibrous California talc, formerly coded Talcron 195, recommended for the manufacture of wall tile. It produces a fine, white burning body ingredient of excellent strength and dimensional stability.

Cerocron CF 96-31, formerly Talcron 200, is a ceramic talc produced from a large deposit in the Death Valley area of California. It is a binding body ingredient in the ceramic ceramic field, particularly in casting slips. In ceramic bodies, it produces excellent whiteness.

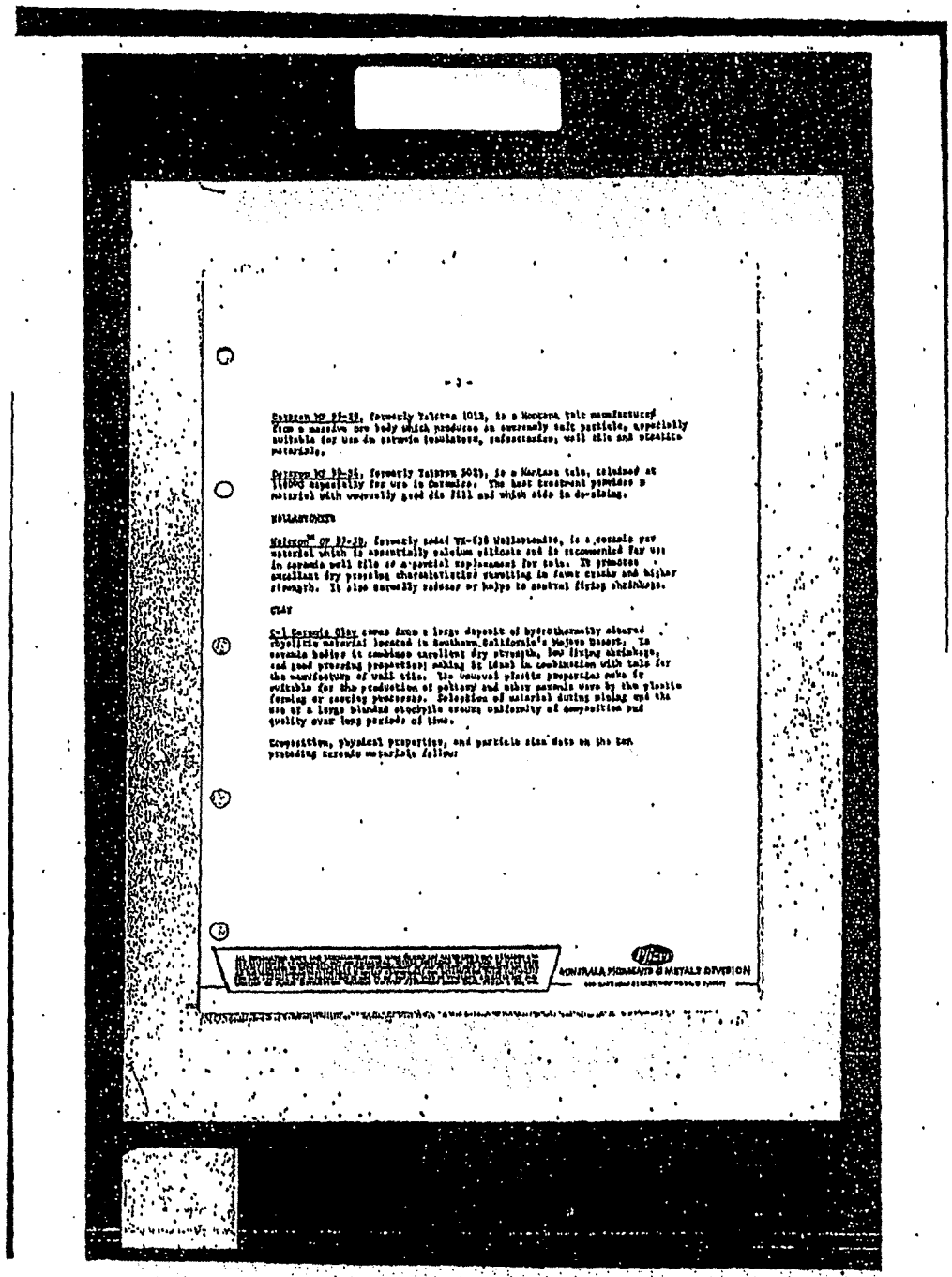
Cerocron CF 96-46, formerly Talcron 2000, is a classified California talc, low in flux, primarily used as an ingredient in ceramic wall tile.

Cerocron MP 97-20, formerly Talcron 1193, is a platy Montana talc used in refractory slabs where it contributes to good, dry pressing and excellent casting.

Cerocron MP 98-15, originally coded Talcron 204, is manufactured at Dorrotte, Montana and is used primarily in steatite ceramics.

Cerocron MP 98-12, formerly Talcron 1455 is a platy Montana talc of high purity, used in steatite ceramic electronic parts.

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Talcron MP 25-38, formerly Talcron 1013, is a Montana talc manufactured from a massive ore body which produces an extremely soft particle, especially suitable for use in extruded insulators, refractories, wall tile and steatite materials.

Talcron MP 53-54, formerly Talcron 5053, is a Montana talc, calcined at 1100C especially for use in Ceramics. The heat treatment provides a material with excellent dry fill and which aids in de-dusting.

WOLLASTONITE

Nyad® G or NY-20, formerly named Vansil G-10 Wollastonite, is a ceramic raw material which is essentially calcium silicate and is recommended for use in ceramic wall tile as a special replacement for talc. It promotes excellent dry pressing characteristics resulting in fewer cracks and higher strength. It also normally reduces or helps to control firing shrinkage.

CLAY

K-1 Ceramic Clay comes from a large deposit of hydrothermally altered rhyolitic material located in Southern California's Mojave Desert. In ceramic bodies it combines excellent dry strength, low firing shrinkage, and good pressing properties; making it ideal in combination with talc for the manufacture of wall tile. The reduced plastic properties make it suitable for the production of pottery and other ceramic ware by the plastic forming or casting processes. Selection of material during mining and the use of a large blended stockpile ensure uniformity of composition and quality over long periods of time.

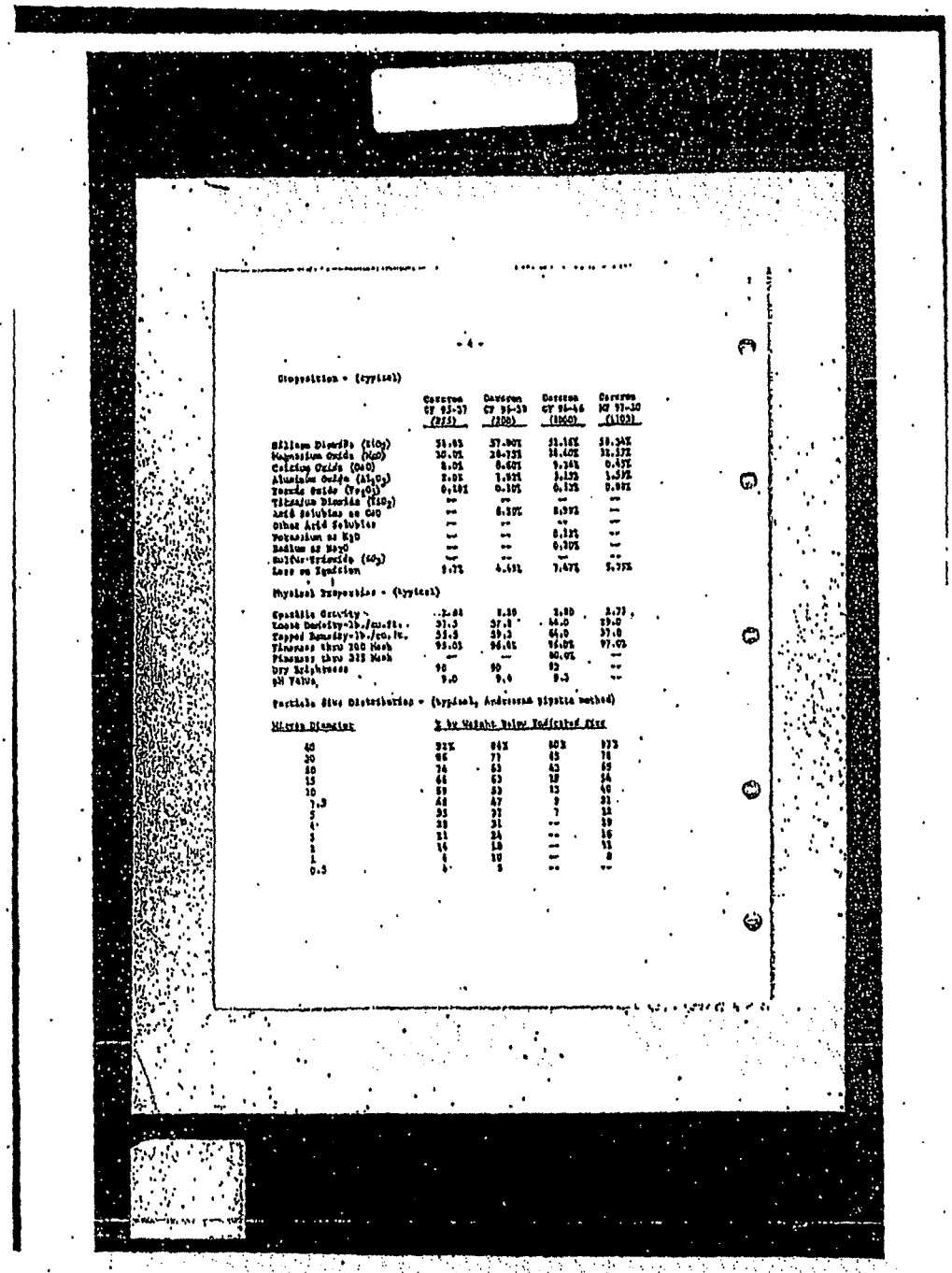
Composition, physical properties, and particle size data on the ten preceding ceramic materials follow:

Pfizer
MINERALS, PIGMENTS & METALS DIVISION

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Composition - (typical)

	Corerun CF 93-37 (#35)	Corerun CF 94-39 (200)	Corerun CF 94-46 (140)	Corerun CF 94-30 (100)
Silicon Dioxide (SiO_2)	51.0%	57.00%	51.10%	58.30%
Magnesium Oxide (MgO)	20.0%	24.75%	18.40%	21.17%
Calcium Oxide (CaO)	8.0%	8.60%	9.10%	8.45%
Aluminum Oxide (Al_2O_3)	2.0%	1.92%	1.13%	1.57%
Ferric Oxide (Fe_2O_3)	0.18%	0.10%	0.13%	0.08%
Titanium Dioxide (TiO_2)	--	--	--	--
Acid Solubles as CaO	--	8.37%	8.57%	--
Other Acid Solubles	--	--	--	--
Potassium as K_2O	--	--	0.11%	--
Sodium as Na_2O	--	--	0.10%	--
Sulfur Trioxide (SO_3)	--	--	--	--
Loss on Ignition	9.7%	4.11%	7.47%	9.75%

Physical Properties - (typical)

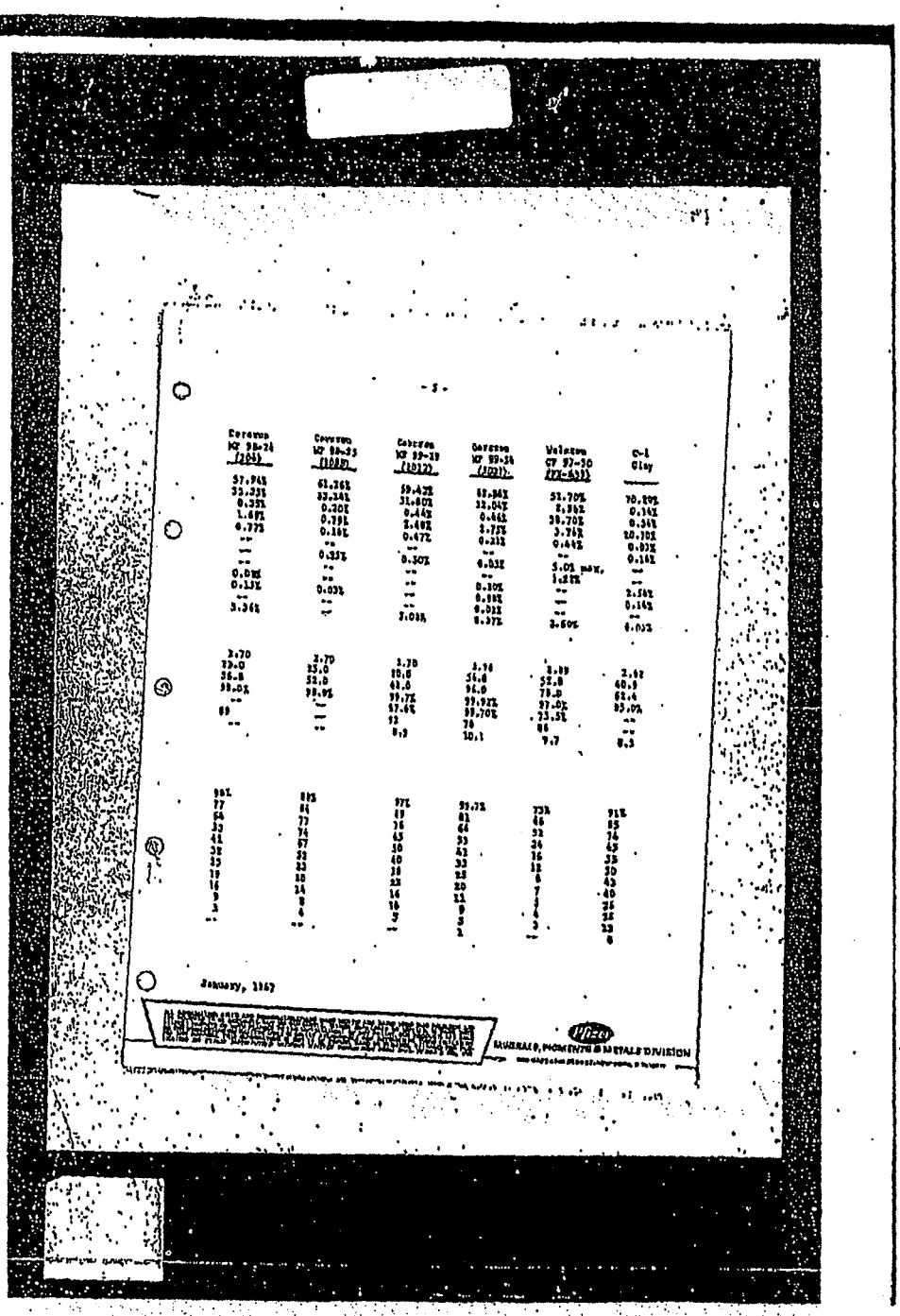
Specific Gravity -	2.81	2.80	2.80	2.73
Loose Density-lb./cu.ft.	31.5	37.0	44.0	33.0
Packed Density-lb./cu.ft.	34.5	39.3	46.0	37.0
Fineness thru 200 Mesh	95.0%	96.0%	96.0%	97.0%
Fineness thru 325 Mesh	--	--	80.0%	--
Dry Brightness	90	90	82	--
pH Value	9.0	9.0	9.3	--

Particle Size Distribution - (typical, Andersen pipette method)

Microns Diameter	% by Weight Below Indicated Size			
40	92%	94%	80%	93%
30	86	77	65	76
20	74	63	45	58
15	66	53	32	44
10	59	43	23	40
7.3	48	47	9	31
5	35	31	7	21
4	28	31	--	19
3	21	24	--	15
2	14	18	--	11
1	6	10	--	6
0.5	2	5	--	--

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EXHIBIT 23

Mesothelioma Associated With the Use of Cosmetic Talc

Jacqueline Moline, MD, MSc, Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald E. Gordon, PhD

Objective: To describe 33 cases of malignant mesothelioma among individuals with no known asbestos exposure other than cosmetic talcum powder. **Methods:** Cases were referred for medico-legal evaluation, and tissue digestions were performed in some cases. Tissue digestion for the six cases described was done according to standard methodology. **Results:** Asbestos of the type found in talcum powder was found in all six cases evaluated. Talcum powder usage was the only source of asbestos for all 33 cases. **Conclusions:** Exposure to asbestos-contaminated talcum powders can cause mesothelioma. Clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma.

BACKGROUND

Asbestos in all forms is recognized by the International Agency for Research on Cancer (IARC) as a human carcinogen and all forms of asbestos are recognized as the primary risk factor for malignant mesothelioma.[1–9] By the mid-1950s, over 60 cases of asbestos-related lung cancer had been published in the literature. In 1955, Doll[10] published a seminal paper describing the increased risk of lung cancer among asbestos-exposed workers. In 1960, Wagner et al[2] published a study of 33 cases of malignant mesothelioma among individuals who were exposed to asbestos in and around the crocidolite mines in South Africa. By the mid-20th century, as asbestos use rose in the industrialized world, diseases associated with its use also began their upward curve.[3,8,11,12] On average between 2003 and 2008 1.05 cases per 100,000 of malignant mesothelioma (MM) were diagnosed in the United States and in 2015, 2597 deaths resulted from the disease.[13,14]

The presence of asbestos in talc and talcum powder consumer products including body powder, baby powder, facial cosmetics, and pharmaceutical talc was first discussed in the medical and scientific literature beginning in the 1940s.[15–17] Asbestos contamination of talc products is understood to occur during the mining process, in which talc deposits overlap or lie in close proximity to naturally occurring asbestos deposits.[18–22] The natural presence of asbestos within talc deposits makes selective mining or the extrication of asbestos from mined talc nearly impossible.[19] During application in its commercial talcum powder form, asbestos fibers become airborne and can be inhaled.[23,24] In 1968, Cralley et al[25] found the presence of three different types of asbestos fibers in 22 of 22 talcum products tested (tremolite, anthophyllite, and chysotile). However, talcum powder is still widely produced and consumed with a reported 58.3 million adults using body and baby powder in the United States in 2017.[26]

While the relationship between occupational exposure to asbestos and mesothelioma is well established, multiple studies have shown that not all individuals who develop mesothelioma can pinpoint exposures to asbestos.[8,11] Among women, occupational exposure explains less than half of malignant mesothelioma cases.[27,28] Some studies have focused on conventional exposure categories that for women only reflect take home exposures from (male) family members who worked in one of the selected occupations. In one such study, data on home or personal use exposures were not collected, yet increased amounts of tremolite asbestos fibers noted in the lungs of women with MM with no identified source of asbestos contact led study authors to hypothesize that the tremolite could be related to talcum powder use.[28] The high prevalence of unexplained or, ''idiopathic mesothelioma'' among women necessitates further inquiry into potential non-occupational exposures, such as exposure to asbestos-contaminated talcum powder.

In light of these gaps in the existing literature, we present 33 cases of individuals with malignant mesothelioma who were exposed to commercial talcum powder products. Of those cases, we present six in detail, where the individuals had no other known exposure to asbestos and for whom tissue studies show the presence of asbestos commonly found in talcum powder (such as tremolite, and/or anthophyllite). For all 33 cases, other potential exposures to asbestos were considered, with no identified source apart from the talcum powder. The cases were referred to author J.M. for medico-legal evaluation as part of tort litigation, and tissue digestions were performed by author R.G. as part of this litigation. In every case, a pathology report confirmed the diagnosis of malignant mesothelioma. This study was conducted with approval from the Northwell Health Feinstein Institute for Medical Research (#18-0225 FIMR).

MATERIALS AND METHODS

Case Histories

Data gathered for all 33 patients were gathered from each individual's medical records and sworn testimony (deposition transcripts) of individuals. All cases were reviewed by an occupational physician with experience evaluating asbestos exposure in thousands of patients. Data abstracted included medical diagnosis, review of pathology reports confirming the diagnosis of malignant mesothelioma, and clinical course. Exposure data was obtained from sworn testimony by the cases, which included extensive questioning regarding all sources of asbestos exposure. This included family occupational histories (parents and anyone cohabitating with the patient) for all cases to assess potential asbestos exposure, hobbies that included use of products that might contain asbestos (such as ceramics), residence in an area that might have had asbestos industry leading to possible environmental exposures, known abatement of asbestos while the patient was in school, home renovations that might have used asbestos containing materials, and any other potential sources of asbestos exposure. Additional data related to family history of cancers was obtained from the sworn testimony. Any data related to potential genetic mutations such as BRCA1 associated protein-1 was collected, if present.

From the Northwell Health Department of Occupational Medicine Epidemiology and Prevention (Dr Moline, Ms Bevilacqua); Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead (Ms Alexandri); Department of Pathology, The Icahn School of Medicine at Mount Sinai (Dr Gordon), New York, New York.

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Conflicts of Interest: Authors J.M. and R.G. have served as expert witnesses in asbestos litigation, including talc litigation for plaintiffs.

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Clinical Significance: This manuscript is the first to describe mesothelioma among talcum powder consumers. Our case study suggest that cosmetic talcum powder use may help explain the high prevalence of idiopathic mesothelioma cases, particularly among women, and stresses the need for improved exposure history elicitation among physicians.

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Talcum powder exposure histories were reviewed based on sworn testimony by patients and in some cases, family members with first-hand knowledge of the use of talcum powder, such as parents who recalled using talcum powder while diapering the patient. Data including type of talcum powder used (Appendix 3, http://links.lww.com/JOM/A651), age at first use of talcum powder, and duration of use was obtained to ensure adequate latency from first exposure was present.[29] In some cases, individuals were also interviewed in person, and these data were merged with the data obtained in medical records and deposition transcripts.

The six cases described below also had tissue digestions performed by author R.G. These case reports are presented in greater detail; their clinical course was similar to all 33 cases evaluated, and the same rigor with respect to obtaining information related to any asbestos exposure was applied to all 33 cases.

Case 1

Case 1 is a 70-year-old woman who presented to a physician with shortness of breath and chest pain in January 2015. A chest x-ray revealed a small pleural effusion with left basilar atelectasis. In August 2015, a CT angiogram showed development of two subpleural nodules anterior to the lingula and a pleural based mass; a pleural effusion was still present. A thoracentesis was done and the cytology showed large clusters of cells suspicious for mesothelioma. A positron emission tomography (PET) scan showed pleural thickening and focal intense uptake inferiorly and posteriorly on the left side of her chest. In September 2015, she underwent thoracoscopic surgery. The pathology showed epithelial malignant mesothelioma with invasion of the visceral pleura and pulmonary parenchyma with tumor present at the stapled margin.

Case 1 applied loose face powder on a daily basis from the 1940s to the 1970s. Her mother also used the same loose face powder and Case 1 cleaned residual powder from her mother's dresser and clothing every other week from 1994 to 2012.

Electron microscopic analysis (EMA) of the lung tissue revealed anthophyllite fibers in a calculated concentrations of 3286 fibers per gram weight. There was also significant amount of fibrous and platy talc and aluminum silicates.

Case 1 was treated with four cycles of combination chemotherapy with cisplatin and pemetrexed for four cycles.

Case 2

In August 2015, Case 2, a 65-year-old woman presented with exertional dyspnea and dry cough. A chest x-ray showed a large left pleural effusion. A chest CT scan in September 2015 showed a freely-movable, large-volume, left pleural effusion, nodularity/lobulation of the left pleura, left lower lobe atelectasis, three nodules in the left upper lobe, and no hilar or mediastinal lymphadenopathy. A thoracentesis showed carcinoma cells. A PET-CT scan on September 22, 2016 reported showed abnormal deposits of tumor in the left pleura. There was no reported disease outside the chest.

Case 2 underwent a bronchoscopy in October, 2015. Pathology showed malignant mesothelioma, biphasic mixed type (50% sarcomatoid, 50% epithelioid). A second opinion confirmed the diagnosis. She underwent two cycles of chemotherapy with doxorubricin, ifosfide, and mensa and completed treatment in November. A PET scan showed no response to the chemotherapy. In December, Case 2 underwent left radical pleurectomy/decortication, resection of left hemidiaphragm, and one lymph node dissection. Surgical pathology showed residual biphasic malignant mesothelioma with negative nodes and negative margins. In January 2016, radiation oncology recommended adjuvant radiation therapy to the left chest, which she received in February and March of 2016. As of April 2016, Case 2 had no evidence of disease recurrence.

Case 2 reported starting to use talc around age eight or nine and would apply powder after her daily shower or bath. She would also use talcum powder when visiting her grandmother because she enjoyed the scent and would apply the powder before going on a date. She continued to use powder after getting married and used baby powder with all three of her children. In the early 2000s she began to regularly apply a fragrance and its matching talcum powder in the morning and at night, describing it as her signature scent. She also sprinkled the powder in her lingerie drawer and traveled with the powder which she would rub on her suitcases and other surfaces.

EMA of the lung tissue revealed anthophyllite fibers in a calculated concentration of 8625 fibers per gram wet weight with a limit of detection of 2875 fibers per gram wet weight. A significant amount of fibrous and platy talc was seen. EMA of the lymph node tissue revealed anthophyllite and tremolite fibers in a calculated concentrations of 34,500 fibers per gram wet weight with a limit of detection of 11,500 fibers per gram wet weight. They were seen in a ratio of 2:1 anthophyllite:tremolite/actinolite. All fibers counted were 5 μm or greater in length with aspect ratios greater than 8. There was also some amount of fibrous and platy talc noted in the lymph node tissue.

Case 3

In September 2014, Case 3, an 84-year-old woman, developed shortness of breath, a cough, and chest tightness. A chest x-ray in November 2014 showed a large left pleural effusion. A CT angiogram showed a large left pleural effusion with compressive atelectasis of the left middle and lower lobes and ground glass opacities in the left upper lobe and right lung. A thoracentesis showed carcinoma cells. Case 3 underwent a video thoracoscopy with pleural biopsy and evacuation of a pleural effusion. Pathology revealed a malignant epithelial neoplasm consistent with malignant epithelial mesothelioma. Case 3 then underwent a left pleurectomy and decortication in June 2015. The mesothelioma had spread to the lymph nodes and chest wall, and the pathology now showed malignant biphasic mesothelioma. Case 3 entered hospice care in September 2015 and died in late October 2015.

Case 3 worked as an elementary school teacher with no known occupational exposure to asbestos. Case 3 used talcum powder "before [she] was 12 and 13 years old," applying it under her arms and in her shoes daily. She shook the powder out of the can and applied it onto her body. She noted that her mother also used talcum body powder, and they shared a small bathroom. She used talcum powder beginning in the 1940s and continuing for decades, until her preferred brand was no longer available for purchase.

EMA of the lung tissue did not reveal any asbestos fibers above the limit of detection of 6900. However, there were a number of very small chrysotile asbestos fibers. Analysis of the lymph node tissue revealed tremolite asbestos fibers in calculated concentrations of 9409 fibers per gram wet weight with a limit of detection of 9409. All fibers counted were 5 μm or greater in length with aspect ratios greater than 20. There was also a significant amount of aluminum silicates, silica particles, and both fibrous and platy talc. Light microscopic analysis revealed a calculated concentration of 409 asbestos bodies per gram wet weight of lymph node tissue by phase contrast light microscopy.

Case 4

In August 2014, Case 4, a 66-year-old woman, developed abdominal pain and had a CT scan of the abdomen and pelvis that showed omental caking, ascites, a fluid pocket in the right lower quadrant, and enlarged diaphragmatic lymph nodes. She underwent a paracentesis and an omental biopsy in August 2014. The cytology revealed atypical mesothelial cells. She then underwent a laparotomy, appendectomy, omentectomy, and left salpingo-oophorectomy. The pathology showed malignant epithelioid mesothelioma. In September 2014, a PET/CT showed increased uptake in the abdomen consistent with malignant ascites, omental metastatic disease, and cardiophrenic

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nodules. A thoracoscopy showed tumor covering the right hemidiaphragm. She was treated with multiple rounds of chemotherapy with cisplatin and pemetrexed and therapeutic paracenteses due to persistent ascites. Her tumor progressed, and she died in February 2016. She was 68 years old.

Case 4 grew up in a home where her mother used talcum powder "for as long as [she could] remember." She recalled personally using talcum powder starting around the age of 9 or 10, applying the powder to her armpits, groin, and around her body, using a powder puff. She applied talcum powder to her body for approximately 40 years. Case 4 had additional exposure to talcum powder in the 1960s while working as a licensed cosmetologist, applying talcum powder on clients' necks after a haircut. She shook the talcum powder onto the client's neck, and would wipe off the excess with a brush or blow dryer. She also used talcum powder inside the gloves that she donned prior to applying hair color.

EMA of the peritoneal tissue revealed chrysotile type asbestos fibers in a calculated concentration of 920 fibers per gram wet weight with a limit of detection of 920 fibers per gram wet weight. Fibrous and platy talc was also observed. Also seen were non-asbestiform tremolite and silica crystals.

Case 5

Case 5 was a 76-year-old woman who developed chest pain and fatigue in September 2015 and was diagnosed with viral pericarditis. A CT scan in October 2015 showed mild pericardial thickening and mild perihepatic ascites. She was treated with steroids for viral pericarditis. In late fall 2015, Case 5 developed decreased appetite, weight loss, tenderness around the umbilicus, and abdominal pain. In December 2015 she had an abdominal ultrasound that showed a mild to moderate amount of ascites. An abdominal CT scan showed slightly bilateral pleural thickening with minimal linear atelectatic change. There was copious perihepatic ascites extending to the right and left paracolic gutter and deep pelvis, nodularity at the paracolic gutter, and a right sided deep pelvic mass. A paracentesis was done and showed atypical epithelioid cells and tissue fragments with an inflammatory background. A laparoscopy showed peritoneal carcinomatosis with a diffuse miliary excrescence, a moderate sized pelvic mass and ascites. In January 2016 she underwent an exploratory laparotomy and resection of the omentum, spleen, resection of abdominal tumor, and resection of the abdominal wall tumor. The pathology showed malignant mesothelioma involving the omentum, spleen, colon, and mesentery, as well as the fibroadipose tissue of the peritoneum. Malignant mesothelioma also involved the parietal peritoneum as well as the appendix, with fibrous obliteration of the appendiceal lumen. Case 5 died in October 2017.

Case 5 had daily personal use of talcum body powder from the 1950s to the mid-1970s. She would pour the powder onto her hands and pat it under her arms, in her genital area, between her toes, and on her legs. When she was menstruating she would apply talcum powder on her feminine napkins and her underwear. She also applied talcum powder to her shoes. Case 5's husband also used talcum powder. Both Case 5 and her husband applied the powder in the bathroom. She shook the bathroom floor mat and cleaned up residual powder from the bathroom sink.

EMA of the omental tissue did not reveal any asbestos fibers above the limit of detection of detection of 651 fibers per gram wet weight. EMA of the lymph node tissue revealed chrysotile and anthophyllite asbestos fibers in a calculated concentrations of 20,700 fibers per gram wet weight with a limit of detection of 10,350 fibers per gram wet weight. All fibers counted were 5 μm or greater in length with aspect ratios greater than 20. There was also a significant amount of fibrous and platy talc as well as fibrous and platy aluminum silicates.

Case 6

Case 6 is a 44-year-old man who developed chest pain after playing hockey in 2012 and was evaluated in the Emergency Department. A CT scan that showed no pulmonary abnormalities. Case 6 continued to have chest pain over the next 4 years and underwent multiple cardiac evaluations. A CT scan in February 2016 showed increased pleural thickening or non-calcified pleural plaque along the right major fissure and anterior right hemithorax along the right upper lobe. A PET/CT scan in March 2016 showed unilateral hypermetabolic pleural fissural and non-fissural soft tissue abnormalities suspicious for malignancies involving the pleura. There were non-specific tiny parenchymal lung nodules. Case 6 underwent a tissue biopsy in March 2016. The pathology showed malignant epithelioid mesothelioma with invasion to the skeletal muscle.

Case 6 underwent neo-adjuvant chemotherapy with pemetrexed, cisplatin, and bevacizumab in April 2016. In May 2016, Case 6 underwent a mediastinoscopy which showed metastatic spread to the level VII lymph node. Additional chemotherapy was administered, which was not well tolerated. In July 2016, a parietal pleurectomy was done along the fissure between the upper and lower lobe. There was spread to the site of previous inferior right chest tube site. Case 6 developed acute thrombus in the right upper extremity. In September 2016, a chest x-ray showed unchanged right pleural thickening versus a small right pleural effusion. Three additional cycles of chemotherapy were recommended. A PET/CT scan in November 2017 showed a persistent hypermetabolic focus in the right anterobasal pleura and a slight increase in a right pleural effusion.

Case 6 was exposed to talcum powder beginning when he was an infant. His mother applied it to him after his bath until he was able to apply it himself, starting around the age of six. Case 6 recalled using the powder in the bathroom and in his room, and that there would be powder on his floor. He applied the talcum powder directly to his torso, groin, legs, and back, often twice a day after showering. He played hockey as a youth and used powder in his hockey gear before donning the equipment. He recalled getting mouthfuls of powder during the application. He often applied talcum powder once or twice a day after showering. He had no occupational exposure to asbestos.

EMA of the lymph node tissue revealed anthophyllite and tremolite asbestos fibers in a calculated concentrations of 17,250 fibers per gram wet weight with a limit of detection of 3450 fibers per gram wet weight. They were seen in a ratio of 2:3 anthophyllite:tremolite. All fibers counted were 5 μm or greater in length with aspect ratios greater than 14.7 or greater. There was also some amount of fibrous and platy talc along with platy aluminum silicates and magnesium aluminum silicates.

Tissue Sample Analysis

Tissue samples from six patients were analyzed: (a) lung and lymph node tissue from four of the patients diagnosed with pleural mesothelioma; and (b) lung and lymph node from two of the patients diagnosed with peritoneal mesothelioma. The tissue samples had been preserved in paraffin blocks or as formalin fixed tissues.

Tissue Digestion Protocols

Paraffin Blocks

The tissue was extracted from paraffin blocks was done according to the methodology described in Heller et al[30] and Wu et al.[31] The tissues were cut from the paraffin blocks and deparaffinized by melting and xylene treatment. They were brought to water, blotted and weighted. The tissues were digested with KOH and the inorganic pellet cleaned with distilled water by multiple centrifugation steps on an asbestos locator grid coated with formvar. In

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addition, 250 μL samples were prepared using a cytocentrifuge onto a standard glass slide to identify ferruginous bodies and longer fibers by phase contrast microscopy.

Formalin Fixed Tissue

This protocol is similar to above without the deparaffinizing step as described in [23,39]. Controls for both the paraffin and formalin fixed tissues included looking at the paraffin, if from blocks, the formalin, if from fixed wet tissue, or any other materials used to process the tissue to view the remaining inorganic material on the grids.

Asbestos Fiber Counting

The grids were analyzed two ways: (a) transmission electron microscopy (TEM) using a standard fiber-counting protocol (23,40)[23,32] on 800 grid openings; and (b) phase contrast light microscopy on two cytocentrifuge preparations per tissue type in accordance with a standard asbestos body-counting protocol (23,40).[23,32] Asbestos fibers were evaluated to determine whether they met the definition of a fiber, which includes having at a 5:1 length:width ratio and parallel sides and at least 5 μm in length. The fibers were also analyzed by Energy Dispersive Spectroscopy (EDS) to determine the ratio of elements contained in the fibers and by Selected Area Electron Diffraction (SAED) to confirm the crystalline structure of the fiber to confirm that they were asbestos. To evaluate for potential contamination, control samples were prepared from the same distilled water used to wash the samples and the paraffin surrounding the tissue. Verification techniques of fiber counting were used for quality control and quality assurance. All fibers, regardless of size, were counted in 800 grid openings.

Calculating Asbestos Fiber Concentration

TEM and PCM

Asbestos fiber concentration in the samples examined with transmission electron microscopy was calculated (see Appendix 1, http://links.lww.com/JOM/A649). The 250 μL samples centrifuged onto standard microscope slides were examined using phase contrast light microscopy (Appendix 2, http://links.lww.com/JOM/A650). The asbestos fiber concentration in these samples was calculated (see Appendix 2, http://links.lww.com/JOM/A650).

Control Samples

Background control samples were obtained at autopsy or from surgical specimens from pulmonary or obstetrical and gynecologic pathologists. Samples included lung, thoracic, mesenteric and abdominal lymph nodes, abdominal tissue, ovaries, fallopian tubes, uteri and mesentery tissue. Exposure histories had been obtained by treating pulmonologists or surgeons from all individuals; all were screened for asbestos exposure from personal use, family exposure, and personal or family use of talcum powder. For those patients in whom there was any question of asbestos exposure from any source, the pathologists conferred with the treating clinician to ensure there was no known asbestos exposure. If there was potential asbestos exposure, the specimens were not included in the group. As a result, the background control specimens reflect only asbestos exposure from the overall community.

RESULTS

The data associated with the exposure history of all 33 patients is presented in Table 1. The table identifies talcum powder as the only asbestos exposure these patients have experienced. No individual identified any asbestos exposure apart from contaminated talcum powder from workplace or household exposures.

Table 2 provides the results of the fiber burden analyses for the six cases in which asbestos fibers were identified in the anatomic vicinity of the patients' mesotheliomas. Uniformly, the tissue fiber burdens reveal the presence of the following: talc, aluminum silicates, aluminum magnesium silicates, silica crystals, and asbestos fibers. The asbestos fibers are all anthophyllite, tremolite, and/or chrysotile. These three types are typical contaminants of talcum powders.[19] They have been identified as contaminants in talcum powders in repeated laboratory testing at numerous institutions.[33–37] The tissue fiber burdens contained no amosite or crocidolite, commercial amphibole asbestos fibers. Testing results of talcum powders have failed to show the presence of commercial amphiboles.

Table 3 presents the asbestos fiber burden results from background controls in tissues from autopsy and surgical population with no evidence of ovarian cancer or other malignancy, and with no known asbestos exposure. The lung and lymph nodes sampled showed only chrysotile and non-commercial amphibole asbestos in a small percentage of control samples—six of the 35 control samples, or 17%. All women with asbestos present were over 60 years of age. While asbestos is present at extremely low concentrations in the ambient air,[38] in the control samples presented in the study, there was no evidence of asbestos in women under the age of 60 years of age. Two fibers were seen in two specimens and one fiber was seen in four samples, all under 1 μm in size. The asbestos fiber burdens in the six talc exposed patients were all greater than the control population. No aluminum silicates, aluminum magnesium silicates, and silica crystals, all components of talcum powder identified in our patients, were not found in the control population that did not use talcum powder.

DISCUSSION

This paper provides the first large case series to identify cosmetic talcum powder contaminated with asbestos as the cause of malignant mesothelioma in cosmetic talc users. In 1960, Wagner presented 33 individuals exposed to crocidolite asbestos from occupational and environmental exposures, providing the first large case series of individuals diagnosed with mesothelioma with clearly identifiable exposure to asbestos.[2] Since then, the high prevalence of idiopathic mesothelioma cases suggested other possible exposures, including exposure to asbestos contaminated talc. Like Wagner, we present 33 cases, predominantly of women, who had no known exposure to asbestos other than prolonged use of talcum powder. This is consistent with the distribution of talcum powder usage in the United Sates, with greater numbers of women using powder than men.[26] Furthermore, the six case histories detailed years or decades of talcum powder use as well as tissue analysis that showed asbestos present in either tumor tissue or lymph nodes. In all six cases, asbestos fibers consistent with those identified as contaminants in repeated laboratory testing of talcum powder samples across several institutions were identified.[20,23,33,39] Notably, the fiber types found were consistent with the types of asbestos found in talc. Amosite and crocidolite, asbestos fibers that are encountered in cases of industrial and occupational exposure, not cosmetic talcum powder,[40] were not found in any of these cases.

This paper is also the first, to the authors' knowledge, to utilize background controls for which an extensive exposure history was elicited and for which no known asbestos exposure had occurred. Background controls are the best comparison when analyzing tissue of asbestos exposed individuals however, one of the biggest challenges is to choose a population of patients with no history of environmental or occupational exposure to asbestos apart from ambient air concentration of asbestos. Previous fiber burden studies of non-occupationally exposed individuals have compared the asbestos content in their tissue to workers in the same community where asbestos mines or asbestos containing factories were

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TABLE 1. Description of 33 Mesothelioma Cases

Talcum Powder Exposure								
Case	Sex	Year of Diagnosis	Age at Diagnosis	Mesothelioma Site	Histology	Talcum Powder Brand	Estimated Years of Use	Occupation (s)
1*	F	2015	70†	Pleural	Epithelial	A	30	Medical technician
2*	F	2015	65	Pleural	Biphasic	C, H, V	50	Homemaker
3*	F	2014	82†	Pleural	Biphasic	C	70	Teacher
4*	F	2014	66†	Peritoneal	Epithelial	B, C	30	Hairdresser
5*	F	2015	75†	Peritoneal	Epithelial	C	25	Teacher
6*	M	2016	43	Pleural	Epithelial	D	40	Finance
7	M	2016	65	Peritoneal	Epithelial	D	62	None provided
8	M	2016	76†	Pleural	Epithelial	U	38	Accountant
9	F	2016	66†	Pleural	Epithelial	C, E	35	Hair dresser
10	F	2015	80	Pleural	Epithelial	F	30	Administrative assistant
11	F	2018	73	Pleural	Epithelial	C, V	30	Flight attendant
12	F	2017	57	Peritoneal	Epithelial	A, D, G, H, I	40	Medical technologist
13	M	2016	56	Peritoneal	Biphasic	D, I, S	15	Maintenance worker
14	M	2017	56	Peritoneal	Epithelial	D	50	Molding press operator
15	F	2016	40	Peritoneal	Epithelial	D, J	12	Retail worker
16	F	2015	30	Pleural	Epithelial	D, K, L, M	19	Retail worker
17	F	2015	80†	Pleural	Epithelial	A, C, N	40	Office worker
18	F	2015	64	Pleural	Sarcomatoid	C	40	Real Estate agent
19	F	2009	62	Pleural	Epithelial	C	15	Teacher and fitness instructor
20	F	2016	69	Peritoneal	Epithelial	D, G	30	Hair dresser
21	F	2013	34†	Peritoneal	Epithelial	C	10	Teacher
22	F	2018	59	Pleural	Epithelial	C, D	42	School custodian
23	F	2016	27	Peritoneal	Epithelial	D, O	10	Not provided
24	F	2016	38	Peritoneal	Epithelial	D, I	18	Social services
25	F	2017	64	Pleural	Epithelial	D, G, J	27	Mathematician
26	F	2016	83	Pleural	Epithelial	C, D, I	60	Not provided
27	F	2017	41	Peritoneal	Epithelial	D	30	Computer programmer
28	F	2016	79	Peritoneal	Epithelial	A, C, T,	21	Not provided
29	M	2015	46	Pleural	Epithelial	D, R, U	15	Informational technology
30	F	2016	88†	Pleural	Epithelial	A, D, C, I	80	Administrative worker
31	F	2017	53	Pleural	Epithelial	D	23	Cleaner
32	F	2017	76	Pleural	Epithelial	D, C	17	Rehabilitation coordinator
33	F	2017	46	Peritoneal	Epithelial	D	25	Clerical worker

*Tissue analysis presented done by author. Tissue analysis might have been done in some cases by other investigator, these results are not presented in this paper.
†Deceased as of writing; vital status of many individuals is currently unknown.

present.[41,42] Autopsy studies have been performed[43–45] in individuals without a specific history of workplace asbestos exposure; full exposure histories were not obtained. Langer measured asbestos fiber burdens in New York City residents with no known history of asbestos.[46] Roggli and Longo[47] measured tissue burdens for individuals who had bystander or household exposure from family members who directly worked with asbestos in their work, such as laundering clothes. However that type of exposure does not truly reflect background or ''unexposed'' individuals. Lee and Van Orden[32] measured background air exposure in and outside of buildings. They found short chrysotile, tremolite, and actinolite fibers, but no anthophyllite or crocidolite, and very small levels of amosite. Lee and Van Orden's results are consistent with the background asbestos fibers found in the older women the present study.[32] While fiber burden studies are rarely undertaken in the course of clinical treatment, and are used primarily for medico-legal purposes, the findings of various fibers in the lung tissues can provide guidance as to potential prior asbestos exposure, whether from occupation, residential, or para-occupational exposure to asbestos. Attention to true background rates for fiber burdens is critical.[48]

Our findings strongly suggest that asbestos exposure through asbestos-contaminated cosmetic talc explains cases once deemed idiopathic or ''spontaneous,'' and underline the importance of

TABLE 2. Tissue Digestion of Six Mesothelioma Cases

Case	Sex	Mesothelioma Site	Asbestos Type	Site Found	Concentration (Fibers/g) (Lung, Lymph)	Limit of Detection (Lung, Lymph)	Asbestos Bodies
1	F	Pleural	Anthophyllite	Lung	3,286	1,643	0
2	F	Pleural	Anthophyllite, tremolite, actinolite	Lung, lymph node	8,625, 34,500	2,875, 11,500	0
3	F	Pleural	Tremolite	Lung, lymph node	0, 9,409	6,900, 9,409	0, 409
4	F	Peritoneal	Chrysotile	Peritoneum	920	920	0
5	F	Peritoneal	Anthophyllite	Lymph node	20,700	10,350	0, 0
6	M	Pleural	Anthophyllite, tremolite	Lymph node	17,250	3,450	0

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TABLE 3. Current Levels of Asbestos Fiber Burden Observed in Digests of Tissue From Autopsy and Surgical Population With no History of Asbestos Exposure (Controls)

Tissue Type	*N*	Asbestos Type	Mean (Fibers/Gram Wet Weight)*	Range (Fibers/Gram Wet Weight)
Lung tissue	35	Chrysotile	892	0–30,000
		Tremolite	84	0–1,552
		Chrysotile and tremolite	35	0–1,208
		Asbestos bodies	<1 bodies/gram wet weight	0–6
Paratracheal or parachronchial lymph node tissue	35	Chrysotile	72	0–1,1035
		Tremolite	29	0–552
		Chrysotile and tremolite	24	0–828
		Asbestos bodies	<1 bodies/gram wet weight	0–5
Peritoneum + gynecological tissue	10	Chrysotile	0	0
		Tremolite	0	0
		Chrysotile and tremolite	0	0
		Asbestos bodies	0	0

*All fibers that were counted were always 1 μm or less in length.

collecting detailed exposure histories that incorporate these findings in patients presenting with mesothelioma. Several factors may hinder the collection of comprehensive exposure histories among individuals diagnosed with mesothelioma. Minimal training in occupational medicine and exposure taking practice among medical students may contribute to a lack of or incomplete exposure history elicitation on the part of clinicians.[49,50] Secondly, long latency periods between exposure and illness pose a challenge both to individual recall as well the ability to establishing causality. Due to the relatively short period between diagnosis and death among mesothelioma patients, patients are often too ill or are deceased before being able to provide a full history. Furthermore, though the presence of asbestos in talc and talcum powder was first discussed in the scientific literature in the 1940s, individuals may not be aware that the products they used contained asbestos. Few clinicians are aware that this is a potential exposure. Typically, patients with mesothelioma will be simply asked whether they worked with or around asbestos, rather than being providing with a listing of potential sources of the types of exposure in which one might encounter asbestos. Cases of mesothelioma among hairdressers characterized as idiopathic also underscore the contribution of an incomplete exposure history; the potential failure to identify the use of talcum powder exposure in their work would prevent the linking of occupational exposure to asbestos to their mesothelioma. In our paper, there were three female hairdressers who regularly used talcum powder in their work. It was unclear from any of the histories noted in the medical records that these women were asked if they used talcum powder as part of the hair cutting process. In a report from the National Mesothelioma Registry of Italy, staff noted a cluster of mesothelioma due to ''unknown exposure'' among hairdressers, but only examined hairdryer use as a potential exposure. There was no discussion of the occupational use of talcum powder.[51] However, McDonald et al,[52] noted that a barber's occupational exposure to asbestos to talc could explain the increased finding of tremolite in the individual's lung fiber burden.

The case series presented should be understood in the context of its limitations. Data were obtained from medication records and transcripts of depositions, rather than structured, in-person interviews. However, the information solicited during the course of the patients' depositions were thorough, and included exhaustive questioning about alternative sources of asbestos exposure, including household exposure, exposures from external industrial sources, occupational exposure, and potential exposure from family members. While deposition testimony is by definition self-report, depositions were given under oath and the potential for recall bias noted would be presented whether patients completed a structured interview or were asked questions during sworn testimony. Furthermore, the utilization of medical records allowed the authors to corroborate important medical information and confirm the pathological diagnosis.

In March 2019 the Federal Drug Administration (FDA) released a statement as an update to their 2017 finding, confirming asbestos contamination of certain cosmetic products marketed and sold to young girls and outlining new steps to work with manufacturers to ensure the safety of their products.[53] While such public acknowledgment of the potential for asbestos contamination in cosmetic talc marks an important turning point, manufacturers are not legally obligated to register cosmetic products with the FDA. The results of this study coupled with the widespread use of such products[26] underline the continued risks posed to consumers through common household and cosmetic products. While these products remain unregulated and on the shelves, the use of talcum powder must be incorporated into standard exposure history practice in order to promote earlier detection of asbestos related disease among non-occupationally exposed individuals. This paper provides evidence that mesothelioma cases once considered idiopathic may be attributable to asbestos-contaminated cosmetic talcum powder usage and that the elicitation of a history of such usage is imperative to obtaining a full exposure history in all patients presenting with mesothelioma.

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EXHIBIT 24

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RESEARCH ARTICLE

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Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients

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Abstract

Background: Asbestos is the primary known cause of malignant mesothelioma. Some cosmetic talc products have been shown to contain asbestos. Recently, repeated exposures to cosmetic talc have been implicated as a cause of mesothelioma.

Methods: Seventy-five individuals (64 females; 11 males) with malignant mesothelioma, whose only known exposure to asbestos was repeated exposures to cosmetic talcum powders, were reviewed in medical-legal consultation. Out of the 75 cases, 11 were examined for asbestiform fibers.

Results: All subjects had pathologically confirmed malignant mesothelioma. The mean age at diagnosis was 61 ± 17 years. The mean latency from exposure to diagnosis was 50 ± 13 years. The mean exposure duration was 33 ± 16 years. Four mesotheliomas (5%) occurred in individuals working as barbers/cosmetologists, or in a family member who swept the barber shop. Twelve (16%) occurred in individuals less than 45 years old (10 females; 2 males). Forty-eight mesotheliomas were pleural (40 females; 8 males), 23 were peritoneal (21 females; 2 males). Two presented with concomitant pleural and peritoneal disease. There was one pericardial, and one testicular mesothelioma. The majority (51) were of the epithelioid histological subtype, followed by 13 biphasic, 8 sarcomatoid, 2 lymphohistiocytoid, and 1 poorly differentiated. Of the 11 individuals whose nontumorous tissues were analyzed for the presence of asbestiform fibers, all showed the presence of anthophyllite and/or tremolite asbestos.

Conclusions: Mesotheliomas can develop following exposures to cosmetic talcum powders. These appear to be attributable to the presence of anthophyllite and tremolite contaminants in cosmetic talcum powder.

KEYWORDS

anthophyllite, females, mesothelioma, peritoneal, pleural, talc, tremolite

1 | INTRODUCTION

Asbestos, a generic term for naturally occurring fibrous mineral silicates, is recognized as a carcinogen by the general medical and scientific communities. In 1960, Wagner et al[1] reported a large series of malignant mesotheliomas in individuals who had been exposed to asbestos from a South African asbestos mine. It has been demonstrated that all types of asbestos and even brief and low-dose exposures are capable of causing malignant mesothelioma.[2-4] In the 1970s, several types of cosmetic talcum powder products were

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demonstrated to contain asbestos.[5-7] Asbestos fibers in commercial talcum powder have also been shown to become airborne upon application, and repeated exposures to cosmetic talc were implicated as a cause of mesothelioma by Gordon et al.[8] Recently, Moline et al,[9] reported a series of 33 subjects with malignant mesothelioma, whose only known exposure to asbestos was cosmetic talc. We present 75 additional subjects, with malignant mesothelioma, whose only known exposure to asbestos was cosmetic talc.

2 | METHODS

One hundred forty subjects with documented exposures to cosmetic talc were initially reviewed. Exposures were identified through sworn deposition testimonies and answers to sworn interrogatories provided from subjects, parents, and spouses. Sixty-five subjects were excluded due to recalled occupational or paraoccupational exposures to other sources of asbestos. Seventy-five subjects, whose only known exposure to asbestos was via cosmetic talc, were included for further examination. The asbestos content of talcum products and airborne asbestos concentrations during simulations of the usage of these products was determined in previously published studies.[10,11]

Tissues from biopsies and/or debulking procedures were examined and the diagnosis of malignant mesothelioma was confirmed by a board-certified pathologist (JCM, TSE, RLK). Immunohistochemical staining results for BAP-1 were available in a few cases but was not routinely performed as a part of this study.

No efforts were made to reconstruct levels of exposure but all subjects had been repeatedly exposed over many years. Eleven cases were examined for the presence of asbestiform fibers (aspect ratio, ≥3:1) in sampled tissues. Nine subjects were examined both by analytical transmission electron microscopy (ATEM) and microprobe analysis (MA) (see Table 2), whereas two were examined by scanning electron microscopy (SEM) and MA (results not shown).

3 | RESULTS

The pertinent data from the 75 subjects is shown in Table 1. All had pathologically confirmed malignant mesothelioma. Sixty-four subjects were females, 11 were males. The mean age at diagnosis was 61 ± 17 years, with a range of 14 to 94 years. The mean exposure duration was 33 ± 16 years with a range of exposure from 6 to 65 years. The mean latency from time of first exposure to diagnosis was 50 ± 13 years with a range of 14 to 72 years. A total of 4 of the 75 cases (5%) occurred in barbers/cosmetologists, or in a family member who swept the barber shop. Twelve (16%) were 45 years old or younger (10 females, 2 males) at the time of diagnosis. Forty-eight mesotheliomas were pleural (40 females; 8 in males); 23 peritoneal (21 females; 2 men). Two presented with both pleural and peritoneal disease. There was one pericardial (woman), and one testicular mesothelioma. The majority, 51 (68%) were of epithelioid subtype, 13 biphasic (17%), 8 sarcomatoid (11%), 2 lymphohistiocytoid (3%), and 1 poorly differentiated (1%). Treatment, therapeutic outcomes, and survival were not determined in this study.

For the 11 subjects whose tissues were examined by ATEM and ASEM, the analysis showed the presence of tremolite and/or anthophyllite in all 11 subjects (Table 2).

4 | DISCUSSION

The 75 individuals with malignant mesothelioma caused by asbestos in cosmetic talc is currently the largest series reported to date. Recently, Moline et al reported 33 cases of malignant mesothelioma attributed to exposures to cosmetic talc. Like Moline's work, most of mesotheliomas in the present series occurred in women. Several mesotheliomas occurred specifically in hairdressers/barbers. Similarly, the asbestos fiber types found by ATEM in the tissues examined were comparable to those found in laboratory testing for cosmetic talc.[10-12]

Mesothelioma is recognized as a "signal tumor" of asbestos exposure, that is, if a patient has mesothelioma, it should signal an inquiry into potential asbestos exposure. The presence of asbestos in talc deposits has been recognized since the late 1940s.[13,14] Since the 1960s, laboratory testing has identified asbestos in samples of cosmetic talc.[15,16] Studies have confirmed that the most common types of asbestos present in cosmetic talc are tremolite, anthophyllite, and chrysotile. Industrial asbestos products used in the United States generally contained chrysotile, amosite, and/or crocidolite,[17] and anthophyllite and tremolite were rarely present.[18]

While the latency between exposure and diagnosis in the present study is similar to the average latency for the development of mesothelioma (50 years) reported in surveillance epidemiology and end results program (SEER) data,[19] the average age at diagnosis in this report (61 years) is 11 years younger than that in the SEER data (72 years). In addition, fewer than 3% of mesotheliomas in the SEER data occurred in individuals less than 45 years of age, whereas 16% of mesotheliomas of the present study occurred in individuals less than 45 years of age, and 83% of these cases were in women.[20]

The present report of 75 cases, together with the 35 cases previously reported[8,9] currently brings the number of individuals with confirmed diagnoses of malignant mesothelioma following repeated exposure to cosmetic talcum powder to more than 100. The presence of anthophyllite and tremolite in the fiber analysis of tissues obtained from the 11 subjects in this series, is consistent with a source in cosmetic talc.

Unlike industrial or occupational exposure to asbestos, where materials have been regulated, exposure to asbestos in cosmetic talc has not been widely reported or recognized within the medical community or to the public. Cosmetic talc products are most frequently used by women in the United States, and while the incidence of mesothelioma in women is less than in men, the majority have previously been reported as "idiopathic," indicating no recognized source of asbestos exposure. The present study supports the contention that asbestos exposure through the use of cosmetic talc accounts may account for an uncertain percentage of these cases.

TABLE 1 Seventy-five mesothelioma cases exposed to talcum powder

Case	Sex	Year of diagnosis	Age at diagnosis	Mesothelioma site	Histology	Estimated years of use	Estimated years of latency
1	F	2017	72	Pleural	Epithelioid	20	57
2	F	2014	51	Peritoneal	Epithelioid	30	50
3	F	2017	50	Pleural	Lymphohistiocytoid	41	50
4	F	2017	57	Peritoneal	Epithelioid	30	52
5	F	2015	65	Pleural	Epithelioid	39	62
6	F	2017	39	Peritoneal	Sarcomatoid	15	39
7	F	2016	29	Pericardial	Epithelioid	29	29
8	F	2017	94	Pleural	Epithelioid	60	72
9	F	2015	80	Pleural	Epithelioid	19	59
10	F	2016	72	Pleural	Sarcomatoid	43	59
11	F	2013	66	Peritoneal	Epithelioid	20	52
12	F	2011	48	Pleural	Lymphohistiocytoid	13	21
13	F	2010	51	Peritoneal	Epithelioid	15	20
14	F	2018	55	Peritoneal	Epithelioid	40	42
15	M	2017	81	Pleural	Sarcomatoid	60	60
16	F	2018	56	Pleural	Epithelioid	48	52
17	F	2017	32	Peritoneal	Epithelioid	25	32
18	F	2017	89	Pleural	Sarcomatoid	40	42
19	F	2019	73	Peritoneal	Epithelioid	47	56
20	M	2016	70	Pleural	Poorly differentiated	50	55
21	F	2015	66	Pleural	Epithelioid	40	43
22	F	2016	45	Pleural	Epithelioid	10	45
23	F	2018	45	Peritoneal	Epithelioid	39	45
24	M	2015	67	Pleural + peritoneal	Epithelioid	35	60
25	M	2017	78	Peritoneal	Biphasic	50	62
26	F	2018	57	Peritoneal	Biphasic	25	57
27	F	2013	14	Peritoneal	Epithelioid	12	14
28	F	2016	67	Peritoneal	Epithelioid	15	59
29	F	2018	73	Pleural	Epithelioid	30	65
30	F	2018	76	Pleural	Biphasic	60	55
31	M	2017	39	Testis	Epithelioid	7	39
32	F	2018	57	Pleural	Sarcomatoid	57	57
33	F	2016	68	Pleural	Epithelioid	38	64
34	F	2017	80	Pleural	Epithelioid	50	60
35	F	2016	63	Pleural	Epithelioid	15	54
36	F	2017	58	Pleural	Biphasic	20	58
37	F	2017	71	Pleural	Biphasic	60	71
38	F	2014	70	Pleural	Epithelioid	41	39
39	F	2016	26	Peritoneal	Epithelioid	20	26

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TABLE 1 (Continued)

Case	Sex	Year of diagnosis	Age at diagnosis	Mesothelioma site	Histology	Estimated years of use	Estimated years of latency
40	F	2016	35	Pleural	Epithelioid	35	35
41	F	2017	72	Pleural	Sarcomatoid	23	60
42	F	2016	68	Peritoneal	Epithelioid	65	68
43	F	2018	77	Pleural	Biphasic	30	55
44	M	2015	58	Plural	Biphasic	6	49
45	F	2017	72	Peritoneal	Biphasic	30	42
46	F	2017	59	Pleural + peritoneal	Epithelioid	15	44
47	F	2016	80	Pleural	Biphasic	16	52
48	M	2019	71	Pleural	Epithelioid	40	57
49	F	2017	72	Pleural	Biphasic	58	58
50	F	2017	43	Peritoneal	Epithelioid	43	43
51	F	2017	75	Peritoneal	Sarcomatoid	55	59
52	F	2015	30	Pleural	Epithelioid	20	20
53	F	2017	79	Pleural	Biphasic	65	61
54	F	2017	66	Peritoneal	Epithelioid	20	60
55	F	2015	64	Peritoneal	Epithelioid	40	40
56	F	2017	24	Pleural	Epithelioid	12	24
57	M	2017	72	Pleural	Epithelioid	30	56
58	M	2017	74	Peritoneal	Epithelioid	30	52
59	M	2015	30	Pleural	Epithelioid	20	30
60	F	2016	81	Pleural	Sarcomatoid	52	52
61	F	2017	58	Pleural	Epithelioid	58	58
62	F	2016	75	Pleural	Epithelioid	8	47
63	F	2011	88	Pleural	Epithelioid	21	71
64	F	2016	73	Peritoneal	Biphasic	41	60
65[a]	M	2017	64	Pleural	Epithelioid	18	40
66[a]	F	2014	69	Pleural	Epithelioid	16	60
67[a]	F	2014	44	Peritoneal	Epithelioid	30	39
68[a]	F	2016	68	Pleural	Epithelioid	53	52
69[a]	F	2016	72	Pleural	Epithelioid	40	51
70[a]	F	2016	67	Pleural	Epithelioid	37	53
71[a]	F	2017	58	Pleural	Epithelioid	41	46
72[a]	M	2016	44	Pleural	Epithelioid	43	44
73[a]	F	2017	51	Pleural	Epithelioid	28	49
74[a]	F	2015	47	Pleural	Epithelioid	15	40
75[a]	F	2014	62	Pleural	Biphasic	14	53

[a]Tissue analysis performed.

The present study has several limitations. It is both retrospective and uncontrolled, and the cases were submitted in medico-legal consultation, all of which potentially introduce bias. However, detailed deposition testimonies provide a level of detail concerning product exposure—including dates of exposure, duration, and frequency—that is rarely obtained in routine medical exposure histories, and which allowed for corroborating witness testimony in some cases. The strengths of the current series include its size, as malignant mesothelioma is a rare disease

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TABLE 2 Fiber detection in tissue digestion from nine cases of malignant mesothelioma

Case	Mesothelioma site	Asbestos type	Tissues examined	Concentration (fibers per gram of wet tissue) Lung, lymph node, omentum, ovary	Limit of detection (fibers per gram of wet tissue) Lung, lymph node, omentum, ovary	Tissue digest weight (g) Lung, lymph node, omentum, ovary
65	Pleural	Anthophyllite, tremolite	Lung, lymph node	8625	4313	0.08, 0.34
66	Pleural	Anthophyllite	Lung, lymph node	15 333, 23 000	7667, 1150	0.06, 0.06
67	Peritoneal	Anthophyllite, tremolite	Omentum, lymph node	1917, 1725	639, 1725	0.54, 0.20
68	Pleural	Anthophyllite, tremolite	Lymph node	3044	1015	0.82, 0.34
70	Pleural	Anthophyllite, amosite, chrysotile	Lymph node	17 250	3450	1.06
71	Pleural	Anthophyllite, tremolite	Lung, lymph node	4313, 857, 3451	2156, 857, 575	0.16
72	Pleural	Anthophyllite, tremolite	Lymph node	17 250	3450	0.02
74	Pleural	Anthophyllite, tremolite	Lung	2300	460	2
75	Pleural	Anthophyllite	Lung, ovary	3450, 2070	1150, 2070	0.6, 0.2

Note: All cases shown were examined by analytical transmission electron microscopy and structures analyzed by microprobe analysis.

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(1-2 cases per 100 000), and its novelty, as exposures to cosmetic talc are rarely considered by most medical practitioners when they are eliciting an exposure history to asbestos.

The findings of the present and other recent studies suggest that cosmetic talc may be a cause of malignant mesothelioma. Large-scale controlled studies will be required to assess the prospective risk of developing mesothelioma following repeated exposures to talc. Although cosmetic talcs are not currently regulated by the Food and Drug Administration, the poor prognosis of malignant mesothelioma may warrant regulation or the withdrawal of cosmetic talcs from the market, as nontoxic alternatives such as corn starch are presently available.

CONFLICTS OF INTEREST

Drs Emory, Maddox, and Kradin have testified in asbestos litigation, primarily for plaintiffs.

DISCLOSURE BY AJIM EDITOR OF RECORD

John D. Meyer declares that he has no conflict of interest in the review and publication decision regarding this article.

AUTHOR CONTRIBUTIONS

JCM and RLK developed the concept and the design of the work. JCM initiated the acquisition and developed the initial data analysis. TSE reviewed the materials, performed the statistical analysis, and was the primary author of the manuscript. RLK revised and gave the final approval of the version to be published.

ETHICS APPROVAL AND INFORMED CONSENT

As these cases were selected from medical-legal consultation practice and no identifying information was included, there was no formal institutional consent nor informed consent required.

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EXHIBIT 25

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Consensus report

Scand J Work Environ Health 1997;23(4):311-316

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Asbestos, asbestosis, and cancer: the Helsinki criteria for diagnosis and attribution

by Tossavainen A, reporter

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Consensus report

Scand J Work Environ Health 1997;23:311—6

Asbestos, asbestosis, and cancer: the Helsinki criteria for diagnosis and attribution

The International Expert Meeting on Asbestos, Asbestosis, and Cancer was convened in Helsinki on 20—22 January 1997 to discuss disorders of the lung and pleura in association with asbestos and to agree upon state-of-the-art criteria for their diagnosis and attribution with respect to asbestos. The group decided to name this document *The Helsinki Criteria*.

The requirement for diagnostic criteria was perceived in part because of new developments in diagnostic methods, with better identification of asbestos-related disorders. Such developments enhance awareness of health hazards imposed by asbestos, lead to practical prevention and appropriate compensation, and also provide an opportunity to carry out international comparisons. They also provide possible models for the risk assessment of other mineral dusts.

The meeting was attended by 19 participants from 8 countries not producing asbestos. The chairmen were Professor Douglas W Henderson (Flinders Medical Centre, Australia) and Professor Jorma Rantanen (Finnish Institute of Occupational Health, Finland). The group was a multidisciplinary gathering of pathologists, radiologists, occupational and pulmonary physicians, epidemiologists, toxicologists, industrial hygienists, and clinical and laboratory scientists specializing in tissue fiber analysis. Collectively, the group has published over 1000 articles on asbestos and associated disorders. This document is based on a more comprehensive report providing scientific evidence for the conclusions and recommendations (*People and Work Research Reports*, no 14, Finnish Institute of Occupational Health, Helsinki, 1997).

The meeting was scientifically supported by leading institutions in the field of asbestos research, and it was funded by the Ministry of Social Affairs and Health and the Finnish Work Environment Fund.

General considerations

Occupational exposures to asbestos dust have been widespread in all industrial countries and continue as a consequence of "in-place" materials. In detailed interviews about 20% to 40% of adult men report some past occupations and jobs that may have entailed asbestos exposure at work. In Western Europe, North America, Japan, and Australia the use of asbestos peaked in the 1970s, and currently about 10 000 mesotheliomas and 20 000 asbestos-induced lung cancers are estimated to occur annually in the population of approximately 800 million people.

In general, reliable work histories provide the most practical and useful measure of occupational asbestos exposure. Using structured questionnaires and checklists, trained interviewers can identify persons who have a work history compatible with significant asbestos exposure. Dust measurements can be used in the estimation of past fiber levels at typical workplaces and in the use of asbestos-containing materials. A cumulative fiber dose, as expressed in fiber-years per cubic centimeter, is an important parameter of asbestos exposure.

The clinical diagnosis of asbestos-related diseases is based on a detailed interview of the patient and occupational data on asbestos exposure and appropriate latency, signs and symptoms, radiological and lung physiology findings, and selected cytological, histological and other laboratory studies. Histopathological confirmation is required for suspected asbestos-related malignancies and for the resolution of differential diagnoses. A multidisciplinary approach is suggested for the evaluation of problem cases.

The chest radiograph is the basic tool for identifying asbestos-related diseases such as asbestosis, pleural abnormalities, lung cancer, and mesothelioma. The limitation of the chest radiograph in the detection of asbestosis and asbestos-associated pleural abnormalities is widely recognized. Computed tomography (CT) and high resolution computed tomography (HRCT) can facilitate the detection of asbestosis and asbestos-related pleural abnormalities, as well as asbestos-related malignancies; they are not recommended as a screening tool but may be invaluable for individual clinical evaluation and research purposes. Examples are the detection of pleural abnormalities in suspected cases of asbestosis and the detection of parenchymal disease obscured on the chest film and also use as an aid to differential diagnosis. As new imaging techniques such as digital radiography are evolving, standard images and interpretations must be developed. The place of other imaging techniques (ultrasound, magnetic resonance imaging, gallium scanning, ventilation-perfusion studies, positron-emission tomography) has yet to be established, and they are not currently recommended for the clinical diagnosis of asbestos-related disorders.

Analysis of lung tissue for asbestos fibers and asbestos bodies can provide data to supplement the occupa-

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tional history. For clinical purposes, the following guidelines are recommended to identify persons with a high probability of exposure to asbestos dust at work: over 0.1 million amphibole fibers (>5 μm) per gram of dry lung tissue *or* over 1 million amphibole fibers (>1 μm) per gram of dry lung tissue as measured by electron microscopy in a qualified laboratory *or* over 1000 asbestos bodies per gram of dry tissue (100 asbestos bodies per gram of wet tissue) *or* over 1 asbestos body per milliliter of bronchoalveolar lavage fluid, as measured by light microscopy in a qualified laboratory.

Each laboratory should establish its own reference values. The median values for occupationally exposed populations should be substantially above the reference values. Efforts to standardize analytical methods for fiber burden analyses by different laboratories are recommended.

Asbestosis

Asbestosis is defined as diffuse interstitial fibrosis of the lung as a consequence of exposure to asbestos dust. Neither the clinical features nor the architectual tissue abnormalities sufficiently differ from those of other causes of interstitial fibrosis to allow confident diagnosis without a history of significant exposure to asbestos dust in the past or the detection of asbestos fibers or bodies in the lung tissue greatly in excess of that commonly seen in the general population. Symptoms of asbestosis include dyspnea and cough. Common findings are inspiratory basilar crackles and, less commonly, clubbing of the fingers. Functional disturbances can include gas exchange abnormalities, a restrictive pattern, and obstructive features due to small airway disease.

Asbestosis is generally associated with relatively high exposure levels with radiological signs of parenchymal fibrosis. However, it is possible that mild fibrosis may occur at lower exposure levels, and the radiological criteria need not always be fulfilled in cases of histologically detectable parenchymal fibrosis. The recognition of asbestosis by chest radiography is best guided by standardized methods such as the classification of the International Labour Organisation (ILO) and its modifications. Standard films must always be used. For research and screening purposes, radiological findings of small opacities, grade 1/0, are usually regarded as an early stage of asbestosis. Inspiratory basilar rales, restrictive impairment, small airway obstruction, and gas exchange disturbances in pulmonary function are considered valuable information for clinical diagnosis, for occupational health practice, and for attribution purposes. HRCT can confirm radiological findings of asbestosis and show early changes not seen on chest X rays, but should be performed only in selected cases.

Smoking effects should be considered in the evaluation of early asbestosis, lung function tests, and respiratory symptoms.

A histological diagnosis of asbestosis requires the identification of diffuse interstitial fibrosis in well inflated lung tissue remote from a lung cancer or other mass lesion, *plus* the presence of either 2 or more asbestos bodies in tissue with a section area of 1 cm^2 or a count of uncoated asbestos fibers that falls into the range recorded for asbestosis by the same laboratory.

In order to achieve reasonable comparability between different studies, a standardized system for the histological diagnosis and grading of asbestosis is required. The Roggli-Pratt modification of the CAP-NIOSH system is recommended as a reasonably simple and reproducible scheme for this purpose.

There is evidence that rare cases of asbestosis occur without significant numbers of asbestos bodies. These cases are recognizable — and distinguishable from idiopathic pulmonary fibrosis — only by analysis of the uncoated fiber burden. Rare cases of asbestosis in relation to the inhalation of pure chrysotile can occur, with a prolonged interval between the last exposure and the diagnosis and few or no detectable asbestos bodies and a low fiber burden. The existence of such cases is speculative and, if the diagnosis can be made, it must be done from other compelling clinical or radiological grounds combined with exposure data.

Fibro-inflammatory patterns other than conventional asbestosis have also been described for workers with occupational exposure to asbestos, including a pattern resembling desquamative interstitial pneumonia (DIP), the occurrence of granulomatous inflammation, a picture that resembles lymphocytic interstitial pneumonia, and organizing pneumonia with bronchiolitis obliterans. Although the DIP-like picture with asbestos bodies is probably asbestos-related, the other patterns have not yet been shown to be so related.

Pleural disorders

Asbestos-related pleural abnormalities are divided into pleural plaques, mainly involving the parietal pleura, sometimes with calcification, and diffuse pleural thickening, which is a collective name for pleural reactions involving mainly the visceral pleura. These include benign asbestos-related pleural effusion, blunted costophrenic angle, crow's feet or pleuroparenchymal fibrous strands, and rounded atelectasis. Avoidance of the term "pleural asbestosis" is recommended. Pleural plaques are usually asymptomatic, and without clinically important findings.

The specificity of pleural plaques according to the ILO 1980 Classification of Radiographs of Pneumoconioses is low unless the plaques are radiographically well

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defined. The most common differential diagnosis is subpleural fat. Radiographic findings are reliable for the diagnosis of asbestos-related pleural plaques when they are characteristic (eg, bilateral circumscribed plaques, bilateral calcification, diaphragmatic plaques).

Pleural plaques represent circumscribed areas of fibrous thickening, typically of the parietal pleura, due to the deposition of paucicellular collagenous tissue with a laminar or basket-weave pattern; they may or may not calcify. In regions where plaques are not endemic, 80—90% of the plaques that are radiologically well defined are attributable to occupational asbestos exposure. The presence of pleural plaques may justify follow-up among occupationally exposed groups.

Diffuse pleural fibrosis designates noncircumscribed fibrous thickening of variable cellularity, which usually affects the parietal, but mainly the visceral, layers. In the setting of occupational asbestos exposure, such diffuse fibrosis is probably a result of benign asbestos pleuritis with effusion. It may or may not be associated with rounded atelectasis. Diffuse pleural thickening can be associated with mild, or rarely moderate or severe, restrictive pulmonary function defects.

Low exposures from work-related, household, and natural sources may induce pleural plaques. For diffuse pleural thickening, higher exposure levels may be required.

Mesothelioma

Malignant mesothelioma affecting any serosal membrane may be induced by asbestos inhalation. The histological, immunohistochemical and ultrastructural markers for the diagnosis of mesothelioma are well established. Expert opinion should be sought on atypical cases, or on those in which the diagnosis is uncertain because of discordant findings or in which the amount of material available is insufficient for definite diagnosis. Mesothelioma is frequently presented with pleural effusion, dyspnea, and chest pain.

With the exception of certain histological types of mesothelioma that are benign or of uncertain or borderline malignant potential (eg, multicystic mesothelioma, benign papillary mesothelioma), all types of malignant mesothelioma can be induced by asbestos, with the amphiboles showing greater carcinogenic potency than chrysotile.

A lung fiber count exceeding the background range for the laboratory in question *or* the presence of radiographic or pathological evidence of asbestos-related tissue injury (eg, asbestosis or pleural plaques) *or* histopathologic evidence of abnormal asbestos content (eg, asbestos bodies in histologic sections of lung) should be sufficient to relate a case of pleural mesothelioma to asbestos exposure on a probability basis. In the absence of such markers, a history of significant occupational, domestic, or environmental exposure to asbestos will suffice for attribution. There is evidence that peritoneal mesotheliomas are associated with higher levels of asbestos exposure than pleural mesotheliomas are. In some circumstances, exposures such as those occurring among household members may approach occupational levels.

The question is unresolved of whether or not a case of mesothelioma for which the lung fiber count falls within the range recorded for unexposed urban dwellers is related to asbestos. More information is needed regarding the interpretation of fiber burdens in the pleura or samples of tumor tissue before these measures can be used for the purposes of attribution.

The following points need to be considered in the assessment of occupational etiology:

- The great majority of mesotheliomas are due to asbestos exposure.
- Mesothelioma can occur in cases with low asbestos exposure. However, very low background environmental exposures carry only an extremely low risk.
- About 80% of mesothelioma patients have had some occupational exposure to asbestos, and therefore a careful occupational and environmental history should be taken.
- An occupational history of brief or low-level exposure should be considered sufficient for mesothelioma to be designated as occupationally related.
- A minimum of 10 years from the first exposure is required to attribute the mesothelioma to asbestos exposure, though in most cases the latency interval is longer (eg, on the order of 30 to 40 years).
- Smoking has no influence on the risk of mesothelioma.

Lung cancer

All 4 major histological types (squamous, adeno-, large-cell and small-cell carcinoma) can be related to asbestos. The histological type of a lung cancer and its anatomic location (central or peripheral, upper lobe versus lower lobe) are of no significant value in deciding whether or not an individual lung cancer is attributable to asbestos. Clinical signs and symptoms of asbestos-related cancer do not differ from those of lung cancer of other causes.

As examples, 1 year of heavy exposure (eg, manufacture of asbestos products, asbestos spraying, insulation work with asbestos materials, demolition of old buildings) or 5—10 years of moderate exposure (eg, construction, shipbuilding) may increase the lung cancer risk 2-fold or more. In some circumstances of extremely high asbestos exposure, a 2-fold risk of lung cancer can be achieved with exposure of less than 1 year.

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The relative risk of lung cancer is estimated to increase 0.5—4% for each fiber per cubic centimeter per year (fiber-years) of cumulative exposure. With the use of the upper boundary of this range, a cumulative exposure of 25 fiber-years is estimated to increase the risk of lung cancer 2-fold. Clinical cases of asbestosis may occur at comparable cumulative exposures.

A 2-fold risk of lung cancer is related to retained fiber levels of 2 million amphibole fibers (>5 μm) per gram of dry lung tissue or 5 million amphibole fibers (>1 μm) per gram of dry lung tissue. This lung fiber concentration is approximately equal to 5000 to 15 000 asbestos bodies per gram of dry tissue, or 5 to 15 asbestos bodies per milliliter of bronchoalveolar lavage fluid. When asbestos body concentrations are less than 10 000 asbestos bodies per gram of dry tissue, electron microscopic fiber analyses are recommended.

Chrysotile fibers do not accumulate within lung tissue to the same extent as amphiboles because of faster clearance rates; therefore, occupational histories (fiber-years of exposure) are probably a better indicator of lung cancer risk from chrysotile than fiber burden analysis is.

A lung fiber burden within the range recorded for asbestosis in the same laboratory should be assigned a significance similar to that of asbestosis. For a patient with lung cancer and a fiber count that falls within the range recorded for unexposed urban dwellers, the relationship of the tumor to amphibole asbestos is doubtful at most.

Estimates of the relative risk for asbestos-associated lung cancer are based on different-sized populations. Because of the high incidence of lung cancer in the general population, it is not possible to prove in precise deterministic terms that asbestos is the causative factor for an *individual* patient, even when asbestosis is present. However, attribution of causation requires *reasonable* medical certainty on a probability basis that the agent (asbestos) has caused or contributed materially to the disease. The likelihood that asbestos exposure has made a substantial contribution increases when the exposure increases. Cumulative exposure, on a probability basis, should thus be considered the main criterion for the attribution of a substantial contribution by asbestos to lung cancer risk. For example, relative risk is roughly doubled for cohorts exposed to asbestos fibers at a cumulative exposure of 25 fiber-years or with an equivalent occupational history, at which level asbestosis may or may not be present or detectable. Heavy exposure, in the absence of radiologically diagnosed asbestosis, is sufficient to increase the risk of lung cancer. Cumulative exposures below 25 fiber-years are also associated with an increased risk of lung cancer, but to a less extent.

The presence of asbestosis is an indicator of high exposure. Asbestosis may also contribute some additional risk of lung cancer beyond that conferred by asbestos exposure alone. Asbestosis diagnosed clinically, radiologically (including HRCT), or histologically can be used to attribute a substantial causal or contributory role to asbestos for an associated lung cancer.

Pleural plaques are an indicator of exposure to asbestos fibers. Because pleural plaques may be associated with low levels of asbestos exposure, the attribution of lung cancer to asbestos exposure must be supported by an occupational history of substantial asbestos exposure or measures of asbestos fiber burden. Bilateral diffuse pleural thickening is often associated with moderate or heavy exposures, as seen in cases with asbestosis, and should be considered accordingly in terms of attribution.

A minimum lag-time of 10 years from the first asbestos exposure is required to attribute the lung cancer to asbestos.

Not all exposure criteria need to be fulfilled for the purposes of attribution. For example, the following can be considered: (i) significant occupational exposure history with low fiber burdens (eg, long exposure to chrysotile and long lag-time between the end of exposure and mineralogical analysis) and (ii) high fiber counts in lung or broncholavage fluid with an uncertain history or without long-term duration (short exposures can be very intense).

At very low levels of asbestos exposure, the risk of lung cancer appears to be undetectably low.

Although tobacco smoking affects the total lung cancer risk, this effect does not detract from the risk of lung cancer attributable to asbestos exposure. No attempt has been made in this report to apportion the relative contributions of asbestos exposure and tobacco smoking.

Prevention and screening

Screening of asbestos-exposed populations can be carried out for practical and scientific purposes. There are 4 goals of screening: (i) to identify high risk groups, (ii) to target preventive actions, (iii) to discover occupational diseases, and (iv) to develop improved tools for treatment, rehabilitation and prevention. Screening should aim to prevent asbestos-related diseases and therefore lead to gained healthy years of life among the screened or among those in similar risk situations. The benefits to the individual person should be viewed cautiously. The substantial morbidity and mortality related to asbestos exposure argue for continued efforts to increase the preventive power of screening.

Any screening for purely scientific purposes requires appropriate methods and criteria (eg, low cost and high predictive value). Before a screening program is initiated, the ethical, financial, and legislative aspects need to be considered. These aspects may include patient notification, data protection, allocation of costs, and follow-up of identified abnormalities. In addition, provision should

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be made for epidemiologic analyses, quality control, primary and secondary prevention, and the assessment of program effectiveness.

As tools for screening, questionnaires and personal interviews should include items related to asbestos exposure, smoking, and other contributing factors. Questionnaires should preferably be validated for smoking habits and occupational histories. When possible, questionnaires should be applied nationally to permit epidemiologic analysis of the results.

Chest X-ray examinations can include frontal and lateral roentgenograms. Appropriate lung function tests can measure respiratory flow volumes and rates. In spirometry, attention should be given to careful calibration, acceptable performance efforts, and reproducibility.

The prevention strategies of asbestos-related diseases can be based on the identification of exposure sources and exposed people. There are 3 main targets for prevention: (i) an individual worker, (ii) a selected group of workers, and (iii) the work environment. At the level of the individual worker, the tools for prevention include health education and the introduction of safe work practices, the avoidance of tobacco smoking, and careful follow-up of health by surveillance. The group level methods are in part the same as at the individual level (ie, health information, education, and recommendations including the use of respiratory protective equipment).

The work environment is the most important target for preventive measures, starting from avoiding the use of asbestos, carefully controlling dust emissions using wet techniques, and controlling passive smoking at the workplace. Many countries have prohibited the use of asbestos, but there are still substantial amounts of asbestos in consumer products and in buildings that can expose workers in repair and removal work. Some countries have permitted asbestos work only under special authorization, training, and protective measures.

From the knowledge on potential exposures to asbestos, high-risk populations can be identified among persons exposed 10 or more years ago. The availability of registers — union, workers' compensation, and employment records — can be explored for this purpose.

Subjects can be assigned to subgroups for intervention or screening as defined by their risk (eg, the current risk of lung cancer and risk projected to given time windows in the future). Criteria for inclusion in each intervention or screening group should be established in the study protocol. Subsequently, the members of each subgroup can serve as separate targets for group-based and individual intervention programs.

Protocols for intervention should be designed in such a way that they serve each subject and subgroup optimally in terms of promoting individual health and the early detection of asbestos-related diseases. Data on these subgroups can also form a basis for more specific studies of disease outcome or various biomarkers. Identified abnormalities should be followed by the best clinical and occupational practices.

Research needs

There are several issues that still require clarification and further study. The following list of recommendations and future directions is not intended to be exhaustive.

- Improvement in the assessment and quantification of exposure to asbestos, to include specific worker groups, with collation of data and the development of an international standardized protocol for the assessment of exposure.
- Further analysis of job-exposure data and further studies on asbestos fiber burdens in tissue in relation to various asbestos-related disorders.
- Studies on chrysotile fiber burdens in lung tissue relative to the risk of lung cancer (also to include experimental investigations).
- Lung cancer relative to the lung tissue burdens of mineral fibers other than asbestos (eg, refractory ceramic fibers and zeolites).
- Improvement of the ILO system for the radiological diagnosis and categorization of pleural abnormalities.
- Development of a standardized system for the reporting of HRCT scans of asbestos-related disorders, analogous to the ILO system.
- Studies on the specificity of lesions of the pleura visualized by CT as markers of asbestos exposure and studies on the prognosis of diffuse pleural abnormalities.
- Improvement in ultrasound imaging of the pleura.
- Development of new digital imaging techniques for the investigation of asbestos-related diseases.
- Standardization of the approach to lung crepitations with the use of special auditory devices.
- Investigation of mesothelioma as a potential outcome of exposure to mineral fibers other than asbestos — such as refractory ceramic fibers — to include experimental studies and a series of mesothelioma patients without exposure to asbestos or erionite, supported by lung tissue fiber analysis.
- Multicenter studies on biomarkers for the detection of early asbestos diseases and the assessment of the response to new treatment modalities.
- Investigation of asbestos-associated tumors other than lung cancer and mesothelioma (eg, laryngeal carcinoma and renal carcinoma).
- Further studies on the effectiveness of screening programs.

Participants: Douglas W. Henderson (Flinders Medical Centre, Australia), Jorma Rantanen (Finnish Institute of Occupational Health, Finland), Scott Barnhart (Universi-

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Reprint requests to Dr Antti Tossavainen, Department of Industrial Hygiene and Toxicology, Finnish Institute of Occupational Health, Topeliuksenkatu 41 a A, FIN-00250 Helsinki, Finland (free of charge).

The reprint plus a copy of the conclusions and recommendations (People and Work Research Reports, no 14) can be obtained from the Finnish Institute of Occupational Health, Suvi Lehtinen, Topeliuksenkatu 41 a A, FIN-00250 Helsinki, Finland, for a price of FIM 80.00 + postage.

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EXHIBIT 26

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(ROUGH DRAFT)

2022-10279, Jeannine Henderson versus Taylor-Seidenbach

JUDGE REESE:

First thing I am going to take up is that alleged stipulated Case Management Order, because if it's a stipulated Case Management Order, there's agreement, but apparently there wasn't. After a lot of consideration of this, kind of came down to the fact that this is a living meso case, so I am going to sign the plaintiff's draft with paragraph 1. Now, given that, December 18th, that also means the plaintiff's experts, if they have any supplemental reports, they need to be deposed, and if the defendants want to comment, they have the opportunity to do that.

MR. HOFFMAN:

Yes, Your Honor.

JUDGE REESE:

Okay. I note the defendant's objection.

Let's take up some of the things I took under advisement. Let's see, the exceptions regarding Janssen, Kenvue and Holdco. The Court looked at this very carefully and I am going to grant the no cause of action. Those corporations were not in existence at the time these arose, so as a consequence , the exception of no cause of action is granted. Additionally, the Motion for Summary Judgment regarding punitive damages, I did a thorough examination of that and read the jurisprudence involved. Punitive damages do not lie. Louisiana has a strong public policy consideration regarding punitive damages. They have to be expressly

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01:47 authorized by statute and/or jurisprudence; though, I don't know if I've seen that. Expanding 2315.3 I think goes beyond the scope of the legislative intent. So as a result, I do not think punitive damages lie in this instance. So that motion for summary judgment is granted for those reasons.

As to Dr. Haber, the expert, we had discussion of that and thank y'all for this. This made some really intriguing reading. The *Daubert* motion to exclude Dr. Haber is denied. I think he may present some possibilities, if anybody cares to take it up on cross examination, but he will be allowed to testify.

Now, we had a couple of other -- I think that's all I had under advisement. Did I miss anything?

MS. ROOKARD:

Your Honor, Kelly Juneau Rookard for the Janssen defendants. I believe that there was an exception and/or Motion for Summary Judgment as to intentional misconduct that I don't know that we got to a ruling on last time.

JUDGE REESE:

Hang on one second. Let me look at my notes.

MS. ROOKARD:

It was argued in context with the civil conspiracy. I know Your Honor granted the exception as to civil conspiracy, but I wasn't sure where we landed with intentional misconduct.

JUDGE REESE:

I know what I want to do with that. I think that's going to be fact driven based upon what was known and whether or not it was obviated or not. So intentional conduct, I think there are genuine issues

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04:48 Very well. And you will be able to obtain that if there is no opposition, or even if there is, I will have a judgment ready at 12 o'clock on Thursday.

What else have we got?

MR. WILKES:

Your Honor, may I be excused at this point? Thank you, Your Honor.

JUDGE REESE:

Good day, sir.

MR. WILKES:

Thanks again to the Court and to counsel for their courtesies.

JUDGE REESE:

Yes, sir. Okay, I tell what you we have to do.

(Off-the-record discussion)

EXHIBIT 27

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Hearing

Hirshberg, et vir v. Johnson & Johnson

April 29, 2021

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF KING

WENDI J. HIRSHBERG and RICHARD)
)
HIRSHBERG, Wife and Husband,)
)
Plaintiffs,) Cause No. 20-2-05603-1 SEA
)
v.)
)
JOHNSON & JOHNSON, et al.,)
)
Defendants.)

HEARING
The Honorable Suzanne Parisien Presiding
April 29, 2021

TRANSCRIBED BY: Chastity M. Feezle, WA-CRL

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INDEX OF PROCEEDINGS

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-o0o-
April 29, 2021

THE BAILIFF: All right. Welcome, everybody. We're going to put everyone's name on the record first to save a little bit of time. So I'm going to call the case now.

This is pretrial motions and motions in limine and hardships for Hirshberg vs. Johnson & Johnson, 20-2-05603-1 Seattle.

For plaintiff, who do we have with us?

MR. ADAMS: Good afternoon. Ben Adams for the plaintiffs.

MS. DEAN: Jessica Dean, also for Wendi and Rich Hirshberg.

THE BAILIFF: All right. For defense?

MS. BROWN: Good afternoon. Allie Brown for the J&J defendants.

MS. BASAURI: Hi, Mr. Hodgman. This is Taryn Basauri, also for the J&J defendants.

MR. BERNARDO: Good afternoon. Also Rich Bernardo for the J&J defendants.

THE BAILIFF: All right. I have one --

MR. WYATT: And good afternoon. Jeff Wyatt for the J&J defendants.

THE BAILIFF: All right. Perfect. Thank you. We'll get started here in just one moment.

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second. I want to make sure that whenever I see an agreement, I try to take it. Is it -- my understanding is that he -- by agreement, he is not going to testify that fibrous talc causes mesothelioma; is that right.
MS. DEAN: Correct.
THE COURT: He's not going to offer that testimony?
MS. DEAN: No. It's going to be somewhat very similar to your ruling on Sanchez; that there is information in the scientific literature to be concerned that any fiber can get to the cell and cause harm, but it's just a possibility. He is not going to claim that it posed the same risk as asbestos. The way they frame it, they will have no problems. And we can get better than that.
They want to prohibit information that non-asbestiform cleavage fragments have the same risks as asbestos. He's never said that.
And I want one thing to be crystal clear here, because it has been so misrepresented in the briefing. They said he didn't mention his basis for these opinions in his report or in his deposition.
First of all, he doesn't use the word "cleavage fragment." It's not something, as a health and professional scientist, he cares about.
Second, they didn't ask a single question. They had hours of testimony, I believe seven, where they didn't ask him

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about cleavage fragments. They didn't ask him about region 9. They didn't ask him about the executive summary.
But what I will say, and I think this probably is critical: How they interpret what a cleavage fragment is causes a lot of confusion. I love that we put in the document where they admit that that was the goal. They don't respond to that.
But here is their expert. This was their exhibit, Mossman. We attached an article by her. She doesn't --
THE COURT: We're going way down -- we are doing down a path that is now only remotely related to the motion, so can --
MS. DEAN: I -- okay. I can -- here's what I'll tell you, is that -- if they would have bothered to ask, as that term is used by Dr. Haber is very similar to other medical professionals and by their own expert, Mossman. She doesn't actually define it, she depicts it. What is on D is a depiction of a non-asbestiform cleavage fragment. What is in A is asbestos.
Because D is both not aerodynamic and can't be breathed in, which is important to get sick, and can't get to the target cell, he's never going to say that that is as harmful as asbestos.
What is in A he absolutely will, as long as you confirm that that shape, that morphology, is one of the six asbestos

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minerals, which, if you look in the article, Dr. Mossman confirms.
THE COURT: But how --
MS. DEAN: So I want to be --
THE COURT: But how can -- how can a pulmonologist be testifying -- he's not a geologist -- as to what -- I'm concerned about what sounds like -- and he can't testify about questions of geology, right?
MS. DEAN: So this is not a question -- I mean, this is coming from an expert who is not a geologist. This is something that Attanoos -- that all of the medical doctors say, and anyone that has studied asbestos.
Attanoos is, again, their pathologist who's published on what asbestos means. And they've said the critical two things you need to know is if it's fibrous and if it's the chemistry of one of those six minerals.
And what they're trying to say is, you know, a cleavage fragment might sometimes overlap with that definition. You are right. He's never going to come in and say, in geology, this does or does not happen. That's not his field.
What he is going to say is, this is what I define asbestos. This is what I understand -- and here I'm pointing to the screen -- as the medical understanding of cleavage fragments. I'm never going to say cleavage fragments are as harmful as asbestos. That's not

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respirable. That's not harmful.
And so they -- they write this bizarre motion. And I don't mean that to be pejorative, but in a -- words that were not used in his report, with questions that they didn't bother to ask, try to conclude opinions that are absolutely clear as mud. That is a recipe for -- you can't, as an MIL, look -- Washington law requires that you be specific. And the suggestion that -- that somehow we didn't disclose this opinion is absolutely wrong.
He identified what he means by asbestos, and they asked not a question. And so then they don't define these terms, and seek you to preclude opinions without any context or bearing.
THE COURT: All right.
MS. DEAN: And it's the strangest motion I've ever seen.
THE COURT: All right. Okay. So I'm denying the motion. I will say that in my notes here, I have that he -- as a pulmonologist, he cannot testify as a geologist would. And to the extent that any of the questions go to him testifying about, you know, things that a mineralogist or a geologist would testify to, he can't do that.
To the extent that he's relying on information given to him by other experts, that is routinely done. But he will need to testify consistently with his role and his credentials as a pulmonologist. That's all I will say on

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things, and I appreciate all of your efforts to come to even small agreements. There's no such thing as a small agreement in my court. Even the teeniest thing that you agree upon together goes a long way. We save time. We work together.

You know, it shows your good faith to me -- and not that you don't have good faith, you do, but it shows your further good faith that you're trying to hammer out even small things matter. So thanks for all your hard work so far. And we'll be -- I'm sure we'll have some e-mail communication tomorrow about various things.

You'll definitely get the chart for Monday to know who's coming in at 9:15, who's coming in in the next one. So it'll be very organized. Mr. Hodgman is a master.

Okay. Have a great evening, everyone. Thank you.

MS. BROWN: Thank you, Your Honor.

MR. ADAMS: Thanks, Your Honor.

(Conclusion of hearing)

CERTIFICATE

STATE OF WASHINGTON)
) ss
COUNTY OF KING)

I, the undersigned, do hereby certify under penalty of perjury that the foregoing court proceedings or other legal recordings were transcribed under my direction as a certified transcriptionist; and that the transcript is true and accurate to the best of my knowledge and ability, including any changes made by the trial judge reviewing the transcript; that I received the electronic recording directly from the trial court conducting the hearing; that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially interested in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand this 30th day of April, 2021.



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EXHIBIT 28

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JPC SE Joint Policy Committee Societies of Epidemiology

Position Statement on Asbestos

from the

Joint Policy Committee

of the

Societies of Epidemiology (JPC-SE)

June 4, 2012

The Joint Policy Committee (JPC) of the Societies of Epidemiology (SE) is a consortium of epidemiology societies and organisations, national and international in scope. The JPC-SE originated in 2006 at the 2nd North American Congress of Epidemiology to coordinate and unify joint policy actions globally among epidemiology societies. The lead organisers of that Congress (the American College of Epidemiology, the Society for Epidemiologic Research, and the Epidemiology Section of the American Public Health Association), in conjunction with the Canadian Society for Epidemiology and Biostatistics, took the leading roles in the formation of the JPC-SE, which now numbers 13 member organisations. The American College of Epidemiology provides substantial administrative and logistical support to its activities.

This Position Statement on Asbestos was developed by representatives of 12 of our member societies, in consultation with these societies. On June 4th, 2012, the JPC-SE approved this Position Statement. Each member organisation then followed its own endorsement process, such as the recusal of its leadership members when appropriate or necessary, such as for some government employees or for those with conflicting interests. Some individual epidemiologists hold the position that epidemiologists should not play any role in advocacy. Some of our member organisations, as per their own internal policies, do not issue or publicly endorse any specific statements.

Endorsers of this Statement are included as appendices (pages 26 onwards).

For more information, contact the Chair of the JPC-SE (Professor Stanley H. Weiss, MD) by e-mail at JPCSE.Chair@gmail.com, or by writing to Dr. Weiss care of the American College of Epidemiology (address immediately below).

The Joint Policy Committee of the Societies of Epidemiology provides a forum for surveillance of and communication about funding, regulatory, and legislative environments relating to epidemiologic research and practice. Through coordinated joint action, the Committee strives to impact policies and influence opinion leaders relevant to policies that rely on epidemiologic evidence.

Contact

Joint Policy Committee of the Societies of Epidemiology
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USA

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POSITION STATEMENT ON ASBESTOS

EXECUTIVE SUMMARY

A rigorous review of the epidemiologic evidence confirms that all types of asbestos fibre are causally implicated in the development of various diseases and premature death. Numerous well-respected international and national scientific organisations, through an impartial and rigorous process of deliberation and evaluation, have concluded that all forms of asbestos are capable of inducing mesothelioma, lung cancer, asbestosis and other diseases[1]. These conclusions are based on the full body of evidence, including the epidemiology, toxicology, industrial hygiene, biology, pathology, and other related literature published to the time of the respective evaluations.

Industrialised countries have virtually ceased using asbestos and over 50 countries have passed laws banning its use. Consequently, the asbestos industry, to establish new markets, is promoting the use of asbestos in low-to-middle income countries, particularly in Asia, and has created lobby organisations to achieve this goal.

In spite of the scientific evidence and calls to end all use of asbestos by many organisations including the World Health Organization, the World Federation of Public Health Associations, the International Commission on Occupational Health, the International Social Security Association, the International Trade Union Confederation and the World Bank, the use of asbestos is increasing in low-to-middle income countries. There is little awareness in these countries of the risk that asbestos poses to health; in addition, safety regulations are weak to non-existent. If unstopped, this continued and increasing use of asbestos will lead to a public health disaster of asbestos-related illness and premature death for decades to come in those countries, repeating the epidemic we are witnessing today in industrialised countries that used asbestos in the past.

[1] IARC, 2012; LaDou et al, 2010; ATSDR, 2001; NTP, 2011; NIOSH, 1972.

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Position Statement on Asbestos

The issue

Over a century ago, factory inspectors in Europe noted the harmful effects of asbestos on workers' health. Since the 1960s, the scientific evidence has become overwhelming that occupational and environmental exposure to asbestos can cause asbestosis, lung cancer, and mesothelioma. More recently, additional lung diseases and other cancers have been added to the list of diseases resulting from asbestos exposure; these include ovarian and laryngeal cancers (IARC, 2012).

In countries in which asbestos has been mined or used, epidemics of asbestos-related diseases have followed. Indeed, over the ten-year period from 1999 to 2008, 70% of deaths from occupational diseases in the Canadian province of Quebec were estimated to be caused by asbestos (Commission de la santé et de la sécurité du travail du Québec, 2010), and asbestos is the biggest single cause of occupational disease across Canada.

Asbestos used in buildings, houses, and ships releases harmful – and potentially lethal – fibres when these structures deteriorate, are renovated or demolished. Government health authorities in privileged, technologically advanced jurisdictions, such as Quebec, Canada, state that it is impossible for any form of asbestos to be used safely – even in their own highly regulated jurisdictions (Quebec, Public Health Directors, 2011).

As a legacy of past use of asbestos, the number of cases of asbestos-related diseases continues to climb every year across Canada and in many other industrialised countries. Consequently, the countries that used asbestos in the past, such as Canada, the United States (US), Australia, and throughout Europe, have either adopted a legal ban, or have virtually ceased using asbestos altogether.

Following the same types of strategies that were used by the tobacco industry (McCulloch and Tweedale, 2008; Michaels, 2008), the global asbestos industry targets low-to-middle income countries where there is limited awareness of the harm caused by the substance and where safety

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protections are weak to non-existent. Also, the asbestos industry denies the scientific evidence concerning harm and uses its political and economic power to promote the use of asbestos in low-to-middle income countries, claiming that it is an excellent and safe product. An international trend has emerged, exemplified by Asia. Le et al. (2011) demonstrate that the proportion of global asbestos use attributed to Asia has been steadily increasing over the years from 14% (1920–1970) to 33% (1971–2000) to 64% (2001–2007). This increase has been reflected in the absolute level of per capita use across a wide range of countries in Asia. For example, in both India and China, the per capita asbestos use has increased. In India, it has increased from 0.04 to 0.13 to 0.20 kg/capita/year over the three successive time periods; and, in China, the increase has gone from 0.07 to 0.24 to 0.39. In other Asian countries, bans on asbestos use are reflected in decreases over the same three time periods.

The continued promotion of asbestos mining and use will result in a continuing epidemic of asbestos-related diseases and death. The situation is particularly unfortunate in that there are safe substitutes[2] for asbestos, as well as the knowledge and means to prevent this epidemic. It is now important that the science of epidemiology be brought to bear in preventive policy.

Context

Recently, the International Agency for Research on Cancer (IARC, 2012) – the highly respected cancer agency of the World Health Organization, a scientific review body – concluded that: "There is sufficient evidence in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary." This assessment had been previously reached by the Collegium Ramazzini (2004, 2010; and LaDou et al., 2010). Furthermore, broad-based objective assessments have also been undertaken by public policy and/or regulatory agencies including the ATSDR (2001), EPA (1986), ILO (2006), WHO (2006), APHA (2009), and CPHA (2009). All have concluded that asbestos – in all of its different forms – is both an occupational and an environmental hazard responsible for on-going increases in the number of cases of mesothelioma, lung cancer, asbestosis, and other diseases.

[2] See Appendix 4, page 14, at The World Bank Guidance Note on Asbestos, 2009 "Some Alternatives to Asbestos-Containing Products" at http://siteresources.worldbank.org/EXTPOPS/Resources/AsbestosGuidanceNoteFinal.pdf

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the harms the substance can cause. It also requires exporting countries to provide information on the safety measures necessary to protect importing country workers and the local population from harm throughout the life cycle of the substance. Warning labels on the packaging of the substance are also mandatory. The Convention thus enables importing countries to make a prior, informed decision regarding their capability to manage the substance safely and gives them the right to refuse importation.

The Convention is organised on two levels: one scientific and the other political. On the political level, any one country can obstruct a recommendation of its scientific review panel. Indeed, Canada, along with Kazakhstan, Kyrgyzstan, Ukraine, and Vietnam, refused the listing of chrysotile asbestos (the only form of asbestos still mined and traded) as a hazardous substance under the Rotterdam Convention in 2011, thus allowing the trade in asbestos to continue without warnings as to its harmful effects. In fact, attempts to list chrysotile asbestos at each of the two previous Conferences were also obstructed by at least one of these five countries.

Asbestos

Asbestos is the generic name for a variety of silicate minerals whose crystals occur in fibrous forms. Asbestos minerals are divided into two main groups, based on their fibre structure: serpentine (which includes only chrysotile or white asbestos), and amphibole (which includes amosite, crocidolite, anthophyllite, tremolite, and actinolite). Chrysotile asbestos accounts for approximately 95% of all asbestos used in the 20th century (Virta, 2006).

Where is asbestos being used, and how much?

In the past century, asbestos was widely used in industrialised countries for a variety of purposes in buildings and in transportation and electrical systems. However, more than 50 countries, including all of the European Union, have now banned asbestos products. Other industrialised countries, such as the US and Canada, although having not officially banned asbestos, have virtually stopped using it in their own domestic industries. Asbestos-containing materials, such as automobile brake pads and even asbestos-containing toys, continue, however, to be imported into Canada and the US. Furthermore, asbestos is in place in many areas where human exposure is possible, including private and institutional housing (in flooring, walls, electrical circuitry, and

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2,158 for India; 21,308 for Russia; 955 for Brazil (this number is the actual reported number); and 123 for Indonesia. For additional asbestos-attributable cases of lung cancer, a multiplier of 3 (with a range from 2–10) can be used for a conservative estimate of the number of lung cancer deaths (Takahashi, K., personal communication, Dec. 10, 2011). Hence, we find for China 15,321 deaths; India 6,474; Russia 63,924; Brazil 2,865; and Indonesia 369 (Le et al., 2011). Although more difficult to quantify, substantial numbers of asbestosis-related fatalities can also be expected.

It should be noted that the above-estimated "hidden" numbers are based on asbestos consumption (not production) up to the year 1970. Because this group of countries, on average, quintupled consumption since 1970, a future surge of asbestos related diseases in Asia should be anticipated in the coming decades (Le et al., 2011). Takahashi and colleagues are developing predictive models to extend this work (personal communication, December 10, 2011).

As noted previously, international agencies such as the International Agency for Research on Cancer (IARC, 2012) have determined that all forms of asbestos are carcinogenic to humans, and can cause mesothelioma and cancers of the lung, larynx and ovary. Indeed, Straif et al. (2009) reported in *The Lancet* on the then-recent IARC findings as follows: "Epidemiological evidence has increasingly shown an association of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) with an increased risk of lung cancer and mesothelioma." Asbestos exposure is also responsible for other non-cancer morbidity, such as asbestosis (fibrosis of the lungs), pleural plaques, pleural thickening, and pleural effusions.

The World Health Organization (WHO, 2006) states that about 125 million people in the world are currently exposed to asbestos in the workplace. According to the most recent WHO estimates, more than 107,000 people die each year from asbestos-related lung cancer, mesothelioma, and asbestosis resulting from exposure at work; one in every three deaths from occupational cancer is estimated to be caused by asbestos. In addition, it is estimated that several thousand deaths annually can be attributed to exposure to asbestos in the environment, particularly in the home. Indeed, asbestos is still used in brake linings that people may replace at home, and, in the course of home renovations, asbestos can be released. Its presence is thus

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environmentally pervasive, albeit generally at relatively lower levels than in the workplace. Because the extent of environmental exposure among the general public is methodologically difficult to assess, there are few studies directly documenting what the attributable risk is in the general population.

What is asbestos being used for today?

Approximately 90% of asbestos produced today is used in asbestos-cement materials, such as roofing, pipes, and water storage tanks, primarily in low-to-middle income countries (Collegium Ramazzini, 2010). The remainder is used in other products, including friction materials such as brake pads, gaskets, certain plastics, and industrial textiles.

Epidemiologic evidence

A large number of studies have reported an excess of mesothelioma and lung cancer among workers who were predominantly exposed to chrysotile asbestos (Kanarek, 2011). For example, excess mortality from lung cancer and mesothelioma has been reported among miners and millers in Quebec (Liddell et al., 1997), among textile workers in South Carolina (Hein et al., 2007) and North Carolina (Loomis et al., 2009), Chinese chrysotile production workers (Wang et al., 2012), and in Italian miners (Pira et al., 2009) exposed primarily to chrysotile asbestos.

There has been some suggestion that the cases of mesothelioma may be due to contamination of chrysotile ores by amphiboles. Truly "pure" exposures to any one form of asbestos in a large cohort may be difficult to study because most exposures described in the literature involve at least some mixture of fibre types. This said, there have been examples of relatively "pure" exposures, and again, such epidemiologic data are consistent with the proposition that all forms of asbestos can cause mesothelioma. For example, an Italian chrysotile mining cohort in Balangero, Italy, has been followed up over the years (Piolatto, 1990; Mirabelli, 2008) and has demonstrated a statistically significant four-fold excess (6 cases vs. 1.5 expected) of pleural mesothelioma among blue-collar workers, and also among other classes of workers as well as among allied workers (Mirabelli, 2008). The chrysotile mined at Balangero was reported to be free of tremolite and other amphiboles. While the ore contains trace amounts of another fibre called balangeroite, this is not an amphibole and is unlikely to be responsible for the excess of

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mesothelioma found in Balangero in past and more recent studies (Turci et al., 2009).

The Canadian asbestos industry is largely responsible for creating and advancing the idea that chrysotile asbestos is safer than asbestos of other fibre types (McCulloch and Tweedale, 2008). Egilman and colleagues (2003) previously evaluated published and unpublished studies carried out by researchers at McGill University and funded by the Quebec Asbestos Mining Association (QAMA). These QAMA-funded researchers had claimed that Quebec-mined chrysotile was essentially harmless and that the contamination of chrysotile with oils, tremolite or crocidolite was the source of occupational health risk. Careful review of these claims revealed unsound selection, sampling, and analytical techniques, with the rejection of their contention that chrysotile was "essentially innocuous". Nevertheless, these refuted QAMA-funded studies have been used to promote the marketing and sale of asbestos, with a substantial effect on policy and occupational health litigation (Egilman et al., 2003; Bohme et al., 2005).

Yano and colleagues (2001), in a 25-year longitudinal study, followed a cohort of 515 male asbestos plant workers exposed to chrysotile only; the control cohort included 650 non-dust-exposed workers. Mortality from all causes, all cancers, and lung cancer was related to asbestos exposure; the relative risks, adjusted for age and smoking, were 2.9, 4.3, and 6.6, respectively. The adjusted relative risk of lung cancer was 8.1 for workers exposed to high versus low levels of asbestos. The authors conclude that exposure to pure chrysotile asbestos can cause lung cancer and malignant mesothelioma in exposed workers (Yano et al., 2001). Other researchers have demonstrated that chrysotile without tremolite can cause peritoneal mesothelioma (Egilman and Menéndez, 2011).

The main controversies today are about relative potency of the different types of asbestos and not about causality. There has been a continuing debate in the literature about the mesotheliogenic potency of chrysotile asbestos relative to other forms of asbestos (Hodgson and Darnton, 2000). The Hodgson and Darnton (2000) article was a quantitative risk assessment (QRA) performed for regulatory purposes. QRA on the relative potency of the different forms of asbestos fibre types has been rejected on the grounds of inadequate data (Kane letter to EPA, 2008). However, Hodgson and Darnton (2000) estimated that, on a fibre-for-fibre basis, the risk ratio from crocidolite to amosite to chrysotile was '500:100:1' for mesothelioma.

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After the Carolina cohort update by Loomis et al. (2009), Hodgson and Darnton modified their estimates, increasing the mesothelioma potency of chrysotile in their QRA model by a factor of 10; by increasing the potency of chrysotile by one order of magnitude, their relative potency ratio is now reduced from '500:100:1' to '50:10:1' (Hodgson and Darnton, 2009). This change reveals the instabilities of regulatory exercises in QRA on the relative potency estimates of the various forms of asbestos.

In their most recent publication, Loomis et al. (2012) conclude that exposure to chrysotile fibres of all sizes is associated with excess lung cancer in asbestos textile workers. Exposure to fibres throughout the range of length and diameter is significantly associated with increased risk of lung cancer. The association is strongest and most consistent for long, thin fibres.

More broadly, evidence from other scientific disciplines also demonstrates that chrysotile alone causes not only lung cancers (and asbestosis), but also pleural and peritoneal mesothelioma. All forms of study – electron microscopy (Frank et al., 1998), biological assessments (Upadhyaya and Kamp, 2003; Wu et al., 2000), inhalation toxicology (Wagner et al., 1974), and autopsies (Suzuki and Yuen, 2002) – indicate that chrysotile, uncontaminated with amphiboles, causes mesothelioma in both animals and humans.

The general consensus today is that chrysotile is less potent than amphiboles for the induction of mesothelioma. However, there is no question as to its significant potency in the causation of lung cancer, other lung diseases, and other cancers (Hodgson and Darnton, 2000; IARC, 2012). Indeed, chrysotile may be as potent as amphiboles in the causation of lung cancer (Stayner et al., 1996). At least three excess lung cancer cases have been observed for each mesothelioma case in most epidemiologic investigations. Thus, even with chrysotile being deemed less potent than the amphiboles for mesothelioma, the overall risk of cancer does not vary substantially by fibre type.

While smoking does not contribute to the development of mesothelioma, the interactive, synergistic and close to multiplicative effects of exposures to both tobacco and asbestos have been demonstrated in the development of lung cancer (Selikoff et al., 1968; Schottenfeld, 2010).

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Indeed, according to the Agency for Toxic Substances and Disease Registry (ATSDR, 2006), when a cigarette smoker is exposed to asbestos, his/her risk of lung cancer increases by 50 to 84 times.

Finally, the countries being targeted for asbestos exports also tend to have some of the poorest urban air quality, both from particulate matter and other airborne pollutants. It is noteworthy that since these pose an increased risk for lung cancer, adding yet another carcinogen (i.e., asbestos) to the mix would likely make these already hazardous environments even more hazardous, further increasing the health burdens on those countries.

Position of the World Health Organization (WHO)

The WHO's efforts to eliminate asbestos-related diseases are targeted, in particular, at countries that continue to use chrysotile asbestos. The WHO depends for its policy positions on the recommendations provided by its scientific affiliate, the International Agency for Research on Cancer (IARC). IARC is part of the WHO, its mission being to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer prevention and control. The most current and pertinent document from IARC (2012) has been referenced above.

The WHO (2006) has called for an end to the use of all types of asbestos as the most effective way to eliminate asbestos-related diseases. It has expressed particular concern regarding the use of asbestos-cement in the construction industry. The workforce involved is large, exposure is difficult to control, and in-place materials have the potential to deteriorate and pose a risk to those carrying out alterations, maintenance, and demolition. The WHO recommends that asbestos be replaced by certain fibrous materials and other products that pose less or no risk to health.

Position of the International Labour Organization

The International Labour Organization (ILO, 2006) has stated that "the elimination of the future use of asbestos and the identification and proper management of asbestos currently in place are the most effective means to protect workers."

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Position of the World Bank

The World Bank Group's guidance document on asbestos (2009) urges that asbestos-containing building materials be avoided in new construction, including disaster relief. It describes the dangers throughout the life cycle of asbestos used in construction materials:

> *"From the industrial hygiene viewpoint, asbestos creates a chain of exposure from the time it is mined until it returns to the earth at the landfill or an unauthorized disposal site. At each link in the chain, occupational and community exposures co-exist. Workers in the mines are exposed to the fibres while extracting the ore; their families breathe fibres brought home on their work clothes. Workers in the mills and factories process the fibre and manufacture products with it; their families are also secondarily exposed. Communities around the mines, mills and factories are contaminated with their wastes; children play on tailings piles and in contaminated schoolyards; transportation of fibre and products contaminate roads and right-of-ways. Tradesmen who install, repair and remove asbestos-containing materials are exposed in the course of their work, as are bystanders in the absence of proper controls. Disposal of asbestos wastes from any step in this sequence not only exposes the workers handling the wastes, but also local residents when fibres become airborne due to insufficient covering and erosion control. Finally, the cycle is often repeated when discarded material is scavenged and re-used in the absence of measures to remove asbestos-containing materials from the waste stream and dispose of them properly."*

Position of leading international health and trade union organisations

The World Federation of Public Health Associations (2005), the International Commission on Occupational Health (2000), the International Social Security Association (2004), and the International Trade Union Confederation (2004) – representing 175 million workers in 151 countries – have all called for a global ban on the use of all forms of asbestos, particularly chrysotile.

The Building and Wood Workers' International (1989), representing approximately 12 million members in 130 countries, has dedicated particular effort to achieving a worldwide ban on chrysotile asbestos. They persist in their efforts because so many construction and maintenance workers around the world have died from asbestos-related diseases.

asbestos. Indeed, this tactic is presently being employed in India, Brazil, and Thailand (documentation available on request[4]).

We thus believe that it is of critical importance to take a clear position in support of the objective scientific evidence that has been accumulated and reviewed by trusted, independent agencies and individual expert scientists, and in support of the health of the public. With irrefutable scientific evidence of harm to human health resulting from exposure to all forms of asbestos, we hereby express our grave concern that governments – particularly in Brazil, Canada, China, India, Indonesia, Iran, Kazakhstan, Russia, Sri Lanka, Thailand, Ukraine, Uzbekistan, and Vietnam – are recklessly putting not only their own citizens in peril by allowing asbestos mining and trading to take place, but also those people in countries where asbestos products continue to be used. We call upon these countries, consistent with the International Covenant on Economic, Social and Cultural Rights (UN General Assembly, 1966), to give priority to the right to health for all, including the workers and populations of asbestos-importing countries.

[4] The asbestos industry has served legal documents on several scientists, threatening to sue them in court. As of our Position Statement date, no case has proceeded to the courts.

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Therefore, the Joint Policy Committee of the Societies of Epidemiology:

- Calls for a global ban on the mining, use, and export of all forms of asbestos;
- Calls specifically on the major asbestos exporting countries – Brazil, Canada, Kazakhstan, and Russia – to respect the right to health by ceasing the mining, use, and export of asbestos, and providing transition assistance to their asbestos-mining communities;
- Calls specifically on the major asbestos-using countries – Brazil, China, India, Indonesia, Iran, Kazakhstan, Russia, Sri Lanka, Thailand, Ukraine, Uzbekistan, and Vietnam – to cease use of asbestos;
- Urges sister societies of epidemiology and/or public health organisations and agencies, particularly in those countries that continue to mine, use and/or export asbestos, such as Brazil, Canada, China, India, Indonesia, Iran, Kazakhstan, Russia, Sri Lanka, Thailand, Ukraine, Uzbekistan, and Vietnam, to adopt a position calling for a ban on the mining, use, and export of all forms of asbestos;
- Urges all countries that have used asbestos to inform their citizens and their healthcare professionals of the hazards of asbestos and to implement safety measures to monitor the health of exposed citizens. To facilitate this, an inventory of asbestos already in place is needed, particularly in schools and places where children are present; and
- Urges all sister societies of epidemiology and/or public health organisations and agencies to support the right of scientists and academics to carry out their work free from intimidation. In situations where the asbestos industry files legal cases to silence scientists and academics, societies of epidemiology and/or public health organisations and agencies are urged to examine the situation and, if warranted by the facts, to support the scientists or academics being threatened and to denounce such tactics of intimidation. The procedure developed by the International Society for Environmental Epidemiology for dealing with beleaguered colleagues could be followed as a model. It is available at: http://www.iseepi.org/About/Docs/iseeprocedurefordealingwithbeleagueredcolleagues.pdf

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[5] Online citations were valid as of at least May 29, 2012. PDFs of other citations are available on request (to JPCSE.Asbestos@gmail.com), if permitted by copyright regulations.

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APPENDICES

Three appendices follow. Each of them is devoted to a category of endorser.

- Appendix A: JPC-SE Member-Society Endorsements
- Appendix B: Organisation/Association Endorsements
- Appendix C: Individual Endorsements

Since we anticipate that additional professional organisations and individual professionals may endorse this Position Statement over time, we shall maintain an on-going list of such parties.

Please register a professional organisation or agency endorsement by sending a signed letter on letterhead to JPCSE.Asbestos@gmail.com (or mailing it to Dr. Weiss care of the JPC-SE address on the cover page), providing the official full name of the organisation and its address, a statement to the effect that this endorsement was officially approved with date of approval, and contact information for whom you designate as a contact of your organisation including their full name, address, city, state or province, country, and e-mail address; their e-mail address will be listed.

Please register an individual endorsement by e-mailing JPCSE.Asbestos@gmail.com, providing your last name, first name plus initials, institutional affiliation, city, state or province, country, and e-mail address. Your e-mail address will not be listed.

Interested parties may contact us at the above e-mail address for an updated list of those who have endorsed this Position Statement.

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APPENDIX A

NINE JPC-SE MEMBER ORGANISATIONS HAVE ENDORSED THE POSITION STATEMENT ON ASBESTOS AS OF JULY 24, 2012*

Member Organisation	Organisation contact(s):	e-Mail address(es)
JPC-SE Chair	Stanley H. Weiss	JPCSE.Chair@gmail.com
• **American College of Epidemiology (ACE)**	Robert A. Hiatt Robert E. McKeown	rhiatt@epi.ucsf.edu rmckeown@mailbox.sc.edu
• **American Public Health Association (APHA), Epidemiology Section**	James A. Gaudino, Jr. Wiley D. Jenkins Robin Taylor Wilson	jag8nw@comcast.net wjenkins@siumed.edu rwilson@psu.edu
• **Canadian Society for Epidemiology and Biostatistics (CSEB)**	Colin L. Soskolne	colin.soskolne@ualberta.ca
• **Council of State and Territorial Epidemiologists (CSTE)**	Pat McConnon	pmcconnon@cste.org
• **International Epidemiological Association (IEA)**	Eduardo Franco	eduardo.franco@mcgill.ca
• **International Society for Environmental Epidemiology (ISEE)**	Wael Al-Delaimy	waldelaimy@ucsd.edu
• **National Association of County & City Health Officials (NACCHO) Epidemiology Workgroup**	E. Oscar Alleyne	alleyneo@co.rockland.ny.us
• **Society for Epidemiologic Research (SER)**	Sandro Galea	sgalea@columbia.edu
• **Society for the Analysis of African American Public Health Issues (SAAPHI)**	Rebecca Hasson	hassonr@umich.edu

* For some organisations, some board members may have abstained from voting or voted against support for the Position Statement; the reader may obtain further information directly from the organisational contact listed. Organisation names are alphabetic, along with their designated contact(s) and respective e-mail address(es).

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APPENDIX B: ENDORSEMENTS FROM ORGANISATIONS

The following epidemiology societies, public health organisations and public health agencies (not presently members of the JPC-SE), and the following public interest organisations have endorsed the JPC-SE Position Statement on Asbestos as of July 24, 2012.

Organisation names are alphabetic. For any further information, contact JPCSE.Asbestos@gmail.com.

ABREA-Associação Brasileira dos Expostos ao Amianto (Brazilian Association of Exposed People to Asbestos**),** Brazil. Eliezer João de Souza, President.

Alliance de la Fonction publique du Canada/ Public Service Alliance of Canada, Ottawa, ON, Canada. Denis St-Jean, National Health & Safety Officer.

American Public Health Association (APHA), Washington DC, USA. Donald Hoppert.

American Public Health Association (APHA) Occupational Health and Safety Section, Washington DC, USA. Walter A. Jones, Section Chair.

Asbestos Disease Awareness Organization (ADAO), USA. Linda Reinstein, President/CEO.

Asbestos-related Research, Education & Advocacy Fund, Canada. Tracy Ford.

Asbestos Victims Support Groups Forum – UK, United Kingdom.
Tony Whitston.

Asian Ban Asbestos Network (A-BAN). Sugio Furua.

Asian Network for the Rights of Occupational and Environmental Victims (ANROEV), Secretariat, New Delhi, India. Mohit Gupta, Coordinator.

Associated Labor Unions-Trade union Congress of the Philippines (ALU-TUCP).
Gerard R. Seno, National Vice President.

Association belge des victimes de l'amiante (ABEVA), Belgium. Président, Eric Jonckheere.

Association Nationale de Défense des Victimes de l'Amiante (ANDEVA), France. Marc Hindry.

A Walk to Remember Victims of Asbestos, Guelph, Canada. Leah Nielsen.

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Ban Asbestos India. Gopal Krishna.

Ban Asbestos Network Japan (BANJAN). Fuyushi Nagakura.

Ban Asbestos Secretariat, UK. Laurie Kazan-Allen, Co-ordinator.

Barrow Trades Union Council, UK. Robert Pointer, Secretary.

Building and Woodworkers International. Fiona Murie, Director Health and Safety, and Construction.

Campaign to Control Cancer, Canada. Pat Kelly**,** CEO.

Canadian Association of Physicians for the Environment/Association Canadienne des Médecins pour l'Environnement. Jean Zigby, MD, President.

Canadian Cancer Society. Paul Lapierre, Vice-President, Public Affairs and Cancer Control.

Canadian Environmental Law Association, Toronto, ON, Canada

Canadian Health Coalition (Canada). Michael McBane, Executive Director.

Canadian Medical Association. Owen Adams,Vice President, Health Policy and Research.

Canadian Public Health Association. Erica Di Ruggiero, Chair.

Canadian Nurses for Health and the Environment. Hilda Swirsky, RN, BScN, MEd President.

Canadian Union of Public Employees, Ottawa, ON, Canada. Anthony Pizzino , National Director, Research, Job Evaluation, Health and Safety.

Canadian Voices of Asbestos Victims. Stacy Cattran.

Collegium Ramazzini, Italy. Dr. Morando Soffritti, MD, Secretary General.

Construction Safety Campaign, UK. Pete Farrell, Chairman.

Cumbria Asbestos-Related Disease Support (CARDS), UK. Dr Helen Clayson.

David Suzuki Foundation, Canada. Mara Kerry, Director, Science and Policy.

Environmental Health Trust, Teton Village, WY, USA. Devra Davis, President.

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European Federation of Building and Woodworkers. Rolf Gehring.

Families Against Corporate Killers, UK, Linzi Herbertson.

Greater Manchester Hazards Centre Ltd, UK. Hilda Palmer, Co-ordinator.

Indian Association of Occupational Health. Dr M V Sreenivasan, President.

Japan Occupational Safety and Health Resource Center (JOSHRC).
Shinichiro Sawada.

Japan Association of Asbestos-Related Disease Victims and Their Families.
Kazuko Furukawa.

Korean Society of Environmental Health. Professor Domyung Paek.

La Coalition Pour que le Québec ait meilleure mine! Ugo Lapointe, porte-parole.

London Hazards Centre, UK, Margaret Sharkey.

Marystown Shipyard Families Alliance committee, Newfoundland, Canada.
Bernadine Bennett, Co chair.

Merseyside Asbestos Victim Support Group, UK. John Flanagan.

Mick Knighton Mesothelioma Research Fund and North East Mesothelioma Support Groups, United Kingdom. Chris Knighton.

MiningWatch Canada. Ramsey Hart, Canada Program Coordinator.

National Hazards Campaign, UK. Hilda Palmer, Chair.

Northeast Asbestos Support & Awareness Group, United Kingdom.
Bob Stephenson, Co-ordinator.

Occupational and Environmental Health Coalition – Peterborough, Canada. Marion Burton, Co-Chair.

Occupational Knowledge International, San Francisco, USA. Perry Gottesfeld, Executive Director.

Occupational and Environmental Health Network of India (OEHNI). Coordinator, Mohit Gupta.

Occupational Health & Safety Association, Ahmedabad, India. R.K.Manwar, Secretary.

Peoples Training & Research Centre, India. Jagdish Patel.

Prevent Cancer Now, Canada. Diana Daghofer, Co-Chair.

Registered Nurses' Association of Ontario, Toronto, ON, Canada. Robert Milling, Director of Health and Nursing Policy.

SARAG Asbestos Victim Support Group, UK. Paula Walker.

Saskatchewan Asbestos Disease Awareness Organization. Howard Willems, co-founder and Chairperson.

School of Public Health and Family Medicine, University of Cape Town, South Africa. Prof Mohamed F Jeebhay.

Sciencecorps, Lexington, MA, USA. Kathleen Burns, Ph.D., Director.

Scottish Hazards. Kathy Jenkins.

Sierra Club Canada, John Bennett, Executive Director.

Société pour Vaincre la Pollution. Daniel Green, président.

Victims of Asbestos/Industrial Disease. Lucie Bechard, Co-founder & Chair.

Women International for a Common Future, Germany, France, The Netherlands (WICF). Alexandra Caterbow.

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APPENDIX C: ENDORSEMENTS FROM INDIVIDUALS

The following individuals have endorsed the JPC-SE Position Statement on Asbestos as of July 24, 2012:

Names are alphabetic, with degree(s) or professional designation(s), and city, state or province, and country.

NOTE: ***Institutions and other affiliations provided for identification purposes only.***

**** Individuals who are current members of the JPC-SE are indicated by an asterisk.***

Elia Abi-Jaoude, MSc, MD, FRCPC, Toronto, Canada

Jason Addy, LLB (Hons), Doctoral researcher of occupational and environmental disease policy and law, Manchester Metropolitan University, School of Law, UK

*Wael K. Al-Delaimy, MD, PhD, Professor and Chief, Division of Global Health, Department of Family and Preventive Medicine, University of California, San Diego, CA, USA

* Elquemedo Oscar Alleyne, PhD, MPH, Director of Epidemiology & Public Health Planning, Rockland County Department of Health, Pomona, NY, USA

Louise Authier, MD, CMFC, FCMFC, Professeur titulaire de clinique, Directrice du programme de résidence de médecine de famille, Département de médecine familiale et de médecine d'urgence, Faculté de médecine, Université de Montréal, Québec, Canada

Micheline Beaudry, PhD, professeure retraitée, Université Laval, Québec, Canada

Warren Bell, Past Founding President, CAPE; past president, Physicians for Global Survival, British Columbia, Canada

*Jonine L. Bernstein, PhD, Co-Chair, 2011 Congress of Epidemiology (Montreal, Canada); Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center, New York, NY, USA

Pierre Biron, MD, professeur retraité, Faculté de médecine, Université de Montréal, St-Laurent, Québec, Canada

John Bogden, PhD, Professor, New Jersey Medical School, Preventive Medicine & Community Health; Newark, NJ, USA

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Susanna Bohme, PhD, Lecturer, Department of History, Philosophy and Social Sciences, Rhode Island School of Design, Providence, RI; Deputy Editor, International Journal of Occupational and Environmental Health (IJOEH), USA

David R. Boyd, PhD, JD, Adjunct Professor, Resource and Environmental Management, Simon Fraser University, British Columbia, Canada

Ray Bustinza, MSc, MGP, Québec, Canada

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EXHIBIT 29

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ASBESTOS (CHRYSOTILE, AMOSITE, CROCIDOLITE, TREMOLITE, ACTINOLITE, AND ANTHOPHYLLITE)

Asbestos was considered by previous IARC Working Groups in 1972, 1976, and 1987 (IARC, 1973, 1977, 1987a). Since that time, new data have become available, these have been incorporated in the *Monograph*, and taken into consideration in the present evaluation.

1. Exposure Data

1.1 Identification of the agent

Asbestos is the generic commercial designation for a group of naturally occurring mineral silicate fibres of the serpentine and amphibole series. These include the serpentine mineral chrysotile (also known as 'white asbestos'), and the five amphibole minerals – actinolite, amosite (also known as 'brown asbestos'), anthophyllite, crocidolite (also known as 'blue asbestos'), and tremolite (IARC, 1973; USGS, 2001). The conclusions reached in this *Monograph* about asbestos and its carcinogenic risks apply to these six types of fibres wherever they are found, and that includes talc containing asbestiform fibres. Erionite (fibrous aluminosilicate) is evaluated in a separate *Monograph* in this volume.

Common names, Chemical Abstracts Service (CAS) Registry numbers and idealized chemical formulae for the six fibrous silicates designated as 'asbestos' are presented in Table 1.1. Specific chemical and physical properties are also presented.

1.2 Chemical and physical properties of the agent

The silicate tetrahedron (SiO_4) is the basic chemical unit of all silicate minerals. The number of tetrahedra in the crystal structure and how they are arranged determine how a silicate mineral is classified.

Serpentine silicates are classified as 'sheet silicates' because the tetrahedra are arranged to form sheets. Amphibole silicates are classified as 'chain silicates' because the tetrahedra are arranged to form a double chain of two rows aligned side by side. Magnesium is coordinated with the oxygen atom in serpentine silicates. In amphibole silicates, cationic elements such as aluminium, calcium, iron, magnesium, potassium, and sodium are attached to the tetrahedra. Amphiboles are distinguished from one another by their chemical composition. The chemical formulas of asbestos minerals are idealized. In

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Table 1.1 Common names, CAS numbers, synonyms, non-asbestos mineral analogues, idealized chemical formulae, selected physical and chemical properties of asbestos minerals

Common Name	CAS No.	Synonyms	Non-Asbestos Mineral Analogue	Idealized Chemical Formula	Colour	Decomposition Temperature (°C)	Other Properties
Asbestos	1332-21-4*	Unspecified		Unspecified			
Serpentine group of minerals							
Chrysotile	12001-29-5*	Serpentine asbestos; white asbestos	Lizardite, antigorite	$[Mg_3Si_2O_5(OH)_4]_n$	White, grey, green, yellowish	600–850	Curled sheet silicate, hollow central core; fibre bundle lengths = several mm to more than 10 cm; fibres more flexible than amphiboles; net positive surface charge; forms a stable suspension in water; fibres degrade in dilute acids
Amphibole group of minerals							
Crocidolite	12001-28-4*	Blue asbestos	Riebeckite	$[NaFe^{2+}_3Fe^{3+}_2Si_8O_{22}(OH)_2]_n$	Lavender, blue green	400–900	Double chain silicate; shorter, thinner fibres than other amphiboles, but not as thin as chrysotile; fibre flexibility: fair to good; spinnability: fair; resistance to acids: good; less heat resistance than other asbestos fibres; usually contains organic impurities, including low levels of PAHs; negative surface charge in water
Amosite	12172-73-5*	Brown asbestos	Grunerite	$[(Mg,Fe^{2+})_7Si_8O_{22}(OH)_2]_n$	Brown, grey, greenish	600–900	Double chain silicate; long, straight, coarse fibres; fibre flexibility: somewhat; resistance to acids: somewhat; occurs with more iron than magnesium; negative surface charge in water
Anthophyllite	17068-78-9*	Ferroanthophyllite; azbolen asbestos	Anthophyllite	$[(Mg, Fe^{2+})_7Si_8O_{22}(OH)_2]_n$	Grey, white, brown-grey, green	NR	Double chain silicate; short, very brittle fibres; resistance to acids: very; relatively rare; occasionally occurs as contaminant in talc deposits; negative surface charge in water
Actinolite	12172-67-7*	Unspecified	Actinolite	$[Ca_2(Mg, Fe^{2+})_5Si_8O_{22}(OH)_2]_n$	Green	NR	Double chain silicate; brittle fibres; resistance to acids: none; occurs in asbestiform and non-asbestiform habit; iron-substituted derivative of tremolite; common contaminant in amosite deposits; negative surface charge in water
Tremolite	14567-73-8*	Silicic acid; calcium magnesium salt (8:4)	Tremolite	$[Ca_2Mg_5Si_8O_{22}(OH)_2]_n$	White to pale green	950–1040	Double chain silicate; brittle fibres; acid resistant; occurs in asbestiform and non-asbestiform habit; common contaminant in chrystotile and talc deposits; negative surface charge in water

* identified as asbestos by CAS Registry
NR, not reported
From ATSDR (2001), USGS (2001), HSE (2005), NTP (2005)

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short fibres are used to reinforce plastics, floor tiles, coatings and compounds, and roofing felts (NTP, 2005).

Since peaking in the 1970s, there has been a general decline in world production and consumption of asbestos. Peak world production was estimated to be 5.09 million metric tons in 1975, with approximately 25 countries producing asbestos and 85 countries manufacturing asbestos products (USGS, 2001; Nishikawa *et al.*, 2008). Worldwide 'apparent consumption' of asbestos (calculated as production plus imports minus exports) peaked at 4.73 million metric tons in 1980. Asbestos cement products are estimated to have accounted for 66% of world consumption in that year (Virta, 2006). In the USA, consumption of asbestos peaked in 1973 at 719000 metric tons (USGS, 2001).

Historical trends worldwide in per capita asbestos use are presented in Table 1.2, and peak use of asbestos was higher and occurred earlier in the countries of Northern and western Europe, Oceania, and the Americas (excluding South America). Very high asbestos use was recorded in Australia (5.1 kg per capita/year in the 1970s), Canada (4.4 kg per capita/year in the 1970s), and several countries of Northern and western Europe (Denmark: 4.8 kg per capita/year in the 1960s; Germany: 4.4 kg per capita/year in the 1970s; and Luxembourg: 5.5 kg per capita/year in the 1960s) (Nishikawa *et al.*, 2008).

Current use of asbestos varies widely. While some countries have imposed strict regulations to limit exposure and others have adopted bans, some have intervened less, and continue to use varying quantities of asbestos (Table 1.2). According to recent estimates by the US Geological Survey, world production of asbestos in 2007 was 2.20 million metric tonnes, slightly increased from 2.18 million metric ton in 2006. Six countries accounted for 96% of world production in 2006: the Russian Federation (925000 metric tons), the People's Republic of China (360000 metric tons), Kazakhstan (300000 metric tons), Brazil (227304 metric tons), Canada (185000 metric tons), and Zimbabwe (100000 metric tons) (Virta, 2008). During 2000–03, asbestos consumption increased in China, India, Kazakhstan, and the Ukraine (Virta, 2006). 'Apparent' world consumption of asbestos was 2.11 million metric tons in 2003, with the Russian Federation, several former Russian states and countries in Asia being the predominant users (Virta, 2006). Consumption of asbestos in the USA (predominantly chrysotile) was 2230 metric tons in 2006, declining to 1730 metric tons in 2007 (Virta, 2008). Roofing products (includes coatings and compounds) accounted for over 80% of asbestos consumption in the USA (Virta, 2008; Virta, 2009). Asbestos products were banned in all the countries of the European Union, including Member States of eastern Europe, effective January 1, 2005 (EU, 1999).

1.4 Environmental occurrence

1.4.1 Natural occurrence

Asbestos minerals are widespread in the environment, and are found in many areas where the original rock mass has undergone metamorphism (ATSDR, 2001; USGS, 2001). Examples include large chrysotile deposits in the Ural Mountains in the Russian Federation, in the Appalachian Mountains in the USA, and in Canada (Virta, 2006). They may occur in large natural deposits or as contaminants in other minerals (e.g. tremolite asbestos may occur in deposits of chrysotile, vermiculite, and talc). The most commonly occurring form of asbestos is chrysotile, and its fibres are found as veins in serpentine rock formations. Asbestiform amphiboles occur in relatively low quantities throughout the earth's crust and their chemical composition reflects the environment in which they form (Virta, 2002). Although most commercial deposits typically contain 5–6% of asbestos, a few deposits, such

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may be especially high for small children who drink seven times more water per day per kg of body weight than the average adult (National Academy of Sciences, 1993).

1.6 Talc containing asbestiform fibres

Talc particles are normally plate-like. These particles, when viewed on edge under the microscope in bulk samples or on air filters, may appear to be fibres, and have been misidentified as such. Talc may also form true mineral fibres that are asbestiform in habit. In some talc deposits, tremolite, anthophyllite, and actinolite may occur. Talc containing asbestiform fibres is a term that has been used inconsistently in the literature. In some contexts, it applies to talc containing asbestiform fibres of talc or talc intergrown on a nanoscale with other minerals, usually anthophyllite. In other contexts, the term asbestiform talc has erroneously been used for talc products that contain asbestos. Similarly, the term asbestiform talc has erroneously been used for talc products that contain elongated mineral fragments that are not asbestiform. These differences in the use of the same term must be considered when evaluating the literature on talc. For a more detailed evaluation of talc not containing asbestiform fibres, refer to the previous *IARC Monograph* (IARC, 2010).

1.6.1 Identification of the agent

Talc (CAS No. 14807-96-6) is a designation for both the mineral talc and for commercial products marketed as 'talc', which contain the mineral in proportions in the range of 35% to almost 100%. Commercial talc is classified as 'industrial talc' (refers to products containing minerals other than talc), 'cosmetic talc' (refers to products, such as talcum powder, which contain > 98% talc), and 'pharmaceutical talc' (refers to products containing > 99% talc) (Rohl *et al.*, 1976; Zazenski *et al.*, 1995). Synonyms for talc include: Agalite, French chalk, kerolite, snowgoose, soapstone, steatite, talcite, and talcum.

1.6.2 Chemical and physical properties of the agent

The molecular formula of talc is $Mg_3Si_4O_{10}(OH)_2$. It is a hydrated magnesium sheet silicate mineral, whose structure is composed of a layer of $MgO_4(OH)_2$ octahedra sandwiched between identical layers of SiO_4 tetrahedra. In nature, the composition of talc varies depending on whether or not the magnesium has been substituted with other cations, such as iron, nickel, chromium or manganese (Rohl *et al.*, 1976; IMA, 2005). Pure talc is translucent, appearing white when finely ground (Zazenski *et al.*, 1995). The colour of talc changes in the presence of substituted cations, ranging from pale-green to dark-green, brownish or greenish-grey. Talc has the following chemical and physical properties: melting point, 1500°C; hardness, 1 on the Moh's scale of mineral hardness; density, 2.58–2.83; and cleavage, (001) perfect (Roberts *et al.*, 1974). Talc is a very stable mineral, and is insoluble in water, weak acids and alkalis, is neither explosive nor flammable, and has very little chemical reactivity (IMA, 2005).

Talc's structure is crystalline. It can have a small, irregular plate structure (referred to as microcrystalline talc) or it can have large, well defined platelets (referred to as macrocrystalline talc). Its platyness and crystallinity determine the specific commercial applications for which it is suitable (Zazenski *et al.*, 1995). Talc is formed by complex geological processes acting on pre-existing rock formations with diverse chemical composition (Rohl *et al.*, 1976). Many talc-bearing rocks are formed from magnesia- and silica-rich ultramafic rocks. These rocks have a central core of serpentinite surrounded by successive shells of talc-abundant rock (e.g. talc carbonate and steatite). The serpentinite core is composed mostly of non-asbestiform serpentine minerals (lizardite

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and antigorite); however, small amounts of chrysotile asbestos may occur. (Zazenski *et al.*, 1995).

More detail on the chemical and physical properties of talc can be found in the previous *IARC Monograph* (IARC, 2010).

1.6.3 Use of the agent

Talc has several unique chemical and physical properties (such as platyness, softness, hydrophobicity, organophilicity, inertness) that make it desirable for a wide range of industrial and commercial applications (e.g. paint, polymers, paper, ceramics, animal feed, rubber, roofing, fertilizers, and cosmetics). In these products, talc acts as an anti-sticking and anti-caking agent, lubricant, carrier, thickener, absorbent, and strengthening and smoothing filler (IMA, 2005).

In 2000, the worldwide use pattern for talc was as follows: paper industry, 30%; ceramics manufacture, 28%; refractories, 11%; plastics, 6%; filler or pigment in paints, 5%; roofing applications, 5%; cement, 3%; cosmetics, 2%; and other miscellaneous uses, 10% (includes agriculture and food, art sculpture, asphalt filler, autobody filler, construction caulks, flooring, and joint compounds) (Roskill Information Services Ltd, 2003). According to a Mineral Commodity Summary published by the USGS in 2009, talc produced in the USA was used for ceramics, 31%; paper, 21%; paint, 19%; roofing, 8%; plastics, 5%; rubber, 4%; cosmetics, 2%; and other, 10% (Virta, 2009).

No information on the use of asbestiform talc in various industries (apart from mining and milling of talc from deposits containing asbestiform fibres) was identified by the Working Group. For a more detailed description of the uses of talc, refer to the previous *IARC Monograph* (IARC, 2010).

1.6.4 Environmental occurrence

(a) Natural occurrence

Primary talc deposits are found in almost every continent around the world. Talc is commonly formed by the hydrothermal alteration of magnesium- and iron-rich rocks (ultramafic rocks) and by low-grade thermal metamorphism of siliceous dolomites (Zazenski *et al.*, 1995). For more detailed information on the formation of commercially important talc deposits, refer to the previous *IARC Monograph* (IARC, 2010).

Talc deposits whose protoliths are ultramafic rocks (or mafic) are abundant in number but small in total production. They are found in discontinuous bodies in orogenic belts such as the Alps, the Appalachians, and the Himalayas; these types of talc deposits form during regional metamorphism accompanying orogenesis. They also occur in the USA (California, Arkansas, Texas), Germany, Norway, Canada (Ontario and Quebec), southern Spain, Finland, the Russian Federation (Shabry and Miassy), and Egypt. Chlorite and amphibole are usually associated with this type of talc deposit although they are commonly separated in space from the talc ore (Vermont). The amphiboles may or may not be asbestiform, depending on the local geological history (IARC, 2010).

Talc deposits formed from the alteration of magnesian carbonate and sandy carbonate such as dolomite and limestone are the most important in terms of world production. Two types are recognized:

- those derived from hydrothermal alteration of unmetamorphosed or minimally metamorphosed dolomite such as found in Australia (Mount Seabrook and Three Springs); USA (Wintersboro, Alabama; Yellowstone, Montana; Talc City, California; Metaline Falls, Washington; and West Texas); the Republic of Korea; the People's Republic of China; India; the

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and West Texas); the Republic of Korea; the People's Republic of China; India; the Russian Federation (Onot); and, northern Spain (Respina)

- those derived from hydrothermal alteration (including retrograde metamorphism) of regionally metamorphosed siliceous dolomites and other magnesium-rich rocks such as in the USA (Murphy Marble belt, North Carolina; Death Valley-Kingston Range, California; Gouverneur District, New York; Chatsworth, Georgia); Canada (Madoc); Italy (Chisone Valley); the Russian Federation (Krasnoyarsk); Germany (Wunsiedel); Austria (Leoben); Slovakia (Gemerska); Spain; France (Trimouns); and Brazil (Brumado) (IARC, 2010).

In a study to examine the amphibole asbestos content of commercial talc deposits in the USA, Van Gosen *et al.* (2004) found that the talc-forming environment (e.g. regional metamorphism, contact metamorphism, or hydrothermal processes) directly influenced the amphibole and amphibole-asbestos content of the talc deposit. Specifically, the study found that hydrothermal talcs consistently lack amphiboles as accessory minerals, but that contact metamorphic talcs show a strong tendency to contain amphiboles, and regional metamorphic talc bodies consistently contain amphiboles, which display a variety of compositions and habits (including asbestiform). Death Valley, California is an example of a contact metamorphic talc deposit that contains accessory amphibole-asbestos (namely talc-tremolite).

1.6.5 Human exposure

(a) Exposure of the general population

Consumer products (e.g. cosmetics, pharmaceuticals) are the primary sources of exposure to talc for the general population. Inhalation and dermal contact (i.e. through perineal application of talcum powders) are the primary routes of exposure. As talc is used as an anti-sticking agent in several food preparations (e.g. chewing gum), ingestion may also be a potential, albeit minor, route of exposure.

As late as 1973, some talc products sold in the USA contained detectable levels of chrysotile asbestos, tremolite, or anthophyllite (Rohl *et al.*, 1976), and it is possible that they remained on the market in some places in the world for some time after that (Jehan, 1984). Some of the tremolite and anthophyllite may have been asbestiform in habit (Van Gosen, 2006).

Blount (1991) examined pharmaceutical- and cosmetic-grade talcs for asbestiform amphibole content using a density-optical method. High-grade talc product samples (n = 15) were collected from deposits in Montana, Vermont, North Carolina, Alabama, and from outside the USA but available in the US market. Samples were uniformly low in amphibole content (with counts in the range of 0–341 particles/mg), and some samples appeared to be completely free of amphibole minerals. In samples containing amphibole minerals, cleavage-type and asbestos-type minerals were observed. Only one sample was found to contain an amphibole particle size distribution typical of asbestos.

More complete information on the levels of exposure experienced by the general population can be found in the previous *IARC Monograph* (IARC, 2010).

(b) Occupational exposure

Inhalation is the primary route of exposure to talc in occupational settings. Exposure by inhalation to talc dust occurs in the talc-producing industries (e.g. during mining, crushing, separating, bagging, and loading), and in the talc-using industries (e.g. rubber dusting and addition of talcs to ceramic clays and glazes). Because industrial talc is a mixture of various associated minerals, occupational exposure is to a mixture of mineral dusts (IARC, 1987b).

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and crocidolite mines, and in persons living with asbestos workers.

Extensive epidemiological research on asbestos has been conducted since then. The associations between asbestos exposure, lung cancer, and mesothelioma have been well established in numerous epidemiological investigations. The epidemiological evidence for other cancer sites is less extensive than it is for lung cancer and mesothelioma, but is still considerable for some. In reviewing these studies, there are some common limitations that need to be borne in mind, which may explain the heterogeneity of the findings from the studies such as:

- The types, fibre sizes and levels of asbestos exposure differed from industry to industry and over time. Most of the heaviest exposures probably occurred in the first two-thirds of the twentieth century in asbestos mining and milling, insulation work, shipyard work, construction, and asbestos textile manufacture. Workers in different industries, eras, and geographic locales were exposed to different types of asbestos fibres, and to fibres of greatly varying dimensions.
- There were differences in how the studies handle the issue of latency or in other words time since first occupational exposure to asbestos. Some studies, especially earlier investigations, accumulated person–years from first exposure, a procedure that may dilute observed risk by including many years of low risk. Others have only accumulated person–years after a certain period of time after first exposure, usually 20 years. Also different studies followed their populations for very different periods of time since first occupational exposure to asbestos.
- The most pervasive problem in interpreting studies was the wide variation among studies in the approaches taken for exposure assessment. Some studies made no attempt to assess exposure beyond documenting employment of study participants in a trade or industry with potential for occupational exposure to asbestos. Other studies used surrogate indices of exposure such as duration of employment or self-reported intensity of exposure, or stratified subjects' exposure by job title. Some used the skills and knowledge of industrial hygienists, obtained direct measurements of asbestos dust levels in air, and developed job–exposure matrices and cumulative exposure indices. Even these analyses are limited by the fact that earlier studies used gravimetric measures of dust exposure, while later used fibre-counting methods based on phase contrast microscopy (PCM). Factors that were used to convert between gravimetric and PCM based measurements are generally unreliable unless they are based on side by side measurements taken in specific industrial operations. Differences in fibre size distributions and fibre type can only be detected using electron microscopy, which has been done in only a very few studies.
- Misclassification of disease was a serious problem for several of the cancer sites. This is particularly true for mesothelioma, which did not have diagnostic category in the ICD system until the 10th review was initiated in 1999.

There were also issues regarding the potential for misclassification of mesotheliomas as colon or ovarian cancers.

For talc that contains asbestiform fibres, previous Working Groups assessed studies on talc described as containing asbestiform tremolite and anthophyllite (IARC, 1987a, b). These fibres fit the definition of asbestos, and therefore a separate review of talc containing asbestiform fibres was not undertaken by this Working Group. The reader is invited to consult the General Remarks

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fibres because of their similarity to asbestos, and because of public concerns regarding this issue.

Several studies have described adverse health associations with the amphibole fibres that contaminated vermiculite mined in Libby, Montana, USA. These fibres were originally characterized as from the tremolite-actinolite series (IARC, 1987a), however, they have been more recently described by the US Geological Society as approximately 84% winchite, 11% richterite, and 6% tremolite (Meeker *et al.*, 2003). Sullivan (2007) reported standardized mortality ratios (SMRs), using cause of death data and expected mortality for the underlying cause of death based on national age-, race-, and sex-specific rates. Using a 15-year exposure lag, there were increased SMRs for all cancer (SMR, 1.4; 95%CI: 1.2–1.6; $n = 202$), and lung cancer (SMR, 1.7; 95%CI: 1.4–2.1; $n = 89$). Increasing risks were observed across categories of cumulative exposure; the SMR estimates were 1.5, 1.6, 1.8, and 1.9 in the 1–4.49, 4.5–22.9, 23.0–99.0, and ≥ 100 f/mL–years exposure categories, respectively. Results from other studies (Amandus *et al.*, 1987; McDonald *et al.*, 2004) of analyses using a continuous measure of exposure also resulted in statistically significant relationships with lung cancer mortality risk. For example, in the updated analysis by McDonald *et al.* (2004), the estimated linear increase in relative risk of respiratory cancer risk per 100 f/mL–years cumulative exposure was 0.36 (95%CI: 0.03–1.2; $P = 0.02$).

2.3 Mesothelioma

Pleural and peritoneal mesotheliomas are very rare malignancies that occur in the mesothelial cells that line these cavities. The first report of a possible association between asbestos exposure and mesothelioma was by Wagner *et al.* (1960) who described an outbreak of mesothelioma in a crocidolite mining region of South Africa. The majority of the cases reported had worked in the mines (23/33) but some of the cases had also occurred among individuals with no history of occupational exposures (10/33). Since then, an excess of mesothelioma has been observed in a large number of cohort and case–control studies (summarized in online Tables 2.2, 2.3 and Table 2.4 available at http://monographs.iarc.fr/ENG/Monographs/vol100C/100C-06-Table2.4.pdf) in a variety of different industries using and producing asbestos. Although the causal association between mesothelioma and asbestos has been well established, several important issues remain to be resolved that are discussed below.

2.3.1 Fibre type

Although all forms of asbestos can cause mesothelioma, there is considerable evidence that the potency for the induction of mesothelioma varies by fibre type, and in particular that chrysotile asbestos is less potent than amphibole forms of asbestos. An excess of mesothelioma has been reported in cohort studies of chrysotile exposed miners and millers in Quebec (Liddell *et al.*, 1997), and in South Carolina asbestos textile workers who were predominantly exposed to chrysotile asbestos imported from Quebec (Hein *et al.*, 2007). However, the fact that the chrysotile asbestos mined in Quebec is contaminated with a small percentage (< 1.0%) of amphibole (tremolite) asbestos has complicated the interpretation of these findings. McDonald *et al.* (1997) found in a nested case–control study for mesothelioma in the Thetford mines of Quebec that an association with asbestos exposure was evident in mines from a region with higher concentrations of tremolite, and not in another region with lower concentrations of tremolite. Bégin *et al.* (1992) noted that although tremolite levels may be 7.5 times higher in Thetford than in Asbestos, the incidence of mesothelioma in these two Quebec mining towns was proportional to the size of their workforce. This suggests that the tremolitic content of the ores may not be a

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chemical modification) are termed biopersistent (Bernstein *et al.*, 2005). Chronic inhalation assays using man-made fibres in rodents have correlated fibre length and biopersistence with persistent inflammation, fibrosis, lung cancer, and malignant mesothelioma (Bernstein *et al.*, 2005). However, there are interspecies differences in alveolar deposition of inhaled particles and fibres that must be considered when extrapolating results of rodent inhalation studies to humans (IARC, 2002).

4.1.2 *Biopersistence of asbestos and erionite fibres*

Asbestos fibres and ferruginous bodies (described subsequently in Section 4.3.1) can be identified and quantified by tissue digestion of lung samples obtained by biopsy or at autopsy (Roggli, 1990). A variety of commercial and non-commercial asbestos fibres have been identified in residents older than 40 years of age living in an urban area with no history of occupational asbestos exposure (Churg & Warnock, 1980). These and other studies confirm that asbestos fibres are biopersistent and accumulate in lung tissue as well as lymph nodes (Dodson *et al.*, 1990; Dodson & Atkinson, 2006). Asbestos fibres have also been identified in the pleura following autopsy (Dodson *et al.*, 1990; Gibbs *et al.*, 1991; Suzuki & Yuen, 2001) and in the parietal pleural in samples collected during thoracoscopy (Boutin *et al.*, 1996). Roggli *et al.* (1980) also identified asbestos bodies in the larynx of asbestos workers at autopsy. Systemic translocation of asbestos fibres to distant organs has also been described in case reports; however, these reports should be evaluated with caution due to the numerous caveats in technical procedures used, comparison with an appropriate control population, and cross-contamination of tissue samples (Roggli, 2006). The route of translocation of asbestos fibres from the lungs to distant sites is unknown, although lymphatic translocation of amosite fibres deposited in the lungs has been shown in experimental animals (Hesterberg *et al.*, 1999; Mc Connell *et al.*, 1999; IOM, 2006; NIOSH, 2009).

Environmental exposure to erionite fibres is associated with diffuse malignant mesothelioma in three rural villages in the Cappadocia region of Turkey (Baris & Grandjean, 2006). Lung fibre digests obtained from humans in these villages showed elevated levels of erionite fibres, and ferruginous bodies surrounding erionite fibres were found in broncho-alveolar lavage fluid (Sébastien *et al.*, 1984; Dumortier *et al.*, 2001).

Talc particles have been found in the lungs at autopsy of both rural and urban residents as well as talc miners (IARC, 1987b, 2010). Talc particles are biopersistent in the lungs, and have been recovered in broncho-alveolar lavage fluid obtained from workers 21 years after cessation of occupational exposure (Dumortier *et al.*, 1989). Talc contaminated with asbestos has been linked to the development of lung cancer and malignant mesothelioma (IARC, 1987b).

The association between exposure to talc, potential retrograde translocation to the ovarian epithelium, and the development of ovarian cancer is controversial (IARC, 2010, and this volume).

The biological plausibility for an association between asbestos and ovarian cancer derives in part from the finding of asbestos fibres in the ovaries of women with potential for exposure to asbestos. Thus, a histopathological study of ovaries from 13 women who had household contact with men who had documented exposure to asbestos, and of 17 women who gave no history of potential for asbestos exposure found "significant asbestos fibre burdens" in the ovaries of nine (60.2%) of the exposed women and in only six (35%) of the unexposed women. Three of the exposed women had asbestos fibre counts in ovarian tissue of over 1 million fibres per gram (wet weight), but only one of the 17

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Table 4.5 Risk factors for the development of diffuse malignant mesothelioma

Exposure	Reference
Asbestos fibres	IARC (1987a, 2012b)
Erionite	IARC (1987a, 2012b)
Talc containing asbestiform fibres	IARC (1987a, 2012b)
Vermiculite contaminated with asbestos fibres	Amandus & Wheeler (1987), IARC (1987a, 2012e), McDonald *et al.* (2004)
Thorotrast	IARC (2001, 2012a)

Compiled by the Working Group

studies that support a role for SV40 viral oncogenes in the transformation of mesothelial cells, the human epidemiological evidence is inconclusive to support a causal association (Weiner & Neragi-Miandoab, 2009).

4.4.2 Genetic susceptibility

(a) Cancer of the lung

Tobacco smoke is the major cause of cancer of the lung; however, only a few rare hereditary syndromes are associated with an increased risk of lung, as well as other cancers: Bloom syndrome, Li-Fraumeni syndrome, and hereditary retinoblastoma (Lindor *et al.*, 2006). Other genetic polymorphisms in genes related to the metabolism and detoxification of tobacco smoke carcinogens, antioxidant defenses, and DNA repair have been suggested as predisposing factors for the development of lung cancer, although individually they contribute minimally to an increased risk (IOM, 2006). Attempts have been made to identify genetic polymorphisms in enzymes involved in xenobiotic metabolism and antioxidant defense that increase the risk for asbestos-related lung cancer; however, no consistent associations have been found (Nymark *et al.*, 2008).

(b) Diffuse malignant mesothelioma

With the exception of certain populations who have been exposed environmentally to asbestos or erionite fibres since birth (NIOSH, 2009), the development of diffuse malignant mesothelioma even in occupationally exposed workers is less common than the development of lung cancer (Nymark *et al.*, 2008). This observation has led to the hypothesis that there may be a genetic predisposition to the development of diffuse malignant mesothelioma following exposure to asbestos or erionite fibres. Isolated case reports provide examples of diffuse malignant mesothelioma in patients with neurofibromatosis type 2 (Baser *et al.*, 2002) or Li-Fraumeni syndrome (Heineman *et al.*, 1996) who are also exposed to asbestos. Several reports of familial cases of diffuse malignant mesothelioma are complicated by a common household exposure history (Weiner & Neragi-Miandoab, 2009). The strongest association between environmental exposure to erionite and genetic susceptibility to diffuse malignant mesothelioma has been provided by pedigree analysis of residents in the Cappadocia region of Turkey (Dogan *et al.*, 2006). However, there is skepticism about the accuracy of this analysis, and a recent review indicated that familial clusters can account for only 1.4% of cases of mesothelioma in Italy between 1978–2005 (Ascoli *et al.*, 2007; Ugolini *et al.*, 2008). One study has reported an association between genetic polymorphisms in the X-ray complementing group 1 gene (XRCC1) and the development of malignant mesothelioma in a population exposed to asbestos fibres (Dianzani *et al.*, 2006). More sensitive genome-wide association studies may uncover new markers for genetic susceptibility that predict increase risks of developing diffuse malignant mesothelioma following exposure to asbestos or erionite fibres.

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4.5 Synthesis

The mechanistic basis for asbestos carcinogenicity is a complex interaction between crystalline mineral fibres and target cells *in vivo*. The most important physicochemical properties of asbestos fibres related to pathogenicity are surface chemistry and reactivity, surface area, fibre dimensions, and biopersistence. Multiple direct and indirect mechanisms have been proposed based on numerous in-vitro cellular assays, and acute and subchronic animal bioassays. These complex mechanisms most likely interact at multiple stages during the development of lung cancer and diffuse malignant mesothelioma.

The following general mechanisms have been proposed for the carcinogenicity of asbestos fibres (Fig. 4.1; Fig. 4.2):

1. Direct interaction between asbestos fibres and target cells *in vitro*:
   - Asbestos and erionite fibres have been shown to generate free radicals that directly induce genotoxicity as assessed by DNA breaks and oxidized bases in DNA.
   - Asbestos fibres have also been shown to interfere with the mitotic apparatus by direct physical interaction resulting in aneuploidy and polyploidy.
2. Indirect mechanisms:
   - In laboratory animals, asbestos fibres have been shown to induce macrophage activation and persistent inflammation that generate reactive oxygen and nitrogen species contributing to tissue injury, genotoxicity, and epigenetic alterations. Persistent inflammation and chronic oxidative stress have been associated with the activation of intracellular signalling pathways, resistance to apoptosis, and stimulation of cell proliferation.

There are significant species differences in the responses of the respiratory tract to the inhalation of asbestos fibres. The biological mechanisms responsible for these species differences are unknown. Based on comparative animal experimental studies, there may be differences in deposition and clearance of fibres in the lungs, in severity of fibrosis, in kinetics of translocation of fibres to the pleura, and in levels or types of antioxidant defense mechanisms.

5. Evaluation

There is *sufficient evidence* in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary. Also positive associations have been observed between exposure to all forms of asbestos and cancer of the pharynx, stomach, and colorectum. For cancer of the colorectum, the Working Group was evenly divided as to whether the evidence was strong enough to warrant classification as *sufficient*.

There is *sufficient evidence* in experimental animals for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite).

All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) are *carcinogenic to humans (Group 1).*

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RESEARCH ARTICLE

Asbestos in Talc and Mesothelioma: Review of the Causality Using Epidemiology

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Abstract

Talcum powder has long been contaminated with asbestos fibers depending on the source of the talc. Pleural and peritoneal mesothelioma are scientifically established as caused by asbestos exposures. However, when investigating causality of mesothelioma from asbestos fibers in talcum powder, epidemiology is complicated by various methodological issues and inadequacies in existing studies. The occupational and case studies are explored in an effort to bring clarity to the issue of talcum powder usage and mesothelioma. Talc is randomly and sporadically contaminated with asbestos fibers including chrysotile, tremolite and anthophyllite. Case studies of mesothelioma victims whose only asbestos exposure was to talc, found anthophyllite, tremolite and chrysotile asbestos fibers in their tissues. Exposure to all three types of asbestos fibers increases the risk of mesothelioma. The Hill criteria of causality, which considers all aspects of toxicology, biology and epidemiology, are applied to the issue. This analysis results in compelling evidence that asbestos in talcum powder is causative for mesothelioma. Thus, precaution would dictate the avoidance of the use of talcum powders.

Keywords: talc, asbestos, mesothelioma, tremolite, anthophyllite, pleural, peritoneal, epidemiology

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1. Introduction

Talc is used for various industrial and cosmetic purposes and has long been known to be contaminated with asbestos [1-4], even though there are persisting legal based arguments about detection of asbestos fibers in talc [3,5,6]. The causal chain between asbestos and mesothelioma has been established in detail for over 50 years [7], and the epidemiology studies concerning perineal talc exposure and ovarian cancer incidence show a consistent association [7,8]. However, when investigating causality of mesothelioma from asbestos fibers in talcum powder, epidemiology is complicated by various methodological issues and inadequacies in existing studies. We aim here to explore the issues in using epidemiology to establish potential causality of talc exposures and mesothelioma.

Mesothelioma

The seminal publication associating mesothelioma of the pleura and peritoneum with exposure to asbestos was by Wagner et al in 1960. [9] Almost sixty years later, there is overwhelming evidence that asbestos is responsible for this fatal cancer. Mesothelioma from asbestos is the most definitive example of an environmental cause-effect cancer, involving a quickly fatal disease that has a long latent period. Due to the extensive occupational, community and para-occupational exposures to asbestos, a worldwide epidemic of mesothelioma has been reported.[10,11]

There are numerous epidemiological studies that have clearly linked all types of asbestos, including the amphiboles crocidolite, amosite, anthophyllite, tremolite and the serpentine chrysotile, to pleural and peritoneal mesothelioma. [7,12,13] The global magnitude of mesothelioma is estimated to be 38,900 in a group of 33 countries that report the disease. The actual number of cases is undoubtedly much greater as one mesothelioma is missed in every four or five reported cases because of the difficulty in establishing a pathologic diagnosis. [10]

There is a long history of asbestos fibers being found in mesothelioma tissue. [14-16] It is the consensus of the medical and scientific communities that there is no known threshold of exposure below which mesothelioma will not occur.[17,18,19] Multiple studies have shown that all levels of exposure to asbestos increase the risk of mesothelioma. [7,20,21] Brief or low exposures to asbestos are capable of causing mesothelioma. [22,23]. In fact, Lacourt et al.[24] found a four-fold increased risk of mesothelioma at cumulative exposure levels less than 0.1 f/cc, the U.S. occupational standard. Mesothelioma incidence is proportional to cumulative asbestos exposure. [25,26,27] Intensity and duration of asbestos exposure are determinant of mesothelioma risk. [26] The mainstream scientific community has concluded that there is no "safe" level of exposure to asbestos of any type and that "…an occupational history of brief or low-level exposure should be considered sufficient for mesothelioma to be designated occupationally related" to asbestos exposure. [28,29]

What is Talc

Talc is a hydrous silicate with a general composition of $Mg_3Si_4O_{10}(OH)_2$, but can contain major amounts of Fe, minor amounts of Al and F, and trace amounts of Mn, Ti, Cr, Ni, Ca, Na, and K. [30] There are two common names for commercial talc: industrial talc and cosmetic talc, even though the terms appear to be commercially and not scientifically derived. Industrial talc varies in composition and is a mixture of mineral particles. Industrial talc is used in the production of ceramics, paint, paper, plastics, roofing, rubber, flooring, caulking, and agricultural applications.[31] Cosmetic talc consists of pure "platiform" talc, meaning the "plates" of microscopic talc can easily slide past one another, which makes cosmetic talc feel smooth to the touch. Cosmetic talc is used in many personal care products like baby powder, adult body and face powder, as well as other make-up products.[32]

Talc used for cosmetic purposes has been taken from mines with higher purity (>95-99 percent) platy talc, free of other minerals, whereas industrial-grade talcs usually contain 75-95% or lower of the talc mineral with other non-platy components. [33]

Talc is found in geologic fault lines and is often contaminated with the amphibole asbestos types tremolite, anthophyllite and the serpentine asbestos type chrysotile. [4,7] The asbestos fibers are more often found in the talc mines used for industrial talc as compared to the cosmetic talc mines. [33]

Van Gosen et al [30] of the U.S. Geologic Survey found that many American talc deposits, including

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Gouverneur, New York, Vermont, and others, contain amphibole asbestos such as tremolite and anthophyllite. In the laboratory, talc has been shown to be contaminated with chrysotile, tremolite, and anthophyllite fibers.[34-37] Chrysotile, tremolite and anthophyllite asbestos have been shown to cause mesothelioma. [7]

3.1 Fibers, EMP's and other terminology

There is no universal method to look for asbestos fibers or particles in talc, and the terminology of the contaminating fibers or particles of asbestos, asbestiform and elongate mineral particle (EMP), is controversial and unresolved. [38]

"The term "mineral fiber" has been frequently used by nonmineralogists to encompass thoracic-size elongate mineral particles (EMPs) occurring either in an asbestiform habit (e.g., asbestos fibers) or in a nonasbestiform habit (e.g., as needle-like [acicular] or prismatic crystals), as well as EMPs that result from the crushing or fracturing of nonfibrous minerals (e.g., cleavage fragments)." Imprecise terminology and mineralogical complexity have affected progress in research." [38] (Exec Summary p. V-VI)

Egilman et al [39] systematically reviewed EMPs, cleavage fragments, short fibers, thin fibers, erionite and fibrous talc according to their potential to cause adverse human health effects. Using the Hill [40] criteria for potential to be causal in health effects, Egilman et al [39] concludes that all fiber types should be counted in laboratory mineral sample detection methodology.

Finkelstein [41] examined two samples of Mouldene industrial talc. The samples were prepared and analyzed for asbestos by polarized light microscopy (PLM), scanning electron microscopy (SEM), analytical electron microscopy (AEM), and X-ray diffraction (XRD). X-ray diffraction analysis showed that the New York industrial talc was composed of talc, tremolite and anthophyllite as major phases (each in the range of approximately 20–30% by weight). Microscopy analysis showed that the talc was composed primarily of fibrous talc, tremolite, anthophyllite and lizardite (serpentine). Some of the tremolite was not of a length and diameter to be of a respirable range.[41]

Several studies of talc workers have shown pleural thickening [4,42] and several have shown pneumoconiosis in workers exposed to talc contaminated with asbestos. [4,43,44]

3.2 Case Studies of Mesothelioma victims

Moline et al. [45] described the exposures to talcum powder leading to mesothelioma among 33 individuals referred for medico-legal evaluation. Tissue digestion was done for six cases according to standard methodology. Asbestos of the types found in talcum powder was found in all six cases evaluated. Two cases had anthophyllite fibers; one case had anthophyllite and tremolite fibers; one case had anthophyllite, tremolite and actinolite; one case had chrysotile fibers; and one case had tremolite fibers. Talcum powder usage was the only source of asbestos for all 33 cases.

Emory et al [46] described a case series of 75 malignant mesothelioma cases (gathered from medico-legal consultation) whose only exposure to asbestos was to cosmetic talcum powders. Nine of the cases were examined for asbestiform fibers by analytic electron microscopy and microprobe analysis. For the nine cases all had anthophyllite; of those, six also had tremolite fibers, and one had amosite and chrysotile fibers, in addition.

3.3 Epidemiology Studies of Miners and Millers and Mesothelioma

There have been several epidemiology studies of talc-exposed miners, millers and others that were considered negative for mesothelioma detection including the studies in Table 1.

Table 1: Studies of Talc Miners and Millers Negative for Mesothelioma Detection

Selevan et al 1979 Vermont [44]
Wild et al 2002 France [47]
Wild et al 2002 Austria [47]
Pira et al 2017 Italy [48]
Wergeland et al 2017 [49]

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However, there have been mesotheliomas, or probable or possible mesotheliomas, found in other studies in talc-exposed miners, millers and others (Table 2):

Table 2: Mesotheliomas in Talc-Exposed Miners and Millers

Kleinfeld et al 1967 New York 1 fibrosarcoma of the pleura and 1 peritoneal mesothelioma [43]
Vianna 1981 New York 6 mesotheliomas (miners) [50]
Enterline et al 1987 New York 11 mesotheliomas [51]
Coggiola et al 2003 Italy 2 peritoneal cancers [52]
Hull et al 2002 New York 5 mesotheliomas (miners) [53]
Honda et al 2002 New York 2 mesotheliomas [54]
Gamble et al 2008 New York 2 mesotheliomas [55]
Finkelstein 2012 New York 5 mesotheliomas [56]
Sanyal et al 2017 New York 11 mesotheliomas [57]
Mirabelli 2018 Italy 1 pleural mesothelioma (talc mill) [58]

Issues in the Epidemiology study of Talc and Mesothelioma

The epidemiology of talc exposures and mesothelioma is not extensive and there are many problems with the existing studies.

Mesothelioma is a long-latency disease (the time between exposure and disease is 15-50 years). There is no definitive biological or environmental measurement of exposure from the distant past and thus exposure histories have to be reconstructed from indirect sources, such as job categories and years working in a certain setting. Industry records, even of these, are not adequate for estimates of exposure. Individual records often rely on memory and are not adequate. The individual is not aware of exposures to invisible-to-the-eye fibers. Sorting out multiple individual jobs and exposures is rife with difficulty.

Mesothelioma is difficult to diagnose. There was not an ICD (International Classification of Disease) code until 1999 (10th Revision).[59] Before 1999 mesotheliomas were often called lung cancer or cancer of another body site. Even in worker populations with high exposures to asbestos (spray insulators, Selikoff et al [60,61,85]) only 10% developed mesothelioma. Thus, when researching a rare disease, even in highly exposed populations, large populations are needed for study.

Epidemiology is an observational science. People cannot be manipulated as in an animal laboratory study or human clinical trial. Thus, epidemiology studies are susceptible to bias. Bias in epidemiology studies means the study variables are not reflective of the true population situation. Epidemiology studies are of convenience samples, meaning what group of people is possible to study, not what group is ideal. There can be bias in the selection of study subjects and controls, in the assessment of exposure and the ascertainment and recording of outcome. Often a specific bias occurs when there is loss of follow-up of workers who are the most affected by the illness or those who have left the job and thus are not included in the study. This is called the "healthy worker effect". The ideal epidemiology study design is often not possible or was not done in the past and we are stuck with trying to draw conclusions from the studies that were not designed for our current purpose or were inadequate for it. As emphasized by IARC[4] "The weakest aspect of epidemiological studies is the qualitative and quantitative assessment of exposure. Deficiencies in environmental data of 20-50 years cannot be rectified." [4] (p. 358) Because of these problems, it is not surprising that there are some epidemiology studies that have not detected mesotheliomas in talc workers.

Studies of Italian Talc Miners

There have been several publications of studies of Italian talc miners (Table 3):

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Table 3: Studies of Italian Talc Miners

Rubino et al 1976 [62]
Rubino et al 1979 [63]
Coggiola et al 2003 [52]
Pira et al 2017 [48]
Finkelstein 2017 [64]
Pira et al 2018 [65]

Some of the studies have not detected mesotheliomas. There are multiple possible difficulties with these studies. The small size of the cohorts studied is of primary importance. Finkelstein[64] pointed out that in order to conclude that there is no risk associated with the exposure, there would need to be a much larger cohort studied for more years. The Pira et al study[48] was between 1946 and 1995, so there was no ICD classification for mesothelioma until 1999. That means that there is a high probability that there were missed cases of mesothelioma in the study. This is important for the Coggiola et al [52] study as well. The Coggiola et al [52] study looked at workers from 1946-1995, before the ICD mesothelioma code was developed. Another critique of the Coggiola et al [52] study is that even though it looked at talc workers, some of them had only been exposed to talc for as little as one year. As calculated by Finkelstein [64], the sample sizes of these studies are extremely small as compared to the potential risk that was being examined.

Some mesotheliomas or possible mesotheliomas have been detected in Italian talc workers. Coggiola[52] in Italy found two peritoneal cancers and Mirabelli, [58] also in Italy, found one pleural mesothelioma in a talc mill. Davis et al 1991 [66] conducted rat interperitoneal injection studies using differing tremolite samples including Italian tremolite (Ala di Stura). 24 of 36 animals developed mesothelioma. The results suggest that a wide-ranging group of tremolite samples all possessed some potential to produce mesotheliomas following injection into the rat peritoneal cavity. The Italian tremolite sample produced tumors in nearly 70% of rats. [66]

3.4 New York State Talc Miner Studies

The major epidemiology studies of New York state talc miners are listed in Table 1.

Hull [53] summarizes issues relating to New York state talc asbestos disease:

"Asbestos-related disease among talc miners and millers in a group of mines in two counties of northern New York State has been noted and disputed since the 1930s. One of the two counties was identified as among the 10 in the USA with the highest mesothelioma mortality up to 1981 for both men and women. Eight talc miners had been identified in previous studies as having mesothelioma. In the current study we: report five new cases of mesothelioma among talc workers; (abstract)….we found a continued trend of increased mesothelioma mortality at 5–10 times the background rate in Jefferson County from 1982 to 1997, with five new male cases (two expected) and three new female cases (0.5 expected)" (p. 134).

In the Hull[53] study, fibers of anthophyllite, tremolite/actinotlite, chrysotile and talc were observed in lung tissue. Some of the fibers were quite long and thus not cleavage fragments.

Taconite Elongate Mineral Particles (EMPs)

Taconite (iron ore) in Minnesota is contaminated with fragments called elongate mineral particles (EMPs) which are amphibole cummingtonite–grunerite short fiber (non-commercial) asbestos. These EMP's amphibole-like fibers were found in the Duluth, MN drinking water supply from Lake Superior from taconite mine tailings included in the Reserve Mining law case in the 1970's. It is well documented that short fibers are potentially toxic and small fibers can cause mesothelioma. [67-71]

There have been numerous mesotheliomas attributed to the taconite EMPs. Allen et al [72] found 30 mesotheliomas attributed to taconite, and Allen et al [73] found 51 mesotheliomas attributed to taconite mining. Lillienfeld [74] points out that this is probably an

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underestimate of the mesotheliomas in this area, as before 1999 mesotheliomas were likely missed and real mesotheliomas were often called lung cancer or something else due to ICD-9 not yet having a code for mesothelioma. The Minnesota taconite exposures are relevant to the potential toxicity of talc because it shows that if one breathes in short asbestos fibers or EMPs, whatever terminology you choose, it increases the risk of mesothelioma. Mazurek et al [75] of the U.S. Centers for Disease Control (CDC) have attributed mesotheliomas in the United States to EMPs in addition to asbestos fiber exposures. "Malignant mesothelioma is a neoplasm associated with occupational and environmental inhalation exposure to asbestos fibers and other elongate mineral particles (EMPs)."[75] (p. 214)

Talc, Tremolite and Mesothelioma

In chrysotile asbestos epidemiology studies, a group of scientists claimed for decades it was the amphibole tremolite contaminant of chrysotile that caused mesotheliomas, not the chrysotile from Canada and elsewhere.[76,77] This was known as the "amphibole hypothesis", that only amphiboles could cause mesothelioma, and the serpentine chrysotile could not. The "amphibole hypothesis" specifically stated that tremolite was the actual causal agent of mesothelioma, not chrysotile. There is tremolite in talc, and these scientists have argued for years that tremolite causes mesothelioma. Roggli et al [78] *ex*amined the lungs of 312 mesothelioma cases and found tremolite in 53% of the cases and chrysotile in 10%, attributing a large proportion (40%) of the tremolite to talc exposures.

Nephrite and Mesothelioma

Nephrite or Jade is a non-asbestosiform asbestos mineral composed of microcrystalline tremolite. It is used for ornamental stones and jewelry in Taiwan. Studies of workers have shown pulmonary fibrosis and lung cancer. [79-81]

"In this study, we did not identify any deaths from cancer of the pleura. We tentatively conclude that the sample size may not have been large enough to detect such an effect in this study. However, this result may also be due to the misclassification of mesothelioma as lung cancer, as the mortality registry in Taiwan continues to use the ICD-9 system which does not contain a diagnostic category for mesothelioma. Thus, mesothelioma may have been misclassified as lung cancer, which would result in an underestimate of the SMR of mesothelioma." [81] (p. 531)

Application of Hill Criteria

A widely accepted method for determining causation in epidemiology are the guidelines that were originally suggested by Hill [40] for evaluating the studies on cigarette smoking and lung cancer and other diseases. These guidelines are not limited to just formal epidemiological studies, but rather, incorporate and evaluate the totality of the science on a given issue including cell biology, animal studies, and mechanistic studies. As Hill stated, "[n]one of [his] nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine quo non*."

The most utilized modern list of viewpoints derived from Hill's work used by epidemiologists is contained in the textbook, Epidemiology, by Leon Gordis.[82] They are:

a. Temporal relationship
b. Strength of the association
c. Dose-response relationship
d. Replication of the findings
e. Biologic plausibility
f. Consideration of alternate explanations
g. Cessation of exposure
h. Consistency with other knowledge
i. Specificity of the association

The application of the Hill Criteria to the issue of talc exposures and risk of mesothelioma:

a. **Temporal Relationship**: This requires that the cause come before the effect. This criterion is easily satisfied in the current context as the exposure to miners and millers occurs years before the outcome of mesothelioma. The exposure to asbestos occurs in the studies of these occupational exposures 15-50 years before the mesothelioma clinical diagnosis.

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b. **Strength of the Association**: In epidemiology, strength of association is most often measured by comparing the incidence of disease in the exposed divided by the non-exposed in a cohort study. In the case of talc occupational exposures even a single or a few mesotheliomas would be an indication of a strong association as even in a group of 10,000, less than one mesothelioma would be expected.

c. **Dose-Response Relationship**: There is clear evidence of asbestos dose-response in mesothelioma causation. Iwatsubo et al [83] did a rigorous assessment of occupational exposure to asbestos in 405 mesothelioma cases and 387 controls. The authors found "a clear dose-response relation between cumulative asbestos exposure and pleural mesothelioma …" Examining data from the French mesothelioma registry, Lacourt et al [24] also found a clear dose-response relationship between asbestos exposure and pleural mesothelioma. In fact, there are many studies cited by IARC [7] that show that every additional exposure to asbestos leads to a greater risk of mesothelioma.

d. **Replication of Findings**: The peer-reviewed published literature contains hundreds of mesothelioma cases that have occurred in workers from exposure to asbestos-containing products encountered in many occupations. The talc worker mesotheliomas reveal another occupation where there is apparent asbestos exposure and the occurrence of mesotheliomas.

e. **Biologic Plausibility**: While the exact biologic mechanism explaining how mesothelioma develops has not been definitively identified, there is abundant literature that conclusively establishes that the exposure to any form of asbestos can result in the formation of mesothelioma. [7] There is also literature that confirms that there can be substantial amounts of asbestos fibers in the talc worker environment. Accordingly, it is biologically plausible that such exposure can cause mesothelioma.

f. **Consideration of Alternate Explanations**: There are very few documented causes of mesothelioma other than exposure to asbestos. The scientific literature contains a handful of mesothelioma cases that were purportedly caused by the administration of therapeutic radiation. In addition, exposure to erionite, an asbestos-like mineral found in Turkey, has been linked with the development of mesothelioma. Neither of these would apply as an alternative explanation for mesothelioma in talc workers. While there have been reports of "idiopathic" or "spontaneous" mesotheliomas, this term has been reserved for those instances where there is no discernable history of exposure to asbestos. Given the strong relationship between mesothelioma and asbestos, it is likely that a significant portion of those cases that have been labeled "idiopathic" are not cases where the asbestos exposure has not occurred, but rather simply could not be adequately documented. It is highly unlikely that the number of reported mesothelioma cases that have occurred in talc workers from exposure to asbestos is due to chance alone.

g. **Cessation of Exposure**: Now that the talc market is potentially shrinking because of issues of mesothelioma and ovarian cancer, it is hoped that the incidence of malignant mesothelioma will decline. However, because of the long latent period, we cannot assess this for another 10-20 or more years.

h. **Consistency with Other Knowledge**: The published literature is replete with data demonstrating that workers exposed to chrysotile, tremolite and anthophyllite asbestos from talc products are at risk for developing mesothelioma. Moreover, there are studies of talc workers that document asbestosis and/or pleural plaques that are also consistent with significant exposures to asbestos.

i. **Specificity of the Association**: This is the one criteria derived from Hill that is not useful in environmental/occupational epidemiology. For instance, cigarette smoke causes multiple diseases including lung cancer, emphysema, bladder cancer, heart disease and many other diseases. Likewise, asbestos causes malignant

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mesothelioma, lung cancer, other cancers, asbestosis and pleural plaques.

Discussion

The epidemiology studies to date of miners, millers and other talc-exposed workers have inherent deficiencies. Lack of an ICD code for mesothelioma until 1999 and lack of adequate exposure data are paramount. Despite these deficiencies, a number of mesotheliomas have been detected in various studies of talc workers in Italy and in New York in the U.S. Given the whole history of mesothelioma causation by asbestos, it is impossible to dismiss those mesotheliomas as unimportant. The asbestos contamination of talc may be random or sporadic, thus accounting for the occurrence of mesotheliomas, but in small numbers. In addition, many mesotheliomas have been detected in the taconite mining areas of Minnesota in the U.S., apparently from small non-commercial EMPs which are essentially small, non-commercial asbestos fibers. Since it appears that talc can be randomly contaminated with fibrous asbestos fibers, it is risky to sell talc as a cosmetic drying agent. Even a small amount of contamination in cosmetic talc can lead to inhalation in babies or their caretakers that can eventually migrate to the pleura or peritoneum and thus cause mesothelioma.

Conclusion

Talc is randomly and sporadically contaminated with asbestos fibers including chrysotile, tremolite and anthophyllite. Exposure to all three types of asbestos fibers increases the risk of mesothelioma.[7,84,85]. Case studies of mesothelioma victims, whose only asbestos exposure was to talc, found anthophyllite, tremolite and chrysotile asbestos fibers in their tissues. [45,46] There have been mesotheliomas documented in talc workers in New York State and Italy. EMPs contaminate taconite and have caused mesotheliomas in workers in Minnesota. Small fibers and EMPs can cause mesothelioma. Exposure to talc can lead to breathing asbestos fibers or EMPs and thus can increase the risk of mesothelioma. Both pleural and peritoneal mesotheliomas have been documented from talc exposures. The International Agency on Research on Cancer [7] concluded "There is sufficient evidence in humans for the carcinogenicity of talc containing asbestiform fibres. Talc containing asbestiform fibres causes cancer of the lung and mesothelioma." (p. 294)

Even though the epidemiology studies to date of talc miners have deficiencies, the evidence of causation using the Hill criteria from all the toxicological, biological and human studies is compelling. Use of talc as a cosmetic agent on adults or babies is elevating the risk of mesothelioma.

Disclosure

Professor Kanarek has served as consultant to government and international agencies on asbestos health effects, and has been a consultant and witness on plaintiff's litigation concerning asbestos and disease.

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EXHIBIT 31

La Medicina del Lavoro

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III Italian Consensus Conference on Malignant Mesothelioma of the Pleura. Epidemiology, Public Health and Occupational Medicine related issues

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Key words
Mesothelioma; pleura; asbestos

Parole chiave
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** Contributed to the document but not component of the Consensus group
*** Could not participate in the group activity

Enrico Pira[13,20] took part in the Consensus Conference activity but on April 8th asked not to sign the last version of the document, with no explanation.

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Summary

The III Italian Consensus Conference on Pleural Mesothelioma (MM) convened on January 29th 2015. This report presents the conclusions of the 'Epidemiology, Public Health and Occupational Medicine' section. MM incidence in 2011 in Italy was 3.64 per 100,000 person/years in men and 1.32 in women. Incidence trends are starting to level off. Ten percent of cases are due to non-occupational exposure. Incidence among women is very high in Italy, because of both non-occupational and occupational exposure. The removal of asbestos in place is proceeding slowly, with remaining exposure. Recent literature confirms the causal role of chrysotile. Fibrous fluoro-edenite was classified as carcinogenic by IARC (Group 1) on the basis of MM data. A specific type (MWCNT-7) of Carbon Nanotubes was classified 2B. For pleural MM, after about 45 years since first exposure, the incidence trend slowed down; with more studies needed. Cumulative exposure is a proxy of the relevant exposure, but does not allow to distinguish if duration or intensity may possibly play a prominent role, neither to evaluate the temporal sequence of exposures. Studies showed that duration and intensity are independent determinants of MM. Blood related MM are less than 2.5%. The role of BAP1 germline mutations is limited to the BAP1 cancer syndrome, but negligible for sporadic cases. Correct MM diagnosis is baseline; guidelines agree on the importance of the tumor gross appearance and of the hematoxylin-eosin-based histology. Immunohistochemical markers contribute to diagnostic confirmation: the selection depends on morphology, location, and differential diagnosis. The WG suggested that 1) General Cancer Registries and ReNaM Regional Operational Centres (COR) interact and systematically compare MM cases; 2) ReNaM should report results presenting the diagnostic certainty codes and the diagnostic basis, separately; 3) General Cancer Registries and COR should interact with pathologists to assure the up-to-date methodology; 4) Necroscopy should be practiced for validation. Expert referral centres could contribute to the definition of uncertain cases. Health surveillance should aim to all asbestos effects. No diagnostic test is recommended for MM screening. Health surveillance should provide information on risks, medical perspective, and smoking cessation. The economic burden associated to MM was estimated in 250,000 Euro per case.

Riassunto

«III Conferenza di Consenso Italiana sul Mesotelioma Maligno della Pleura. Aspetti di Epidemiologia, Sanità Pubblica e Medicina del Lavoro». *La III conferenza di consenso sul Mesotelioma Maligno della Pleura (MM) si è riunita il 29 Gennaio 2015. Questo rapporto presenta le conclusioni della sezione 'Epidemiologia, Sanità Pubblica e Medicina del Lavoro'. L'incidenza di MM nel 2011 in Italia è stata 3.64 per 100,000 persone/anno tra gli uomini e 1.32 tra le donne. I trends di incidenza nella popolazione sembrano non crescere ulteriormente. Dieci casi su cento sono associati ad esposizione non lavorativa. L'incidenza tra le donne è molto elevata in Italia, a causa sia di esposizione lavorativa sia non lavorativa. La rimozione dei materiali in amianto in opera procede lentamente, con esposizione residua. La letteratura recente conferma il ruolo del crisotilo nel MM. La Fluoedenite fibrosa è stata classificata come cancerogeno (gruppo 1) dalla IARC, sulla base di dati relativi al MM. Un tipo di nanotubi di carbonio (MWCNT-7) è stato classificato 2B. Per i MM pleurici, dopo circa 45 anni dalla prima esposizione l'aumento dell'incidenza tra gli esposti rallenta, ma sono necessari studi di approfondimento. L'esposizione cumulativa è stima dell'esposizione biologicamente rilevante, ma non consente di distinguere se il ruolo principale dipenda da intensità o durata di esposizione e non consente neppure di valutare la sequenza temporale dell'esposizione. Studi hanno mostrato che durata ed intensità sono determinanti indipendenti del MM. La proporzione di MM con legami di parentela è inferiore al 2,5% in Italia. Il ruolo delle mutazioni genetiche di BAP1 sono limitate ai rari casi ascrivibili alla omonima sindrome familiare, mentre è irrilevante per i restanti casi. La correttezza della diagnosi è basilare; le linee guida concordano sull'importanza dell'aspetto macroscopico del tumore, e dell'esame istologico di sezioni colorate con ematossilina-eosina. I markers immunoistochimici contribuiscono alla conferma diagnostica: la scelta dei marcatori dipende da morfologia, sede e diagnosi differenziale considerata. Il Gruppo di Lavoro suggerisce che 1) I registri generali di popolazione e le sezioni regionali (COR) del ReNaM interagiscano e confrontino sistematicamente casi di MM; 2) ReNaM dovrebbe presentare le casistiche di MM separatamente per certezza diagnostica e per modalità diagnostica; 3) Registri generali di popolazione e COR dovrebbero interagire con le unità di Anatomia Patologica*

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per garantire che siano impiegate le metodiche più aggiornate; 4) Autopsie dovrebbero essere effettuate, a scopo di validazione. Centri di riferimento esperti possono contribuire alla migliore definizione dei casi incerti. La sorveglianza sanitaria deve riguardare tutti gli effetti sanitari dell'amianto. Non sono disponibili tests diagnostici applicabili a scopo di screening. La sorveglianza sanitaria dovrebbe fornire informazioni su rischi, prospettive sanitarie, e cessazione del fumo. Il costo economico associato al MM è stato stimato in 250,000 Euro per caso.

Final document - Epidemiology, Public Health and Occupational Medicine' section

Asbestos consumption, descriptive epidemiology and trend predictions

Italy was an important asbestos producer and user country until the ban in 1992, with an estimated total of 3,748,550 tons of raw asbestos consumption, peaking in the period between 1976 and 1980. MM incidence is correspondingly high: 3.64 and 1.32 per 100,000 person/years in 2011 in men and women respectively with 1,428 (1,035 in men and 393 in women) recorded incident cases (V ReNaM Report, in press, 2015). Data suggest that national incidence and mortality trends for MM are starting to level off. Data from other countries show that level off started earlier where asbestos control programs were enforced earlier.

Occupational and non-occupational asbestos exposure

Raw asbestos and asbestos-based products have been used in large amount in several industrial activities, such as asbestos-cement industry, construction and maintenance of railroad vehicles and ships, chemical industry, steel industry, metal works, building and others, as documented by reports of the National Mesotelioma Registry (ReNaM) (21), with an increasing relevance of a variety of unconventional circumstances of exposure. Incidence of MM among women is very high in Italy, because of both non-occupational (environmental and domestic) and occupational asbestos exposure; in particular the female workforce was very large in the textile industry and asbestos-cement production. The findings of Italian MM incidence surveillance system documented that 10.2% of MM cases are due to non-occupational exposure to asbestos (15). Non-occupational exposures to asbestos is more difficult to detect than the occupational but its relative importance is likely to increase. For a better assessment, interview information should be enriched by other parameters (such as historical reconstruction of asbestos pollution and biological markers of exposure). To date the definition of exposure relies on interview (50.3% direct to the patient 46.1% to proxies). Prompt notification of MM cases by physicians is recommended as a crucial issue for the efficiency of interview. The potential of sharing databases for case identification and for the assessment of exposure was noticed and the Working Group (WG) recommends its prompt and exhaustive implementation.

Background airborne asbestos fibers in the environment

Information from Italian regions is scanty: a recent monitoring campaign conducted in the city of Modena showed an average concentration around 0.1 ff/l, similar to the data reported in the IARC monograph n. 100 (10). WHO (26) estimated that for a continuous exposure to 0.4–1 ff/l (as measured with current methodology), a lifetime risk of MM would be from 4 to 10) × 100,000. Linear extrapolation to the 0.1 ff/l (current background level), would correspond to a lifelong excess in the order of one case (from 0.4 to 2.5) of MM every 100,000 persons. Local sources of contamination may determine higher levels of fiber concentration, that should be monitored for proper risk assessment.

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Waterborne asbestos fibers

The presence of asbestos in water is becoming a matter of concern for a large part of the population, however there is no evidence of risk for pleural MM related to ingested fibers. Risk of exposure to airborne asbestos fibers because of the use of asbestos contaminated water can occur indoor and outdoor; in circumstances when an important level (millions/l) of fibers in water is detected, the possible increase of airborne fibers should be controlled and the level compared to the background.

Chrysotile

The recent literature confirms that chrysotile causes MM although with a lower potency than amphiboles.

Talc containing asbestos fibers

Epidemiological studies and case reports from ReNaM underlined the causal role of talc containing asbestos fibers. The need for greater understanding of this material, its source, where and how it was used in Italy, was acknowledged, with priority for epidemiological studies.

Current risk of exposure

There is still a risk of exposure for those employed in the construction industry. The removal of asbestos in place is proceeding too slowly and the entire process should be revised.

Association of MM and mineral fibers other than asbestos

Fibrous fluoro-edenite was classified as carcinogenic to humans by IARC (Group 1) on the basis of sufficient evidence including MM in humans (9). In Italy exposure is known in the area of Biancavilla (Sicily); it was found in other volcanic areas in Japan. SiliconCarbide (SiC) whiskers were classified as probably carcinogenic to humans (Group 2A), in absence of human data, but with clear evidence of MM in experimental animals (9). The IARC Monograph took in consideration different types of Carbon Nanotubes (CNT), of which a specific type (MWCNT-7) was classified as 'possibly carcinogenic' (group 2B), while the classification could not be extended to other CNTs for lack of consistent data (group 3) (9). The group acknowledges the general concern on the possible health effects of CNTs, as their physical-chemical characteristics, in vitro data and several experimental animals outcomes suggest that some CNT types, albeit not all, might cause MM.

Does MM incidence increase indefinitely over latency time?

The mathematical model predicting MM incidence after exposure to asbestos in humans was adopted by the Second Italian Consensus Conference on Pleural MM, after considering the original literature and reviews then available. The model predicts incidence to increase indefinitely according to time since exposure, while studies with observation time longer than 40-50 years since first exposure suggested that, at such latency, model predictions were no longer correct and differences existed between pleural and peritoneal MM; results were imprecise because of the relatively small number of cases of interest. A recent pooled analysis (22) showed that in pleural MM, after about 45 years since first exposure, the trend in incidence and mortality increase is slowed down but the same is not observed for peritoneal MM. Further studies are appropriate.

Role of cumulative exposure in the dose-response relationship

After examining the results of a systematic literature review (15), the Second Italian Consensus Conference on Pleural MM concluded that risk of MM increased with cumulative exposure and lung fibre burden, and that time since exposure gives more weight to exposures that occurred early (19). In the study of MM epidemiology, the use of cumulative exposure to asbestos has a long standing tradition and cumulative exposure is a proxy of the relevant exposure.

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The relevance of distinct exposure periods

MM cases commonly exhibit complex exposure patterns. It was suggested that the dose-response relationship may be used to assess the proportional causal weight of any distinct exposure period (15, 20). The Working Group noticed that it is necessary, however, to adopt assumptions about several key factors which are not precisely known in most instances, including among others, the relative potency of the different varieties of asbestos, the exposure intensity, and the duration of the preclinical phases of MM.

Is cumulative exposure a valid risk index?

To quantitatively investigate cancer etiology it is important to assess occurrence in relation to long-term exposure patterns, which often consist of a complex temporal sequence of exposure circumstances which are difficult to analyse separately disentangling the relative relevance of duration, intensity, and cumulative exposure (13, 23, 25). Cumulative exposure is a useful summary exposure index, successfully employed in various fields in cancer research (including etiological research and risk assessment), as it offers a solution to the difficulty of analytically dealing with complex exposure patterns (24). It is acknowledged that cumulative exposure does not allow to distinguish which of its components, duration or intensity, may possibly play a more prominent role, neither it allows to establish whether the temporal sequence of exposures is important (6). As regards separate analyses by duration and intensity, six different studies were found in a literature search and overall, these papers offered evidence that duration and intensity are independent determinants of MM occurrence.

Does exposure affect latency?

Even if the analysis of latency among MM cases is intuitively appealing, under the expectation of a shorter latency for the most exposed, it is fallacious because its results do not depend on the relationship between exposure and disease, but on the time boundaries of the observation (18): the observation time is fixed (by the observer), and the dynamic of the distribution of exposures in the population from which cases originate had been historically determined. In cohort studies, furthermore, latency can be determined only for a minority of at risk individuals, due to the combined effect of administrative censoring and competing mortality (12). An increase in exposure causing an increase in incidence in the target population necessarily entails the acceleration of failure time (i.e. latency time), as the relationship between increase in incidence and acceleration of failure time is mathematically determined (3); nevertheless and contrary to what intuition might suggest, the average latency is unaffected[1].

Genetic factors in MM

The proportion of blood related MM cases in Italy is between 1.3 and 2.5%, considering only population based surveys (1, 2). In the population living or working in Wittenoom, blood related MM cases represented 7%, and a twofold increase of MM risk for blood relatives of cases was estimated, after adjustment for asbestos exposure (7). The role of BAP1 germline mutations is limited to the cases occurring in familial aggregations corresponding to the BAP1 cancer syndrome, while it is negligible (at most 1.4%) for sporadic MM cases (4). GWAS studies suggest a possible role of common genetic variants but results are still preliminary and agreement of different studies is limited (5, 16).

Evaluation of methods for diagnosis and for classification of MM under an epidemiological perspective

International guidelines underline the importance for the diagnosis of MM of the gross appear-

[1] Note: C. Bianchi did not agree and expressed the following comment, sent during the revision of the report: "Claudio Bianchi believes that an inverse relationship exists between intensity of asbestos exposure and length of the latency period".

ance of the tumour, in the context of appropriate clinical, radiologic, and surgical findings and of the hematoxylin-eosin-based histology. Immunohistochemical markers provide an important contribution to the diagnostic confirmation and to the interpretation of uncertain morphology. The selection of markers depends on the initial morphological evaluation. The role of immunohistochemistry varies depending on the histologic type of mesothelioma (sensitivity of immunomarkers is high in epithelioid and low in sarcomatoid types), the location of the tumor (pleural versus peritoneal) and the type of tumor being considered in the differential diagnosis (e.g. adenocarcinoma, squamous cell carcinoma, malignant melanoma, epithelioid hemangioendothelioma). Even if a large selection of immunohistochemical markers is currently available, not all MM cases can be definitely identified. Even after the diagnostic revision by a panel of expert pathologists, a proportion of cases is classified as probable or doubtful MM. Cancer registries adopt standard rules for the identification, coding, and registration of cases, as a prerequisite for analysis of incidence, and for geographic and trend analyses (8). Cancer registries do not diagnose cases but search them in the appropriate clinical departments or in the appropriate data files. Cases are accepted on the basis of the clinico-radiologic and pathological diagnosis, on the basis of the methods in use at the time of diagnosis. More severe selection procedures would cause a loss of cases. The Working Group suggested that 1) General Cancer Registries and ReNaM Regional Operational Centres (COR) interact and systematically compare MM cases; 2) ReNaM should report results presenting the diagnostic certainty codes and the diagnostic basis, separately; 3) General Cancer Registries and COR should interact with pathologists in order to assure that current diagnoses are made using the up-to-date methodology, including immunohistochemistry panels; 4) Necroscopy should be practiced at a larger extent, in order to validate in vivo diagnoses. Expert referral centres for the revision and confirmation of diagnoses could contribute to the definition of uncertain cases.

Health surveillance programs

Programs aimed to workers formerly exposed to asbestos or engaged in occupations with potential asbestos exposure are defined according to current laws [257/2006 and 81/2008]. Health surveillance should not aim at the prevention of a single disease but be planned with a broad perspective, in consideration of the different diseases associated to asbestos exposure and of the joint effect of asbestos and tobacco smoking on lung cancer. So far, no diagnostic test, including imaging and biochemical tests, has sensitivity and specificity high enough to be adopted for early diagnosis of MM in asymptomatic. Health surveillance activity should provide also information on risks and on medical perspective, collect information on occupational history, especially regarding asbestos exposures, and provide counseling for smoking cessation. For asbestosis, high resolution computer tomography (HRCT) is the recommended imaging technique, and International Classification of HRCT for Occupational and Environmental Respiratoy Diseases. (ICOERD) standardized criteria should be used (17). Pneumococcal and influenza vaccination and early treatment of respiratory infection should be encouraged among exposed workers with lung fibrosis (17).

Given these considerations, health surveillance of asbestos exposed workers has: 1) To inform asbestos exposed subjects about their risk related to (present or past) asbestos exposures; 2) To inform relatives of asbestos exposed subject of their possible health risks; 3) To fully reconstruct occupational history, especially regarding asbestos exposures; 4) To provide information about diagnostic tools, therapy and forensic medicine perspectives; 5) To support claims for compensation; 6) To give counselling on smoking cessation and on other relevant matters related to health and life style.

Social and economic costs of MM

A reliable estimate of the economic burden associated to mesothelioma, including medical care, insurance and fiscal costs, and human capital costs related to productivity loss, provided an estimate of 250,000 Euro per MM case, as the sum of medical

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(33,000), insurance (25,000) and productivity loss (192,000) costs (11).

Extrapleural Malignant Mesotelioma

The Working Group decided to expand its activity and to consider also MM in other sites, i.e. peritoneum, pericardium and vaginalis lining of the testis. MM can spread to the peritoneum and pericardium from the adjacent pleura and the reverse also can occur. The histology of extrapleural MM is not peculiar and the typical frequency distribution of epithelioid, fibrous, and mixed forms is observed, similar to the pleural location. In women, differential diagnosis between peritoneal MM and ovarian cancer can be challenging.

Cases of peritoneal MM are diagnosed and treated in different hospital wards than pleural MM cases. These difference are relevant for the organization of data collection from cancer registries, in particular for the specialized mesothelioma registries.

Incidence of peritoneal MM is lower (roughly 1/10) than pleural MM. In Italy, the IV report of the National Mesothelioma Registry (ReNaM) indicated 0.22 (/100.000 py) in men and 0.10 in women). Incidence of MM of the pericardium and vaginalis lining of the testis is further lower.

All types of asbestos fibres cause extrapleural, as well as pleural, MM (10). In addition to the internal body transport of inhaled fibres, the peritoneum can be exposed to asbestos fibres directly because of talc containing asbestos fibres used on surgical gloves or for personal hygiene. Prevalence of asbestos exposure appear lower for extrapleural, than for pleural, MM.

After asbestos exposure, risk of peritoneal MM shows a continuous increase, contrary to pleural MM, that shows a flattening of the increase of risk after 40-50 years of latency (22).

Conflict of interest

The report of conflicts of interest regarded the participants in the Consensus Conference for the 3 years period before the meeting (2012 – 2014). No authors reported economical or financial conflicts of interest. Out of Nineteen components of the Consensus Conference Group, two could not contribute at any extent and are not considered here. Of the seventeen who actually contributed, ten have been asked to provide scientific information in criminal or civil court cases related to asbestos related diseases: six of them served as expert or expert witness for the court, nine for the public prosecutor, four acted as expert for the plaintiff(s), and three for the defendant(s). Seven were never involved in court cases in the period considered. A detailed report was provided to the Editor of "La Medicina del Lavoro".

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STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	CIVIL ACTION NO. 2023-CP-40-04072
MICHAEL L. PERRY AND LONNIE L. LONG,	)	*In Re:* Asbestos Personal Injury Litigation Coordinated Docket
Plaintiffs,	)	**JOHNSON & JOHNSON DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE NO. 15 TO EXCLUDE ANY SPECULATIVE TESTIMONY THAT BLAMES LABORATORY CONTAMINATION FOR THE PRESENCE OF ASBESTOS IN A TALC SAMPLE**
vs.	)	
AMERICAN INTERNATIONAL INDUSTRIES, ET AL.,	)	
Defendants.	)	

Defendants Johnson & Johnson ("J&J"), LLT Management LLC, Johnson & Johnson Holdco (NA) Inc. ("Holdco"), and Kenvue, Inc. ("Kenvue"), (collectively "J&J Defendants"), through undersigned counsel, respectfully request the Court to deny Plaintiffs' Motion *in Limine* No. 15 to Exclude Any Speculative Testimony that Blames Laboratory Contamination for the Presence of Asbestos in a Talc Sample (the "Motion").

INTRODUCTION

The crux of Plaintiffs' argument is that J&J Defendants—and their witnesses—have no evidence that test results of talc samples suggesting the presence of asbestos resulted from contamination. But Plaintiffs spend most of their Motion reciting all the evidence the J&J Defendants ***do have*** regarding such contamination, and then attempt to discount this evidence. Plaintiffs allege that Mr. Perry used Johnson's Baby Power and Johnson's Shower to Shower that were contaminated with asbestos, and that his use of these products caused his mesothelioma. Thus, whether third-party testing found asbestos in J&J Defendants' talc products—or instead, whether the "findings" were a result of lab contamination—goes to the heart of Plaintiffs' allegations and is relevant. Rule 402, SCRE. Further, evidence of lab contamination is not unfairly

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prejudicial. Plaintiffs are within their rights to pursue certain theories in cross-examination, but evidence cannot be excluded merely because Plaintiffs are concerned that it may weaken her case. *State v. Gilchrist*, 329 S.C. 621, 630, 496 S.E.2d 424, 429 (Ct. App. 1998) ("All evidence is meant to be prejudicial; it is only *unfair* prejudice which must be avoided."); *State v. Collins*, 409 S.C. 524, 536, 763 S.E.2d 22, 28 (2014) ("[T]he standard is not simply whether the evidence is prejudicial; rather, the standard under Rule 403, SCRE is whether there is a danger of unfair prejudice that substantially outweighs the probative value of the evidence.")

For these reasons, Plaintiffs' motion should be denied.

FACTUAL BACKGROUND

Over the years, numerous third parties have tested the J&J Defendants' talc for asbestos. Plaintiffs in this case, and plaintiffs in talc litigation generally, have pointed to certain testing documents from third-party testing facilities that they claim show the presence of asbestos fibers in J&J Defendants' talcum powder products. But many of those same testing documents explicitly state that the sub-trace findings identified by testers were likely the result of laboratory contamination, rather than present in the talc sample itself. The jury is entitled to hear about this evidence and the impact on Plaintiffs' allegations.

LAW AND ARGUMENT

A. Expert Testimony Regarding the Likelihood of Laboratory Contamination is Admissible at Trial.

Plaintiffs argue that any testimony or opinions that asbestos fibers found in talc samples were caused by laboratory contamination should be excluded under Rules 402 and 403 of the South Carolina Rules of Evidence because "there is no foundation for the assertion that laboratory contamination was responsible for the presence of asbestos in the talc sample." Pl's Mot. at 5; *see also id.* at 10 (claiming "there is no foundation" for Dr. Matthew Sanchez's opinion that

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contamination occurred). This argument is meritless.

As an initial matter, Plaintiffs do not move to exclude Dr. Sanchez's opinion under Rule 702, SCRE. In fact, Plaintiffs' Motion does not even mention Rule 702. This alone should be grounds to deny Plaintiffs' Motion as to Dr. Sanchez. In any event, under Rule 702, expert witnesses can provide opinions on "scientific, technical, or other specialized" matters if such testimony will "assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." Rule 702, SCRE; *see also Kelley v. Wren*, 415 S.C. 379, 393, 782 S.E.2d 406, 413 (Ct. App. 2016) (holding that an expert's testimony was relevant and admissible because it assisted the jury in determining the central issue in the case).

J&J Defendants' experts' testimony on contamination is admissible because: (1) it has a reliable basis in fact and will aid the jury in understanding the evidence concerning alleged asbestos findings; and (2) Plaintiffs' arguments to the contrary all go to the weight of this testimony, not admissibility.

i. Contamination evidence has a reliable basis in fact and will aid the jury.

Plaintiffs argue that the evidence at issue would not assist the trier of fact because the J&J Defendants—and their witnesses—have no "foundation" or evidence of contamination. But Plaintiff's own motion refutes this argument because it sets forth several pages worth of evidence that the Defendants ***do*** have to support their theory of laboratory contamination. For example, Plaintiffs acknowledge that, on a number of "occasions," "a laboratory found a small number of fibers" and that ***the laboratories*** attributed the asbestos detection to contamination. Pls.' Mot. at 5[1]; *see also* Pls.' Mot., Ex. 10 (Letter from Richard Shimps et al. to Roger Miller (June 6, 1974))

[1] While Plaintiffs take issue with the fact that these laboratories described the contamination "in noncommittal" terms, *see* Pls.' Mot. at 5, Plaintiffs' gripe with particular word choice is no basis to discount the laboratories' findings.

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(noting that although "2 chrysotile fib[ers]" were detected, "it [wa]s impossible, in view of the extremely low level of chrysotile detected in this sample, to exclude the possibility that the fib[ers] . . . derive[d] from atmospheric contamination"); Pls.' Mot., Ex. 23 (Letter from Gene R. Grieger to Dr. Robert Rolle (July 8, 1974)) (noting that the "low levels of asbestiform minerals [detected] [were] so low that they might well be caused by contamination"); Pls.' Mot., Ex. 24 (Letter from Gene R. Grieger to Robert Russell (Dec. 9, 1974)) (stating "[baby powder] can be considered asbestos free" because only one chrysotile fiber was found, and "it may well have originated as stray contamination"); Pls.' Mot., Ex. 25 (Letter from Gene R. Grieger & Ian M. Stewart to Roger Miller (Oct. 5, 1978)) (finding "two" "small chrysotile fiber[s]" that "could easily be contamination from outside sources"). And in another testing document cited by Plaintiffs, the McCrone lab explained in 1987 that while "monitoring Windsor's talc products for a number of years," on one occasion there was "possible chrysotile contamination" "and the contamination source was subsequently pinpointed as a deteriorating clutch in some mechanical equipment." *See* Pls.' Mot., Ex. 26 (Letter from Ian M. Stewart to Donald M. Benninger (May 21, 1987)). In short, there is ***ample evidence of contamination***.

Plaintiffs also argue that some of the tests used "blanks," which are control devices that are known not to contain any asbestos, and that "for at least six . . . samples" where contamination is believed to have occurred, the control blanks have no asbestos. Pls' Mot. at 10. But Plaintiffs are misrepresenting the precision of blanks and ignoring the commonsense reality that asbestos could contaminate one object and not another, even in the same room, or that asbestos on a blank could fail to be detected by the microscopist. Indeed, Plaintiffs' own expert in this case, Mr. Mark Bailey, has previously testified that "***just because you don't see a fiber in your blank doesn't mean it isn't there***." **Ex. A** (Dep. of R. Mark Bailey, P.G., *Garcia v. Colgate-Palmolive Co.*, JCCP Case No.

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4674 (Cal. Super. Ct. May 23, 2018) ("*Garcia* Bailey Dep.") at 103:5-12 (emphasis added).[2]

For similar reasons, Plaintiffs' assertion that J&J Defendants' expert Dr. Sanchez has "no foundation" for his conclusion that contamination events can occur where the blanks are clean is clearly wrong. As Mr. Bailey's own testimony reveals, the possibility that blanks fail to identify contamination is well understood in the scientific community. And Dr. Sanchez cited "[c]ommon knowledge" and his prior experience for his knowledge regarding blanks. *See, e.g.*, **Ex. B** (Dep. of Matthew Sanchez, Ph.D., *Hirshberg v. Johnson & Johnson*, Case No. 20- 2-06720-8 (Super. Ct. of Washington for King County March 1, 2021) ("*Hirshberg* Bailey Dep.") at 204:14-208:24.[3] Such experience is sufficient for purposes of Rule 702. *Honea v. Prior*, 295 S.C. 526,530, 369 S.E.2d 846, 849 (Ct. App. 1988) (noting that "[t]here is no exact requirement concerning how knowledge or skill must be acquired" and that a witness may be competent to testify "although the witness acquired his or her knowledge through practical experience and not by scientific study, training, or research") (internal citations omitted). Moreover, Dr. Sanchez explained that he "recall[ed]" specific testing documents and reviewed those testing documents because "blanks [are] specific to sets of samples" and "aren't universal through all time and all space." **Ex. B**, Sanchez Dep. 142:3-144:14.

ii. Plaintiffs' arguments against the admissibility of contamination evidence goes to weight, not admissibility.

Plaintiffs' disagreements with the contamination evidence (or J&J Defendants' experts' opinions on contamination) are fodder for cross-examination and go to weight, not reliability or

[2] Plaintiffs also generally contend—without citation or support—that "[t]he consensus opinion is that laboratory contamination is rare." Pls.' Mot. at 10. But once again, their own expert agreed that in the 1970s and 1980s – when many of the tests at issue occurred – "it was not uncommon for laboratories to experience [asbestos] contamination extrinsic to whatever material they were analyzing." **Ex. A**, *Garcia* Bailey Dep. 102:2-18.

[3] Dr. Sanchez is an expert in geology, mineralogy and microscopy, **Ex. C** (Curriculum Vitae for Matthew S. Sanchez, Ph.D.), whose qualifications are not subject to serious challenge.

admissibility. *See, e.g.*, *State v. Tillman*, 304 S.C. 512, 518–19, 405 S.E.2d 607, 611 (Ct. App. 1991) (explaining how evidence that potentially contradicts a witness' testimony implicates the weight of the witness' opinions, not its admissibility). As Plaintiffs' Motion reveals, Plaintiffs are amply prepared to challenge the weight of the opinions of Dr. Sanchez and the historical testing documents on which he relies via cross-examination. Therefore, there is no basis to exclude this evidence.

For all of these reasons, J&J Defendants' witnesses—including Dr. Sanchez— should be allowed to testify about the likelihood of laboratory contamination in certain testing.[4]

B. Dr. Kuffner's Testimony Regarding the Likelihood of Laboratory Contamination is Admissible.

Plaintiffs also seek to exclude testimony from any of "J&J's corporate representatives," concerning lab contamination because they lack personal knowledge. This argument seeking to exclude Dr. Kuffner's testimony[5] is wrong for two reasons.

First, Dr. Kuffner has personal knowledge of contamination issues based on his work at J&J, and on that basis alone has an adequate basis to testify on the issue. *State v. Douglas*, 380 S.C. 499, 502, 671 S.E.2d 606, 608 (2009) ("Lay witnesses are permitted to offer testimony in the form of opinions or inferences if the opinions or inferences are rationally based on the witness'[s] perception, and will aid the jury in understanding testimony, and do not require special knowledge."). Dr. Kuffner joined Johnson & Johnson in 2006 as the Senior Director for Medical Affairs within McNeil Consumer and Specialty Pharmaceuticals. He currently serves as Chief

[4] Throughout their motion, Plaintiffs reference testing of talc products from Brazil. *See* Pls.' Mot. at 3, 8-10. But Plaintiffs fail to show how testing of talc products from Brazil, which Mr. Perry never used, is relevant to Plaintiffs' claims. It is not.

[5] Plaintiffs specifically reference only Dr. Susan Nicholson (Pls.' Mot. at 10). Dr. Nicholson is not testifying in this case. Dr. Edward Kuffner, however, is testifying in this case based on his personal knowledge.

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Medical Officer for Consumer Health Products at Johnson & Johnson Services Inc. During his tenure at Johnson & Johnson, Dr. Kuffner has acquired substantial personal knowledge about talc (including instances where laboratory asbestos contamination resulted in false testing results) through an investigation of company documents that are equally available to Plaintiffs. *See* J&J Defs.' Opp'n. to Pls.' Mot. in Limine No. 13 (filed separately and incorporated herein) at 4, 11. Moreover, for all the reasons set forth above, there is ample foundation to support Dr. Kuffner's testimony that asbestos contamination occurred in certain talc testing. Accordingly, Dr. Kuffner is appropriately considered a fact witness pursuant to Rule 701, SCRE and can testify to these events, in the form of facts or opinions.

Second, Dr. Kuffner's testimony on contamination issues is also proper for the independent reason that he was designated as a corporate representative in this case. As established in J&J Defendants' Opposition to Plaintiffs' Motion *in Limine* No. 13, and pursuant to an agreement among the parties, Dr. Kuffner can testify at trial as a corporate representative beyond the scope of his personal knowledge. *Id.* at 1, 4-9 (citing numerous opinions holding that corporate representatives are entitled to testify beyond the scope of their personal knowledge at trial, just as they may at a Rule 206(a)(1) deposition).

CONCLUSION

For the foregoing reasons, J&J Defendants respectfully request that the Court deny Plaintiffs' Motion.

Respectfully submitted,

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Columbia, South Carolina

July 24, 2024

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Exhibit A

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

LAOSD ASBESTOS LITIGATION	)	
	)	
Coordinated Proceeding Special Title (Rule 3.550)	)	
	)	
PAUL M. GARCIA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	JCCP Case No. 4674
	)	
COLGATE-PALMOLIVE COMPANY, ET AL.,	)	LASC Case No. BC660333
	)	
Defendants.	)	

DEPOSITION OF R. MARK BAILEY, PG
Emeryville, CA
Wednesday, May 23, 2018

REPORTED BY:
SUSAN F. MAGEE, RPR, CCRR, CLR, CSR No. 11661
Job No. 141837

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A. When the method was written.
Q. Right. And that would have been in the 19- -- late '70s, early '80s?
A. '70s into the early '80s, yeah.
Q. So in that time frame it was not uncommon for laboratories to experience chrysotile contamination extrinsic to whatever material they were analyzing; correct?
MR. CONNETT: Overbroad.
THE WITNESS: They -- potentially.
BY MR. TOVEY:
Q. And when a laboratory experiences that kind of contamination, typically we were talking about one or two or three or -- fibers; right?
MR. CONNETT: Overbroad.
THE WITNESS: I can't say the exact number, but it was probably somewhere in that range.
They use five as the limit.
BY MR. TOVEY:
Q. Well, five is derived from Poisson, P-o-i-s-s-o-n, distributions; right?
A. Right. Four or five. Different people use different numbers.
Q. Right. That's exactly right. So what a detection limit says is in most asbestos testing

methods, is the minimum number of fibers to count in the test material to be 95 percent certain that the true value is greater than background?
A. Yes. It's above background.
Q. Right. And because you're blank, you're going to have a distribution that can vary between 0 and 3.69 than -- just because you didn't see a fiber in your blank doesn't mean it isn't there; right?
A. Right. Statistically you don't -- you know, any given analysis in and of itself doesn't tell you that, so it's got to be a whole range of analysis for them.
Q. So the first whole number after 3.69 would be 4.
A. 4.
Q. And so to have a fiber count that you could say with a 95 percent degree of confidence that the true value is greater than background is I would need 5 over here in my test material to make sure that I had at least one more than 4 on my blanks; right? That's how that number is derived?
A. Well, I mean, it depends. If you have blanks that have you finding asbestos fibers on those, it's got to be higher than that number.
Q. Right, right. Good point.

A. So you're assuming no background.
Q. I'm assuming the best-case scenario.
A. You're assuming the best-case scenario --
Q. I haven't detected anything on my blanks.
A. Right.
Q. But if I detected fibers, then it goes up.
A. Yes.
MR. TOVEY: Could you mark this, please.
(Exhibit 5, July 1984 Methodology for the Measurement of Airborne Asbestos by Electron Microscopy (112 pages), marked for identification.)
BY MR. TOVEY:
Q. And Mr. Bailey, I've handed you a document that we've marked as Exhibit 5.
For the record it is titled Draft Methodology for the Measurement of Airborne Asbestos By Electron Microscopy by George Yamate, Y-a-m-a-t-e, and others. Bears a date of July 1984, and this is what we've been referring to shorthand as the Yamate method.
Correct?
A. Correct.
Q. I want to direct your attention to page 70 of Exhibit 5. Under the paragraph 2, comparison of two Poisson variants.
Do you see that?

A. I do.
Q. And it states -- or Dr. Yamate states, Mr. Yamate states, In certain cases, a new test sample is compared to a blank or control sample. Table 7 gives those differences between control and test samples that are significant at the 5 percent level.
Did I read that correctly so far?
A. Yes.
Q. Inspection of Table 7 reveals that the minimal detectable difference between test and control samples is 5 fibers in the test sample and 0 fibers in the blank.
Did I read that correctly?
A. Yes.
Q. Typically inspection of 20 grid openings for a blank control reveals between 0 and 5 fibers.
At the upper bound; i.e., 5 fibers -- now it skips over to page 73 -- 5 fibers in the control sample; 18 fibers in the test sample are required for statistical significance.
Did I read that correctly?
A. Yes.
Q. And that comports with what you were just explaining; correct?
A. Right.

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C E R T I F I C A T E

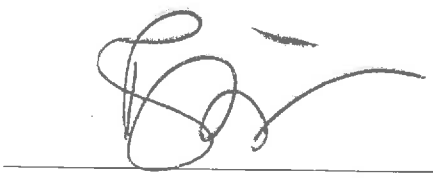
State of California)
) ss:
County of Alameda)

I, Susan F. Magee, RPR, CCRR, CLR, Certified Shorthand Reporter No. 11661 within and for the State of California, do hereby certify:

That R. MARK BAILEY, PG, the witness whose deposition is hereinbefore set forth; was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 31st day of May, 2018.



Susan F. Magee, RPR, CCRR, CLR
CSR No. 11661

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Exhibit B

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SUPERIOR COURT OF WASHINGTON FOR KING COUNTY

WENDI J. HIRSHBERG AND RICHARD HIRSHBERG, WIFE AND HUSBAND, PLAINTIFFS, VS. JOHNSON & JOHNSON, ET AL., DEFENDANTS.	CERTIFIED COPY CASE NO. 20-2-06720-8

DEPOSITION OF MATTHEW SANCHEZ, PH.D.

VOLUME 1

MONDAY, MARCH 1, 2021

JOB NO. 302317

REPORTED BY KATIE HRON, C.S.R. NO. 13483

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is attached hereto.)
BY MS. DEAN:
Q. With that, Dr. Sanchez, I've seen a document from McCrone in the 1970s indicating that there were concerns about contamination from transport, but not from the lab. That the -- the lab itself had had in its history zero blanks.
First of all, are -- are you familiar with the concept of blanks in -- in this context to understand what -- what that's referencing?
A. Yeah, the blanks -- the blanks would be relevant to an analysis at a given point in time. It would be appropriate to take blanks from different time periods and compare them. So blanks are run in concurrence with the sample from the laboratory as a means for the laboratory to help control or help monitor with potential contamination within the process within the laboratory itself.
Q. Have you been provided documents from Johnson & Johnson where McCrone indicates that as a lab they don't believe lab contamination is a reasonable explanation because it's their history of blanks?
A. I -- I -- again, it would depend on the nature of the situation. There were situations where when they went ahead and looked at their materials, they looked at

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their -- the filter batches and other blanks that they had when they had detected it, so that -- that -- that couldn't have been -- you know, so that would lend itself not to be a source of what was observed in the sample.
So again, to take -- to take a, you know, a specific kind of time -- time frame and then an analysis and then extrapolate it everywhere would be inappropriate. You would have to look at what happened at the time in the laboratory.
So I would not compare something that happened in 1972 to something that may have been happening in 1983 within the laboratory environment itself. So if you're looking at data from 1983 you would wanna look at what was happening in 1983.
Q. And because the time frame in this case covers kind of both those time frames --
Let me first start, and say in the 1970s, have you been provided information, to your knowledge, from Johnson & Johnson about McCrone's claims about not having in-lab contamination as it relates to asbestos?
A. Yeah. I recall documents where they were -- they were being questioned whether what they were seeing, what it was, and they went ahead and looked kind of internally what they could do to see if it was

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something that was potentially a problem from their side.
Sometimes it came out like, "We don't see a problem on our side," but most of the time where they have these chrysotile findings, a lot of times, you know, they would come out and, "Yes, we found there was an issue on our side."
So in that first instance, if that happened in 1972 and their blanks were all clean, that's a different situation than in 1983, where they go look at their blanks and the blanks were not clean.
So again, those -- those blanks -- those blanks were specific to sets of samples. Those blanks aren't -- aren't universal through all time and all space.
Q. And so when you indicate that there were filters or testing issues that were identified by McCrone and others, then is there anything, as we sit here today, that you can view to help me find what actual documents you're talking about?
A. Well, you -- what I could say is you would -- you would find the document where they claimed to have found asbestos, for instance, or they're reporting of chrysotile. Then you would look for subsequent analyses of that sample, communications about that sample and subsequent analyses. And usually that -- that is where

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those things are found. Where there's more work being done on those samples to better understand what's actually happening.
Q. And -- and that's -- I -- almost exactly what I did. I found where I saw asbestos, I asked Johnson & Johnson why they believe that was not informative. They provided me contamination documents. I could look at them concretely.
I just --
I don't know if your universe of documents are different, overlapping or not, and so in terms of just actually looking at what you're relying on, is there any way to identify that for me with any --
A. No. I'd have to do the same thing. I mean, I'd have to go and find those specific documents, and then look at the subsequent documents that were provided to me. And that would be the only way I could do it, as well, as I sit here now.
I know they exist there. I just I don't remember the dates, and the time frames exactly, or the Bates stamp number page.
Q. And there's not like a search or something we could do with your list to try to figure that out without looking at all of the source material?
A. Right. I didn't -- I have not organized it in

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that the Hutchinson report, specifically the practices and methods, are unreliable and not a robust report.

Just identify all of them for me.

A. Yeah, I already talked about the sample preparation issues with handling asbestos. We don't know how that was done.

His actual findings of any chrysotile was by using transmission electron microscopy.

There's no discussion of having control blanks. We talked about blanks earlier in this deposition. There's no idea about control blanks, process blanks, any type of protection or -- of monitoring whether or not contamination existed in the laboratory, either just inherent to the environment in 1972, or specific to his handling of -- of the specimens or the -- the bulk asbestos samples as he was preparing them.

Q. I don't wanna interrupt, but I didn't know if you were still looking. Okay.

A. No, I'm done. Sorry.

Q. Okay. Nope. That's one of the things that's hard with not being in the same space.

Have you, in your examination of testing done by McCrone and by Colorado School of Mines, seeing that in many of their reports they don't provide information about blanks or contamination handling at the lab?

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A. Was that -- I don't -- I missed your questioning, I'm sorry. I heard like a set up for a question, but not the question.

Q. Sure.

For testing done by McCrone and Colorado School of Mines in the same time frame, which I can see from your reliance list is some of the materials Johnson & Johnson gave you, did you note that in their reports they often provided no information about their use of process blanks or protections in monitoring to keep cross-contamination from occurring?

A. Well, in the case of the -- the Colorado School of Mines they were not performing transmission electron microscopy types of analyses where the chance for contamination is the most -- the highest risk.

When you're talking about the McCrone group, McCrone work, we -- you would have to -- we'd have to reference their -- their operating procedures and -- but we, again, whether -- whether or not that existed to opine is difficult to say.

However, we do know from looking at stuff in the '80s we discussed earlier, the process blanks were being prepared, filters were being held aside and not, so we evaluated the potential contamination.

You know, back in the '70s, as well, there was

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actually an issue of the filters you'd get direct from the manufacturers having already been contaminated with the manufacturing process with chrysotile. So these -- these kind of procedures became put into -- put into place and became much more robust as you went from the late '70s -- early '70s later on.

But again, you'd have to reference what little -- little information we have based upon the standard operating procedures of McCrone for the TEM testing to understand what they were doing and what time frames they were doing it.

Q. You had just referenced an indication about manufacturing problems that resulted --

Well, what is the basis of your understanding for that?

A. Common knowledge. There are -- for instance, when you look at -- when you look at the -- the PCM methodologies by NIOSH and OSHA, they have a background fiber count, and -- and what you do is you go through and you do your counts on the -- on the air samples. And you actually -- you have to analyze blank filters at the same time in the same amount of area. And then you actually blank correct your -- your samples with the understanding that you're -- that you're blank. The filters themselves could be contaminated with fibers,

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and you have to account for that as part of your quantitation procedure.

So it's because of that issue of the contamination that these controls and these processes are put into the analytical methods to guard against it.

MS. DEAN: Let me object to nonresponsive, and see if maybe I can ask a clearer question.

BY MS. DEAN:

Q. So you provided to me enough information that I could find that ATSM document that we marked as Exhibit 16 that talks about how quantification analysis occurred.

Do you broadly remember talking about that this morning?

A. Yes.

Q. Okay. I thought I understood in an answer you gave two answers ago that the manufacturing process caused contamination in Johnson & Johnson --

A. No.

Q. Maybe I -- maybe I misunderstood.

Which is why --

A. So -- yeah. What I was speaking to is: In order to prepare a sample of a -- for example, a Johnson & Johnson talc sample for a TEM analysis, you have to somehow get it onto these very small grids to be able to

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go into that instrument -- instrument so you can look at these things at a high magnification.

Historically, especially in the '70s, when asbestos was much more ubiquitous in -- in the environment based upon the use of it, a lot of times you'd get a set of filters in that you would be using to put materials down on to analyze for asbestos where the filters would show up already contaminated with asbestos.

So the analytical methods have you run blanks in those types of analyses in order to protect you from that. So that -- that is one of those reasons you run the blanks of the filters that you're using.

In this case they're using foam board grid, but it would be the same -- the same would apply. You'd have to make sure that the -- the foam board grids that you've received are not contaminated. And then you would have additional kind of blank samples that you would have in order to protect against your processing of the samples to make sure that you are not introducing asbestos into that -- into that sample by your -- by your handling and your lab practices.

Q. In terms of the ideas that the filters could be contaminated with asbestos, is there something on your reliance list that you could point me to that would

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support that that was happening back in the '70s?

A. Well, it's a fact. Whether it's something that's on my reliance list or not, I'm not sure. I think I would ultimately cite toward the standard method which require blank analyses. That's the purpose of the blank analyses is to make sure that the raw materials that you're -- the -- the raw -- the -- you know, the raw materials you're using in order to prepare the samples for analysis don't, themselves, contain any -- any asbestos. And where they do, you need to make sure that -- you need to account for that on your detection and quantification.

MS. DEAN: I'll object nonresponsive, and I just --

BY MS. DEAN:

Q. In -- in having an opinion so strongly that it is a fact in time from before -- just given your age, you weren't doing this.

I'm just wondering if anything -- I guess, other than current protocols, and we marked that as Exhibit 16, talking about why we have blanks, that you can -- you can reference for me, either by referencing it on your list or otherwise, that indicates that filters were contaminated with asbestos back in the '70s.

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A. I mean, I could find a reference. Whether there's one in my reliance list, I'm not sure of.

But again, the whole -- the whole point of running the blank is to guard against that. And it was a particular problem early on when asbestos was used as, you know, so broadly in society in so many environments. It was much more of a problem in the past than it's become today.

Q. Okay. Is that something that you could -- that -- you said you weren't sure if it's on your reliance list, but you, you know, you could find that.

Is that something that you can do as we sit here now, or would you need time to -- to figure that out?

A. I'm not gonna do that, as I sit here now.

Q. Okay.

A. We've looked into this issue in the past. I'd have to go back and see what I found or things -- I just don't recall what that would have been. It's been a few years since I --

These are issues I looked at like 15 years ago.

I'm trying to understand the methods and why certain steps were required, so it's going back quite a few years.

Q. In terms of the kind of broader opinion you

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gave there is that asbestos is ubiquitous in the environment.

Do you --

A. It's much more ubiquitous.

Q. Huh?

A. It's much more ubiquitous.

Q. Oh, sure.

In terms of the amount of asbestos in the environment, are you -- are you meaning by that the repeated testing done in the '70s and '80s of ambient levels of asbestos or background levels of asbestos in rural and urban environments, or do you mean something different?

A. I mean something just more -- more broad. Just the fact of, if you contrast the -- the amount of asbestos consumed by the United States in various products and in manufacturing in -- you know better than I how many different types of materials asbestos was used in probably.

Just it's general use as a -- as a building material. It's used in sciences. You know, filtration, caustic filtration units. Crucibles. They used to make the hoods -- the hoods of -- sorry -- the -- a lot of older hoods will have cement boards and the internal lining, which is that type of transite, which contains

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deposition.
Q. Okay.
MS. DEAN: Well, I understand you need to go.
I have some other questions, but I'm sure we can sort something out.
I also think we're talking to you in another case soon, and maybe we can double up on those or something to save you time.
But let me talk to Johnson & Johnson folks and get you to your family event today.
THE WITNESS: Thank you.
MR. EWALD: Thank you, Dr. Sanchez.
THE WITNESS: The court reporter had some spellings. I don't know if she wants to email those to me, or I can -- I can respond to an email for the spellings if she has them.
THE REPORTER: Can we go off the record?
MR. EWALD: Yeah.
MS. DEAN: Sorry.

(A discussion was held off the record.)

MS. DEAN: So this is Jessica. After a little bit of a break and looking at the exhibits, there was reference to Exhibits 1 through 27. Some of those

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exhibits we are asking the witness to work with Johnson & Johnson to attain them to provide me the information. The others have been provided to the court reporter -- to the court reporter with one exception, Exhibit 2 was not referenced or marked.
I think other than that, we're gonna work with Counsel to just figure out when and how to take the deposition, and we're done for today.
MR. EWALD: Great.
Thanks everybody.
MS. DEAN: Thanks.
Take care.
(Whereupon at 2:14 p.m. the deposition of Matthew Sanchez, Ph.D., Volume 1, was concluded.)

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STATE OF CALIFORNIA)
)
COUNTY OF RIVERSIDE)

I, Matthew Sanchez, Ph.D., hereby certify under penalty of perjury under the laws of the state of California that the foregoing is true and correct.
Executed this _____ day of _____, 20__, at _____, _____.

_____
Matthew Sanchez, Ph.D.

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STATE OF CALIFORNIA)
)
COUNTY OF RIVERSIDE)

I, KATIE HRON, C.S.R. No. 13483, in and for the State of California, do hereby certify:
That prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth.
That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and the same is a true, correct, and complete transcript of my shorthand notes so taken.
That if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript { } was { } was not requested.
I further certify that I am not interested in the event of this action.
In witness whereof, I have hereunto subscribed my name on March 12, 2021.

Katie Hron
Katie Hron, C.S.R. No. 13483

Exhibit C

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Matthew S. Sanchez, Ph.D.

Education

- Ph.D., Geology, University of Idaho, 2012
- M.S., Geology, University of Idaho, 2007
- B.S., Geology, University of Idaho, 2005

Employment History

- RJ Lee Group, Inc., Principal Investigator, 2015-Present
- RJ Lee Group, Inc., Technical Manager, Technical Consulting Services, 2012-2014
- RJ Lee Group, Inc., Technical Manager, Optical, TEM and XRD Services, 2011-2012
- RJ Lee Group, Inc., Technical Manager, Optical and XRD Services, 2009-2011
- RJ Lee Group, Inc., Scientist, 2007-2009

Summary

- Quantitative mineralogy of minerals and building materials by light microscopy
- Determination of asbestos minerals in bulk materials samples
- Determinative mineralogy of rock quarry samples by light microscopy
- Characterization of amphibole minerals
- Quantitation of amphibole and chrysotile group minerals by powder X-ray diffraction
- Conducts site investigations of mines worldwide
- Developed microscopy method for identification and quantification of coal ash residues to screen for impacted areas as part of cleanup efforts following containment failure. Methodology has been accepted by the EPA
- Provides technical oversight of optical microscopy, transmission electron microscopy and x-ray diffraction services
- Applied analytical techniques include polarized light microscopy (PLM), scanning electron microscopy, powder X-ray diffraction, and electron probe microanalysis.

Memberships

- Mineralogical Society of America
- Mineralogical Association of Canada
- Geological Society of America
- USP Talc Expert Panel

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STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	CIVIL ACTION NO. 2023-CP-40-04072
MICHAEL L. PERRY AND LONNIE L. LONG,	)	*In Re:* Asbestos Personal Injury Litigation Coordinated Docket
Plaintiffs,	)	**JOHNSON & JOHNSON DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* NO. 17 TO PRECLUDE THE TESTIMONY OF DR. GREGORY DIETTE**
vs.	)	
AMERICAN INTERNATIONAL INDUSTRIES, ET AL.,	)	
Defendants.	)	

Defendants Johnson & Johnson ("J&J"), LLT Management LLC, Johnson & Johnson Holdco (NA) Inc. ("Holdco"), and Kenvue, Inc. ("Kenvue"), (collectively "J&J Defendants"), submit this brief in response to Plaintiffs' Motion in Limine No. 17 to preclude the testimony of Dr. Gregory Diette (PLF MIL #17)[1]. As set forth below, Plaintiffs' motion is without merit and should be denied.

INTRODUCTION:

Plaintiffs seek the wholesale preclusion of Dr. Diette's causation opinions concerning Mr. Perry under the exact same basis for which his testimony was limited in the *Payne* and *Plant* cases. In so doing, Plaintiffs misconstrue both the substance and data underlying Dr. Diette's proffered opinions. Following the review of significant case materials, medical and scientific literature, and

[1] In Plaintiffs' Omnibus MIL No. 1, Plaintiffs label this motion as "Motion *in Limine* No. 17 to Exclude the Testimony of Gregory Diette and Dr. David Weill." However, Plaintiffs' motion itself only sought to exclude the opinions of Dr. Diette.

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testing reports, Dr. Diette reached the following opinions with respect to the cause of Mr. Perry's mesothelioma:

- There is no objective evidence that Mr. Perry had any exposure to asbestos from any of the cosmetic talc at issue;
- Based on the available medical and scientific literature, it is not plausible that asbestos as a potential contaminant of any of the cosmetic talc at issue could have caused Mr. Perry to develop pleural mesothelioma;
- If Mr. Perry did not have significant commercial asbestos exposure, it is most likely that his mesothelioma developed spontaneously or was naturally occurring; and
- It is possible that Mr. Perry has a hereditary risk for developing cancer especially given his young age, and personal and family history.

(*See* Ex. A, Diette *Perry* Rep., Pgs.62-64).

Plaintiffs claim his opinions still lack sufficient foundation. Yet, the fundamental flaw in Plaintiffs' quest to exclude these opinions is that they ***completely*** ignore the significant work Dr. Diette has done in this case to overcome each one of this Court's prior foundational criticisms of his opinions. In concluding that Dr. Diette, and others, did not have sufficient information to testify as to the cause of mesothelioma, this Court made three separate observations:

(1) these doctors have not made an attempt to determine the products at issue contined asbestos at all.

(2) They did not make an attempt to determine the fiber type of asbestos potentially associated with any talc product at issue in this case.

(3) these doctors have not reviewed any studies relating to the products at issue in this case either purporting to demonstrate the presence or lack of presence of asbestos in the products or for purposes of determining the amount of asbestos released from the normal and expected use of these products.

(*See* Ex. B, February 28, 2023, *Payne*/*Plant* MIL Order, Pgs 3-4.) Notably, this Court did not find that Dr. Diette was unqualified to render his opinions; rather, this Court focused on what he had not reviewed, or made efforts to determine, in reaching his causation opinions. When investigating

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the cause of Mr. Perry's mesothelioma, however, Dr. Diette took great care to avail himself of additional information and data he had not reviewed in *Payne* and *Plant* which directly correlates to each one of the substantive areas of inquiry this Court previously found lacking. Thus, the same limitation of his causation opinion is not warranted here, and Plaintiffs' motion should be denied.

STANDARD OF REVIEW

Rule 702 of the South Carolina Rules of Evidence provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." The trial court must act as a gatekeeper over scientific evidence and make three preliminary findings before expert testimony may be admitted. *Watson v. Ford Motor Co.*, 389 S.C. 434, 445, 699 S.E.2d 169, 175 (2010) (Toal, C.J.). In determining admissibility of expert testimony, the court must make three inquiries: First, the court must determine whether 'the subject matter is beyond the ordinary knowledge of the jury, thus requiring an expert to explain the matter to the jury.'" *Graves v. CAS Med. Sys. Inc.*, 401 S.C. 63, 74, 735 S.E.2d 650, 655 (2012) (quoting *Watson*, 389 S.C. at 446, 699 S.E.2d at 175). "Second, the expert must have 'acquired the requisite knowledge and skill to qualify as an expert in the particular subject matter,' although he 'need not be a specialist in the particular branch of the field.'" *Id*. Third, "the substance of the testimony must be reliable." Id. The reliability prong is the "central feature" of the analysis. *Id*. (citing *White*, 382 S.C. 265, 270, 676 S.E.2d 684, 686 (2009)). If the proffered expert testimony is scientific in nature, the court must determine the reliability prong under the factors set forth in *State v. Council*, 335 S.C. 1, 515 S.E.2d 508 (1999). *See Graves*, 401 S.C. at 74, 735 S.E.2d at 655. South Carolina courts look to four factors: "(1) the publication and peer review of the technique; (2) prior application of the

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method to the type of evidence involved in the case; (3) the quality control procedures used to ensure reliability; and (4) the consistency of the method with recognized scientific laws and procedures." *Id*. (quoting *Council*, 335 S.C. at 19, 515 S.E.2d at 517).

ARGUMENT

A. Dr. Diette is Well Qualified to Offer a Causation Opinion.

Dr. Diette is a licensed and board-certified physician in pulmonary medicine and internal medicine. (*See* Ex. A, Dr. Diette Report, p. 2). He is an attending physician at the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center. (*Id*.) Dr. Diette is also a Professor in the Division of Pulmonary & Critical Care Medicine at The Johns Hopkins University School of Medicine and a Professor of Epidemiology and Environmental Health and Engineering at the Bloomberg School of Public Health at Johns Hopkins. (*Id*.) Dr. Diette has focused his research on environmental causes of human disease. (*Id*.) In addition to his medical degree, Dr. Diette has a master's degree in epidemiology from Johns Hopkins University. (*Id*.)

B. Dr. Diette's Opinion that Mr. Perry's Mesothelioma Was Not Caused By Asbestos In Cosmetic Talc is Reliable and Supported by Data.

Plaintiffs attack the foundation of Dr. Diette's opinion that Mr. Perry had no asbestos exposure from cosmetic talc by falsely claiming he "has not reviewed any materials specific to the asbestos content of the products at issue in this case". (*See* Pl.'s Motion No. 17, pg. 10.) Plaintiffs repeatedly misrepresent the scope of what Dr. Diette has unambiguously reviewed in this case, even stating: "[T]wo pieces of evidence that would educate Dr. Diette about the asbestos content of the products Mr. Perry used are testing of those products and epidemiological studies of the talc mines. **Dr. Diette has reviewed neither.**" (*See* Pl.'s Motion No. 17, pg. 11)(emphasis added.) **This is completely false**. In fact, Dr. Diette reviewed those *exact* two pieces of evidence to educate himself. Dr. Diette not only reviewed a significant number of epidemiological studies, **but also**

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reviewed every single one of Plaintiffs' expert reports that contain testing data – the very reports, data and opinions which will be proffered by Plaintiffs in support of their position that there is asbestos in talc. Specifically, Dr. Diette relied on the following, as fully set out in his report:

- **Epidemiological studies:**
  - Dr. Diette reviewed and relied upon significant epidemiological evidence, to include a study conducted by the National Institute for Occupational Safety and Health which supported his conclusion that cosmetic talc exposure does not cause mesothelioma. (*See* Ex. A, Dr. Diette Report, p. 45-49.) The epidemiological studies he reviewed included data from Italy and Vermont mines and mills. He reviewed peer reviewed literature about cosmetic talc miners and millers where no asbestos was detected in the talc and the conclusions were consistently reached that exposure to cosmetic talc is not associated with the development of mesothelioma. (*Id*.)

- **Airborne dust concentration studies:**
  - Dr. Diette reviewed and relied upon substantial evidence concerning the airborne dust concentrations in talc mines and mills in reaching his conclusion that exposure to talc does not cause mesothelioma. (*See* Ex. A, Dr. Diette Report, p. 49-53.) Notably, Dr. Diette reviewed several studies pertaining to Vermont mining and milling operations. (*Id*. at 49.) Dr. Diette compared that data to peer reviewed literature demonstrating that the potential for a consumer to be exposed to asbestos in cosmetic talc was very low and below general population background airborne cumulative lifetime exposure. (*Id*. at 53.) Dr. Diette reviewed and relied upon peer reviewed literature concerning the lifetime ambient cumulative exposure to asbestos in the US population. (*Id*. at 54.)

- **Testing of Talcum Powder Products for Asbestos**
  - Dr. Diette reviewed and relied upon the expert reports and opinions of Defendants' experts and Plaintiffs' experts in this case. He specifically reviewed and relied upon the following Plaintiffs' expert reports: R. Mark Bailey, PG., Dr. William E. Longo, PhD., Dr. Mark W. Rigler, PhD., William B. Egeland, MS, PG., Martin Bennett, and Dr. Steven P. Compton, PhD. (*See* Ex. A, Dr. Diette Report, p. 54-59.)
  - Dr. Diette reviewed the reports and data proffered by Plaintiffs' experts that purported to show that Johnson & Johnson talc products sourced from Italy and Vermont mines contained asbestos. (*Id.* at 55.)

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- He reviewed the reports and data of Plaintiffs' experts that opined the application of talcum powder, to include Johnson & Johnson talcum powder, would cause significant exposure over background to asbestos. (*Id.* at 56.)
- Dr. Diette reviewed all of Dr. Longo's MAS Analytical reports submitted in this case where he tested Johnson & Johnson products from all three source mines for Johnson & Johnson cosmetic talcum powder products sold in the United States: Italy, Vermont and China. (*Id.* at 57.)
- Dr. Diette reviewed the reports of Defendants' experts that contained testing data and opined the cosmetic talcum powder at issue is free from asbestos, and that the hypothetical exposure experienced by Mr. Perry did not present any significant risk towards his development of mesothelioma. Dr. Diette reviewed reports and data of Defendants' experts that any hypothetical exposure to asbestos from talcum powder products at issue would be substantially less than Mr. Perry's ambient exposure and presented no significance towards the development of mesothelioma. (*Id*.)

In short, Dr. Diette did *exactly* what Plaintiffs claim he should do to establish the sufficient foundation necessary to opine that the talcum powder products Mr. Perry used did not contain asbestos. By reviewing a substantial set of medical and scientific literature, as well as Plaintiffs' expert reports and testing data, Dr. Diette made significant efforts to determine whether or not the cosmetic talcum powder products at issue contained asbestos, the fiber type of asbestos potentially associated with the cosmetic talc products at issue in this case, and to further educate himself on studies relating to the product at issue pertaining to the presence or absence of asbestos or the amount of asbestos, if any, released into the air upon use of the product. Dr. Diette followed the blueprint set by this Court in the *Payne* and *Plant* cases, and thus has far overcome the foundational challenge presented by Plaintiffs.

C. Dr. Diette's Opinion that Mr. Perry's Mesothelioma Developed Spontaneously or was Naturally Occurring is Reliable and Supported by Data.

After his review of all the case specific evidence, medical literature, scientific evidence, testing data and expert reports in this case, it is Dr. Diette's opinion that Mr. Perry's mesothelioma most likely developed spontaneously or was naturally occurring:

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> I have not seen evidence in this case of any significant exogenous exposure (including asbestos) that would raise his risk of developing pleural mesothelioma, though I cannot rule out a contribution from his claimed occupational exposures. If Mr. Perry did not have significant exogenous exposure from commercial amphibole asbestos, it is most likely that his mesothelioma developed spontaneously or was naturally occurring.

(*See* Ex. C, Diette's *Perry* Supp. Ex. Rep., July 2, 2024, Pg. 4.)

Importantly, this Court in *Payne* and *Plant* did not preclude Dr. Diette from giving his general opinion regarding the rates of mesothelioma which are "spontaneous" or "naturally-occurring". (*See* Ex. C, Pg. 4.) Instead, Dr. Diette was precluded from giving his specific causation opinion that their mesotheliomas most likely developed spontaneously or were naturally occurring. In seeking to get the same outcome in this case, Plaintiffs once again falsely state that "Dr. Diette has not reviewed any evidence about the asbestos content of the talcum powder products at issue" before declaring that Mr. Perry's mesothelioma is spontaneous. (*See* Pl.'s MIL No. 17, pg, 8.) Yet, as set forth above, Dr. Diette not only reviewed "evidence" about asbestos content of talcum powder products at issue, he reviewed all of Plaintiffs' experts testing data on the talcum powder products at issue.

Plaintiffs concede there is scientific literature supporting the proposition there are cases of mesothelioma which cannot be attributed to asbestos exposure. (*See* Ex. Pl. MIL No. 17 at 5-7.) Furthermore, Plaintiffs do not rebut Dr. Diette's well-founded opinion with any scientific literature concluding that mesothelioma cannot occur spontaneously. Nor did they submit any conflicting testimony from their experts. To the contrary, Plaintiffs' own expert, Dr. Arnold Brody, has testified many times that any form of cancer, including mesothelioma, can occur spontaneously. (*See* Ex. D, Garcia, March 20, 2024, Brody Trial Tr. 137:12-138:14; Ex. E, February 22, 2021, Brody *Eggers* Dep., 28:10-13.) Instead, Plaintiffs focus much of their argument on this issue on an entirely different expert that is not in this litigation – Dr. Suresh Moolgavkar – and his opinion

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in a different case concerning the background rate for spontaneous mesothelioma (*Id*. at 7-8.) This is an odd red herring, as nowhere in Dr. Diette's expert reports does he offer the same opinion. (*See generally* Ex. A (Report) and Ex. C (Supp. Report.)

Any difference of opinion between Plaintiffs' experts and J&J Defendants' experts on spontaneous mesothelioma or the rate of mesothelioma not exposed to asbestos is not a basis for preclusion but fodder for cross-examination. After ruling out talcum powder as the cause of Mr. Perry's mesothelioma, noting that there is no clinical evidence that Mr. Perry had any exposure to asbestos, and noting Mr. Perry's prevalent family history of cancer, Dr. Diette logically concluded that Mr. Perry mesothelioma was most likely spontaneous or naturally occurring. Dr. Diette should be allowed to proffer his well-informed opinion.

D. Dr. Diette's Opinion that Mr. Perry May Have a Hereditary Risk for Developing Cancer is Reliable and Supported by Data.

Mr. Perry's mesothelioma was first diagnosed in 2023 (age 52). (*See* Ex. A, pgs. 2-3.) He has a family history of cancer including: mother had lung cancer, and reported breast cancer and uterine cancer, father had prostate cancer, a maternal grandmother who had colon cancer, maternal grandfather that had liver cancer, paternal grandfather that is reported in medical records to have had mesothelioma, and a paternal aunt with breast cancer. (*See* Ex A.) On July 12, 2023 Mr. Perry's tumor was tested and the BAP-1 was intact and later noted that it "did not harbor a BAP-1 mutation." (*See* Ex. A, Diette Report, Pg. 24, citing August 10, 2023 Op Note.) Mr. Perry has yet to undergo any additional genetic testing. (*See* Ex A, Diette Report Pg. 63.) While J&J Defendants do not dispute that BAP-1 has been ruled out as a germline mutation for Mr. Perry, BAP-1 is only one of several genes that have been identified as potentially being involved in a predisposition to malignant mesothelioma. The fact that Mr. Perry does not have a BAP1 germline mutation does not foreclose the possibility of having other germline mutations. (*See* Ex. F, Diette

Dep., July 3, 2024, 46:3-9.) Given Mr. Perry's young age and personal and family history of malignancies, which are clinical characteristics associated with germline mutations, Dr. Diette opines that it is possible Mr. Perry had an inherited genetic risk factor for cancer especially. (*See* Ex. A at p. 63.)

J&J Defendants are entitled to explore that possibility with Dr. Diette and on cross examination of Plaintiffs' experts and need not establish with certainty that these factors proximately caused Mr. Perry's injuries. Accordingly, Dr. Diette's opinion pertaining to known clinical characteristics associated with germline mutations, Mr. Perry's personal and family history, and the lack of complete germline testing is proper expert testimony he should be allowed to provide to the jury.

CONCLUSION

For all the reasons discussed above, J&J Defendants respectfully requests that the Court deny Plaintiffs' Motion *in Limine* to Exclude the Testimony of Dr. Gregory Diette, in its entirety.

Respectfully submitted,

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Columbia, South Carolina

July 24, 2024

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Exhibit A

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Gregory B. Diette, M.D., M.H.S.

27 June 2024

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Columbia, Maryland 21045

Ms. Lucy Willson, Esq.
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RE: Michael Perry v. Johnson & Johnson, *et al*.

Dear Ms. Willson,

This report has been prepared at your request as a summary of my opinions regarding claims that Mr. Michael Perry contracted pleural mesothelioma as a result of asbestos exposure.[1] Mr. Perry claimed that he was exposed to asbestos from occupational and non-occupational sources.[2]

I have reviewed the materials, in this case, to determine the potential role, if any, of talcum powder containing products from Johnson & Johnson ("Johnson's Baby Powder" and "Shower to Shower") that were allegedly purchased at Wal-Mart locations, Avon ("Avon Deep Woods," "Avon Musk," "Avon Spicy," "Timeless," "Soft Musk," "Cotillion," "Birds of Paradise," and "Skin So Soft"), Vi-Jon ("Equate"), Estée Lauder Companies ("ELC" for "White Linen"), Gold Bond and Ammens products allegedly bottled by PTI Royston, and cosmetic talc allegedly produced by IMI-Fabi, LLC, IMI Fabi (USA), LLC and IMI Fabi (Diana) LLC allegedly containing asbestos, as a cause of Mr. Perry's disease.

A list of case materials and literature relied upon may be found in Appendices A, B, and C.

[1] Summons and Complaint, p. 13.
[2] Summons and Complaint, p. 15-16, 26, 59-60.

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PROFESSIONAL QUALIFICATIONS.

I am a physician licensed to practice in the State of Maryland and am Board Certified in pulmonary medicine and internal medicine. I am an attending physician at the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center which includes outpatient and inpatient care. I am Professor in the Division of Pulmonary & Critical Care Medicine at The Johns Hopkins University School of Medicine. Additionally, I am Professor of Epidemiology and Environmental Health and Engineering in the Bloomberg School of Public Health at Johns Hopkins. My research is focused on the environmental causes of human diseases. I obtained my undergraduate degree from the University of Pennsylvania, my medical degree from Temple University, and my Master's in Epidemiology from Johns Hopkins University, School of Hygiene and Public Health. My residency training in internal medicine was at the Hospital of the University of Pennsylvania and Pulmonary Critical Care Fellowship was at Johns Hopkins Hospital.

BACKGROUND AND EMPLOYMENT HISTORY FOR MR. PERRY.

Background.

Mr. Michael Perry was born on 20 December 1969 in Springfield, IL. In 1976 Mr. Perry moved with his family to a house in Springfield that was built on pastureland, where his family kept chickens and a large garden.[3] Mr. Perry stated that his parents did not utilize chemicals, fertilizers, or pesticides on this property.[4] He lived on a sailboat for spring breaks and summers during college and after he graduated he moved to the sailboat full time.[5] Mr. Perry has lived in Charleston, South Carolina since 1996, and was living there at the time of his deposition in 2023. From approximately 2003 to 2020, he lived on a 15-acre horse farm and raised horses, cows, chickens, and goats.[6]

Mr. Perry's father was an aviation mechanic and inspector, working in the cockpit of planes at Springfield Capital Airport.[7] At the time of Mr. Perry's deposition, his father was age 78 and had late-stage prostate cancer.[8] Mr. Perry's mother was a computer programmer for Horace Mann

[3] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 24; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 267-269; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 663.
[4] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 665, 668.
[5] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 18-19, 24; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 267-270; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 459-461, 497; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 655-656, 677-678, 680, 682-683, 686.
[6] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 23-24, 28, 76-77; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 271-273; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 457, 498; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 656-658, 667, 689.
[7] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 22-23; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 284-285.
[8] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 250; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 865.

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Insurance Co.[9] She was diagnosed with "*uteral cancer*" [sic] that was discovered when she gave birth to Mr. Perry, she had a massive heart attack in 2007, and she died of small cell carcinoma lung cancer in 2010.[10,11] Mr. Perry has an older sister named Michelle who is reportedly in good health, although he had not spoken to her in over twenty years.[12] Mr. Perry's maternal grandmother died of colon cancer sometime prior to 2010.[13] His maternal grandfather died of pancreatic cancer.[14]

Mr. Perry married his husband, Mr. Lonnie Long, in approximately 2006. Mr. Long is a retired realtor.[15]

Mr. Perry has a history of kidney stones, knee and hernia operations, lipoma removal from the back of his neck, and oral surgeries, such as root canals and tooth extractions.[16] He had a partial colectomy in 2010, where nine inches of ascending colon was removed because of recurrent diverticulitis.[17]

Mr. Perry was diagnosed with COVID-19 in January 2023.[18] After testing negative 14 days later, he had a persistent cough that worsened and he developed night sweats.[19] He went to see his physician for an annual checkup and was told his labs were "*awful*."[20] He was put on an antibiotic and steroid to rule out pneumonia.[21] He received a chest x-ray which was "*a little hazy*" and was sent in for a CT scan with contrast on his lung.[22] After receiving the results, he was sent to a thoracic surgeon who stated he could have mesothelioma, lung disease, or a noncancerous aggressive skin disease.[23] They performed a biopsy the following day (in July 2023) which, with pathology, confirmed a diagnosis of mesothelioma.[24]

[9] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 22-23; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 388.
[10] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 54-56; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 249; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 865, 899.
[11] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 865.
[12] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 211, 250; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 505.
[13] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 249; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 427-428.
[14] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 249.
[15] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 192-193.
[16] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 327, 329.
[17] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 328; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 825.
[18] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 147-148.
[19] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 147-148.
[20] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 147-148.
[21] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 147-148.
[22] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 149.
[23] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 150-151.
[24] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 150-151.

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Employment History.

Mr. Perry graduated from Riverton High School in Springfield, IL in 1988 before attending and graduating from the University of Illinois with a degree in communications in 1993.[25] He then attended the College of Charleston where he sought a degree in finance and hotel management. He did not obtain a degree.[26]

Mr. Perry and his sister "*walked beans and corn*" as a summer job in their rural farming community when they lived in the family home.[27]

When Mr. Perry was 15 years old, in approximately 1985, he worked as a lifeguard at the Holiday Inn Holidome pool in Springfield, IL. He was ultimately promoted to resident manager.[28] He worked this job through college until he left around 1993.[29]

Starting in 1989, Mr. Perry spent his spring and summer breaks as a sailboat operator, providing one-week charters through the Florida Keys and Bahamas for the general public before moving to the boat to continue this work full time from approximately 1993 through 1996.[30]

After moving to South Carolina, Mr. Perry worked for Hilton Hotel Worldwide from 2000 to 2017, where he was a general manager and consultant, traveling to various hotel properties to ensure integrity and cleanliness.[31] From 2017 to 2020, he was the general manager at Homewood Suites. In 2020, he started working as the general manager at Market Pavilion. He was on medical leave at the time of his deposition.[32]

Social Security Records reflect earnings from various jobs reported on his behalf including country clubs, YMCA/YWCA, a farm supply store, Boy Scouts, a sporting goods store, insurance companies, other hotels or management companies, a pizza store, a clothing store, FedEx, transportation and leasing companies, and a baking company, however, no testimony was provided regarding these employments.[33]

[25] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 19; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 196; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 445.
[26] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 19.
[27] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 211.
[28] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 26-27; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 206-208, 274; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 840.
[29] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 840.
[30] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 49-50; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 270, 356, 358; Videotaped Deposition of +Michael Perry, Vol III, taken 12 October 2023, p. 354-355, 497; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 719, 841.
[31] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 52; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 276-278.
[32] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 282.
[33] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 5-11.

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Work History Chart:

Approximate Dates	Employer (Location)	Title/Task	Claimed Asbestos Exposure
1985	Oakcrest Country Club (Springfield, IL)[34]	No testimony provided	Not specified
1985 to 1993	Holiday Inn "Holidome" (Springfield, IL)[35]	Lifeguard, management	Drywall, joint compound[36]
1986	Springfield Pleasure Driveway and Park District Bookkeeper (Springfield, IL)[37]	No testimony provided	Not specified.
1987	Illini Country Club (Springfield, IL)[38]	No testimony provided	Not specified
1987	Young Men's Christian Assn of Springfield (Springfield, IL)[39]	No testimony provided	Not specified
1987 to 1991, 1994, 1997 to 2000	Raynor Hotel Co. (Dixon, IL)[40]	No testimony provided	Not specified
1987	MM&B Management Inc (Springfield, IL)[41]	No testimony provided	Not specified
1987 to 1990	Springfield Park District (Springfield, IL)[42]	No testimony provided	Not specified
1988	Young Women's Christian Association of Springfield (Springfield, IL)[43]	No testimony provided	Not specified
1989 to 1996	Midnight Dragon Boat Tours (Florida, Bahamas)[44]	Operator	None claimed.

[34] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1985 to 2000, p. 4.
[35] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 127-129.
[36] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 127-129; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 273; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 843-846, 877.
[37] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1985 to 2000, p. 4.
[38] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 5.
[39] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 5.
[40] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 5-6.
[41] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 6.
[42] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 6.
[43] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 6.
[44] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 26-27, 49-50; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 197, 270, 354-356, 358; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 656.

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Approximate Dates	Employer (Location)	Title/Task	Claimed Asbestos Exposure
1989 to 1990	Farm Supply Services Inc (Springfield, IL)[45]	No testimony provided	Not specified
1990 to 1993	Boy Scouts of America (Irving, TX)[46]	No testimony provided	Not specified
1990 to 1992	Illini Sporting Goods Inc (Springfield, IL)[47]	No testimony provided	Not specified
1991	Adventures Underwater (Springfield, IL)[48]	No testimony provided	Not specified
1993	Vics Pizza Inc (Springfield, IL)[49]	No testimony provided	Not specified
1994	Lincoln Land FS Inc (Jacksonville, FL)[50]	No testimony provided	Not specified
1994	General Car & Truck Leasing System Inc (Davenport, IA)[51]	No testimony provided	Not specified
1994 to 1995	Gap Inc (San Fransisco, CA)[52]	No testimony provided	Not specified
1995 to 1996	Viacom Inc. (Torrance, CA)[53]	No testimony provided	Not specified
1996 to 1997	Springfield Enterprises Inc (Scottsdale, AZ)[54]	No testimony provided	Not specified
1996	Federal Express Corporation & Subsidiaries (Collierville, TN)[55]	No testimony provided	Not specified
1997	Metropolitan Life Insurance Co (Saint Louis, MO)[56]	No testimony provided	Not specified

[45] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 6.
[46] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 7.
[47] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 7.
[48] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 7.
[49] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 7.
[50] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 8.
[51] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 8.
[52] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 8.
[53] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 8.
[54] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 8.
[55] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 9.
[56] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 9.

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Approximate Dates	Employer (Location)	Title/Task	Claimed Asbestos Exposure
2000	Bunch Transport Inc (Columbia, SC)[57]	No testimony provided	Not specified
2000 to 2009	Promus Operating LLC Sole MBR (Hilton Hotels)[58] (Memphis, TN)	General Manager and Consultant	Drywall, joint compound[59]
2010	Aetna Life Insurance Company (Hartford, CT)[60]	No testimony provided	Not specified
2010 to 2011	Park Hotels & Resorts Inc (Tysons, VA)[61]	General Manager and Consultant	Not Specified
2011 to 2015	City Market Hotel Associates LLC (Doubletree Guest Suites)[62] (Charleston, SC)	General Manager and Consultant	Drywall, joint compound[63]
2015 to 2016	Derst Baking Company (Savannah GA)[64]	No testimony provided	Not specified
2016 to 2020	Trinet HR II Inc (Lakewood Ranch, FL)[65]	No testimony provided	Not specified
2016	Oasis Outsourcing V Inc (West Palm Beach, FL)[66]	No testimony provided	Not specified
2017 to 2020	Homewood Suites (Mount Pleasant, SC)[67]	General Manager	Not specified
2020 to 2021	WHHG Mt. Pleasant Management LLC (Boston, MA)[68]	No testimony provided	Not specified

[57] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 9.
[58] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 9.
[59] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 129-130, 132-135; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 280; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 848, 850, 877.
[60] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 10.
[61] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 10.
[62] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 10.
[63] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 132-133.
[64] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 10-11.
[65] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 11.
[66] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 11.
[67] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 24, 32, Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 282.
[68] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 11.

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Approximate Dates	Employer (Location)	Title/Task	Claimed Asbestos Exposure
2021 to 2022	Aimbridge Employee Service Corp (Plano, TX)[69]	No testimony provided	Not specified
2022 to 2023	Market Pavilion Hotel Inc (Charleston, SC)[70]	General manager	Not specified

PLAINTIFF'S POTENTIAL ENCOUNTERS WITH ASBESTOS.

Occupational

From approximately 1985 through 1993, Mr. Perry worked as a lifeguard and as a general manager at a Holiday Inn Holidome in Springfield, IL, where renovations and repairs were completed in hotel rooms due to water damage, mold, and mildew from an indoor pool.[71] He was present while this work was performed and witnessed people cutting sheetrock, taping joints, using compound, and dry sanding.[72] He walked around with the general manager to check rooms for completion of work.[73] Mr. Perry testified there were no barriers in place as the work was completed and claimed there was drywall dust throughout the hotel.[74] He claimed drywall typically only lasted a few months in the pool area before it was replaced.[75]

While working at Embassy Suites in Charleston, SC as a general manager from 2000 to 2001, Mr. Perry testified there was sheetrock replacement done due to water damage.[76] He alleged that he was in proximity to this work as it was completed, and he went to the rooms to verify the work was done properly after completion.[77]

Mr. Perry testified that there was a library next to Embassy Suites that the hotel used for storage. The building was reportedly condemned by the county because it contained asbestos.[78] Mr. Perry reportedly entered the library "*on a semi-regular basis*" or possibly more than two times a month

[69] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 11.
[70] Social Security Administration - Itemized Statement of Earnings for Michael Perry – 1987 to 2023, p. 11.
[71] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 127-128; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 273.
[72] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 843-845
[73] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 129; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 273; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 843.
[74] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 844-845.
[75] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 127-128; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 845-846.
[76] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p.129-130; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 278; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 848.
[77] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 132; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 848.
[78] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 130-131; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 279-280; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 849.

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to add or retrieve furniture for the hotel. He stated workers may have hit the ceiling while moving things "*because the ceilings were starting to cave in at that point in time*.[79]

During Mr. Perry's time working as a general manager and consultant for Hilton Hotel Worldwide, he reportedly visited Hampton Inn in the early 2000s and oversaw sheetrock replacement following a flood that collapsed the ceilings of the first floor.[80] He testified he was required to take pictures of the damage and had to check every room after completion to verify the work was done properly before they reopened to guests.[81] He claimed there was a "*white haze of sheetrock dust*" when he walked into the hotel.[82]

From 2014 to 2017 or 2020, Mr. Perry worked at Homewood Suites in Mount Pleasant, SC where there was a construction defect in the ceiling of the lobby, causing it to collapse.[83] Workers ripped out the entire ceiling, and he was present while the work was done. He inspected the work following completion.[84]

Mr. Perry claimed that work done at these properties left "*a chalk residue*" all over his body and believed he may have been exposed to asbestos at these jobs if any of the work was done with sheetrock or joint compound that contained asbestos.[85,86,87]

Non-Occupational.

Mr. Perry reportedly had talcum powder applied to him or personally applied talcum powder to himself as part of his daily hygiene routine from approximately 1974 until 2019.[88,89] He and his husband began reducing their powder usage prior to completely stopping in 2019.[90]

Mr. Perry recalled his mother applied powder to him, from 1974 to 1976, after showering.[91] He applied body powders to himself after showering beginning in 1976. He showered a minimum of two times each day, sometimes three times daily if it was hot outside, and he applied powder

[79] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 130-131; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 278-279.
[80] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 133-134; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 280; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 850.
[81] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 280.
[82] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 133-134.
[83] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 132-133; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 282.
[84] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 132-133.
[85] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 135; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 877.
[86] Summons and Complaint, p. 59-60.
[87] Plaintiffs' Responses to Defendant's Interrogatories, p. 3-4.
[88] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 34-35, 37, 93-94; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 290-293, 299, 307; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 423; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 750, 762
[89] Summons and Complaint, p. 16.
[90] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 331
[91] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 289-291; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 463

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after each shower.[92] He used body powder multiple times a day on a daily basis and switched the powders he used, depending on what the day entailed.[93] He rotated using four or five different brands of "*vanity*" or fragrance powders from the 1980s through 2019 and he explained that he did not wear the same scent multiple days in a row.[94] He applied one brand of fragrance powder in his shoes while living on the sailboat.[95]

Mr. Perry had talcum powder applied to him after each haircut every other week from the time he was a small child until approximately 2019.[96,97]

While living on the sailboat, Mr. Perry occasionally applied powder to his hands, arms, and face to dry them before he entered the engine room.[98]

Mr. Perry stated he occasionally had a "*dry powder fight*" with friends on the boat, which filled the area with powder, leading them to cough and sneeze.[99]

Mr. Perry testified that he applied talcum powder to his hockey gear before putting it on when he played in the winter season (from approximately 1976 through the mid-1980s).[100]

Mr. Perry was in close proximity to his mother as she applied powder after showering.[101,102] She applied the powder to her hands or to a poof before applying it to her body.[103] She wore certain fragrance powders to work, out to dinner, or while entertaining.[104]

Mr. Perry was responsible for cleaning the bathroom and other areas after powdering from the time he was a child until approximately 2019.[105]

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[92] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 59-61, 93-94; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 463; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 753-754, 757.
[93] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 59-60, 79-80,
[94] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 44-48, 51, 64, 79-80, 98-101; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 411-414; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 756, 802-803, 888-889, 894.
[95] Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 417.
[96] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 93-94; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 776, 782-783, 787-789, 791-793, 795-796, 798-799, 803-804.
[97] Summons and Complaint, p. 16.
[98] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 892-893.
[99] Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 758.
[100] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 203-204; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 802-803, 893
[101] Summons and Complaint, p. 16.
[102] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 36, 53, 55-56, 66-68, 70-71, 83-84, 102-103; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 292-293, 380, 382, 387, 393; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 499, 506, 509; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 878-879, 881, 883-884, 899.
[103] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 70-72; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 472-473.
[104] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 83-85; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 386.
[105] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 63,74-77

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Mr. Perry was in close proximity to his father when they both applied powder after fishing on weekends in the 1980s.[106,107] His father also used talcum powder on himself for hygiene, however, Mr. Perry was not in close proximity to him while he applied it.[108]

Mr. Perry believed he was exposed to asbestos when he performed brake work under his father's supervision "*more than six dozen times*" on two different family vehicles between 1984 and 1987, but specified that he considered each wheel its own separate job.[109,110,111] This work included changing both drum and disc brakes, sanding or grinding the shoes on drum brakes, and blowing them out with his mouth or an air compressor.[112] Mr. Perry also broke down the engine and changed the head gaskets on both vehicles and replaced four rotors on two separate occasions.[113]

PLAINTIFF'S ENCOUNTERS WITH MATERIALS PRODUCED BY JOHNSON & JOHNSON.

Mr. Perry used Johnson & Johnson baby powder on a regular basis from 1974 to 2019 as a part of his daily routine after showering, sometimes multiple times a day.[114,115] Mr. Perry's mother showered with him as a child five days a week until 1976 and he recalled his mother applying Johnson & Johnson baby powder and Shower to Shower to him after showering from 1974 to 1976.[116] He began independently showering and applying powder to himself from 1976

[106] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 97; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 286; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 423-424
[107] Summons and Complaint, p. 16.
[108] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 286; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 813-814.
[109] Plaintiffs' Responses to Defendant's Interrogatories, p. 3-4.
[110] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 113-115, 122-123; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 239-240; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 592, 608; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 853, 877.
[111] Work History Affidavit, p. 1
[112] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 116-120, 125-126; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 215-217, 225-227; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 621; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 860-861.
[113] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 122-124; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 222; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 613-614.
[114] Summons and Complaint, p. 16.
[115] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 38-43, 79-80, 87, 89-90; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 299
[116] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 111; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 289-291; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 463.

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onwards.[117] If Johnson & Johnson baby powder was not available, he used Shower to Shower. He recalled last using Shower to Shower prior to 2010, when his mother was still alive.[118]

Mr. Perry applied Johnson & Johnson baby powder to himself when he lived on a sailboat between 1989 and 1996, if he needed to work in the engine room.[119]

Mr. Perry used Johnson & Johnson baby powder in combination with one other brand of powder on his hockey gear prior to putting it on during the winter hockey season.[120] He applied Johnson & Johnson baby powder after swimming which he did year-round.[121]

Mr. Perry was in close proximity to his mother when she applied Johnson & Johnson baby powder and Shower to Shower to herself after showering five to seven days a week from 1974 to 1992 and once a month until 2007 or 2008.[122,123,124]

Mr. Perry's sister applied Johnson & Johnson baby powder and Shower to Shower in the bathroom they shared in the family home, but he did not specifically see her applying it.[125]

Mr. Perry and his husband alternated applying Johnson & Johnson baby powder with another brand of powder to each other after showering, possibly multiple times a day, from approximately 2002 through 2019.[126] He used Johnson & Johnson baby powder more frequently in the summer months.[127]

PLAINTIFF'S ENCOUNTERS WITH MATERIALS PRODUCED BY AVON.

Mr. Perry's father reportedly used Avon Deep Woods, Avon Musk, and Avon Spicy talcum powders from approximately the 1970s until approximately 1984. Mr. Perry testified he did not see his father apply body powder. Mr. Perry's Plaintiff's Responses to Defendant's Interrogatories include claims that he was in close proximity to both of his parents while they

[117] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 59-61, 93-94; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 307; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 463; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 753-754, 757.
[118] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 111; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 317.
[119] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 88-89.
[120] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 60; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 203-204.
[121] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 60; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 203-204.
[122] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 53, 56-57, 66-68, 83-84, 102-103; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 508.
[123] Summons and Complaint, p. 16.
[124] Plaintiff's Responses to Defendant's Interrogatories, p. 4.
[125] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 295.
[126] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 91; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 317-319, 344.
[127] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 310.

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applied body powders.[128,129] Mr. Perry allegedly played with the Avon Deep Woods powder bottle in the 1970s.[130]

Mr. Perry's mother allegedly used multiple Avon powders including Timeless, Soft Musk, Cotillion, Birds of Paradise, and Skin So Soft in his presence from approximately 1974 or 1975 to 2010.[131,132,133] He witnessed her application of body powder approximately five to seven days a week from 1974 to 1992 and once a month from 1992 to 2010.[134] His mother also allegedly "*poofed*" his face with powder if he was "*acting up*."[135]

PLAINTIFF'S ENCOUNTERS WITH MATERIALS PRODUCED BY VI-JON/EQUATE.

Mr. Perry and his husband alternated applying Equate powder with another brand of powder to each other after showering, possibly multiple times a day, from approximately 2002 through 2019.[136]

PLAINTIFF'S ENCOUNTERS WITH MATERIALS PRODUCED BY ESTÉE LAUDER.

Mr. Perry was allegedly in close proximity to his mother when she applied White Linen as a part of her hygiene routine from the 1980s to the 1990s.[137,138] She used this powder in addition to another brand of body powder.[139] Mr. Perry was in close proximity to his mother as she applied powder products at least five days a week after showering from 1974 or 1975 until approximately 1992, and then at least once a month from approximately 1992 until she died in 2010.[140]

[128] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 73; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 484, 486-487, 489-492.
[129] Plaintiff's Responses to Defendant's Interrogatories, p. 4.
[130] Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 489.
[131] Summons and Complaint, p. 16.
[132] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 53-54, 108, 110; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 466-473, 475-478, 481, 483.
[133] Plaintiff's Responses to Defendant's Interrogatories, p. 4.
[134] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 66-68, 83-84, 102-105.
[135] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 72; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 461-462.
[136] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 38, 91; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 317-319, 344.
[137] Summons and Complaint, p. 16.
[138] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 53, 56-57; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 430-432, 442.
[139] Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 442, 470-471.
[140] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 36, 53, 55-56, 66-68, 70-71, 83-84, 102-103; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 292-293, 380, 382, 387, 393; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 499, 506, 509; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 878-879, 881, 883-884, 899.

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PLAINTIFF'S ENCOUNTERS WITH MATERIALS PRODUCED BY PTI ROYSTON (WITH RESPECT TO GOLD BOND AND AMMENS PRODUCTS).

Mr. Perry reportedly used medicated Gold Bond from approximately 1989 to 2019.[141,142] From 1989 to 1993, he applied Gold Bond to his shoes.[143] During spring and summer breaks from 1989 to 1993 and full time from 1993 to 1996, he applied Gold Bond to his shoes, to his hands and face to dry off in the engine room.[144] He used Gold Bond in his boots or deck shoes when living on a farm in South Carolina.[145,146] He testified that if he applied it to his feet, he massaged it in and did this multiple times per day.[147]

Mr. Perry testified that he used Ammens medicated powder from the 1990s until the mid to late 2000s.[148] He reportedly used Ammens more frequently when he was living on the boat than on the farm.[149]

PLAINTIFF'S ENCOUNTERS WITH MATERIALS PRODUCED BY IMI-FABI LLC.

Mr. Perry testified that he applied talcum powder to himself as part of his daily hygiene routine from approximately 1974 until 2019.[150,151] Mr. Perry testified that he recalled his mother applied powder to him after showering from 1974 to 1976.[152] He also testified that his barber applied talcum powder to him after his biweekly haircuts from the time he was a child until approximately 2019.[153,154] Mr. Perry was in close proximity to his mother as she applied powder products at least five days a week from 1974 or 1975 until approximately 1992, and then approximately once a month from approximately 1992 until she died in 2010.[155,156] Mr. Perry

[141] Summons and Complaint, p. 16.
[142] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 43, 95-96; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 339-341, 356, 359; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 836-837.
[143] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 356, 359.
[144] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 43, 95-96; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 339-340, 356.
[145] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 339-340, 348.
[146] Summons and Complaint, p. 16.
[147] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 341; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 836-837.
[148] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 47-49; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 419.
[149] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 49, 97.
[150] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 34-35, 37, 93-94; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 290-293, 299, 307; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 423; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 750, 762
[151] Summons and Complaint, p. 16.
[152] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 289-291; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 463
[153] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 93-94; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 776, 782-783, 787-789, 791-793, 795-796, 798-799, 803-804.
[154] Summons and Complaint, p. 16.
[155] Summons and Complaint, p. 16.
[156] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 36, 53, 55-56, 66-68, 70-71, 83-84, 102-103; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 292-293, 380, 382, 387, 393;

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testified that he was in close proximity to his father when they both applied powder after fishing on weekends in the 1980s.[157,158]

Mr. Perry claims that he used or was in proximity to others' use of various brands of talcum powder products including Ammens, Avon, Calvin Klein, Cashmere Bouquet, Chanel, Clubman, Coty, Drakkar Noir, Estee Lauder, Gold Bond, Johnson and Johnson, Shower to Shower, Mennen, Old Spice, Pinaud, Polo Ralph Lauren, Stetson, Walgreens, Walmart, and White Linen.[159]

TOBACCO HISTORY.

Mr. Perry was a nonsmoker.[160] His mother and father were smokers; he believed his father smoked less than one pack a day "*inside the home limitedly or in the garage*."[161]

SELECTED MEDICAL DOCUMENTATION.

02.08.03 CT abd. The limited images of the lower thorax reveals no evidence of basilar lung disease, pleural or pericardial effusion. IMPRESSION: Focal inflammatory changes within the mesentery, left side of the abdomen adjacent to the left paracolic gutter. A small amount of fluid is seen in that region as well. There is no evidence of distinct mass or abscess.[162]

02.08.03 AXR. Frontal projection of the chest demonstrates cardiomediastinal silhouette within normal limits. No evidence of acute pleural or parenchymal lung disease. No evidence of pneumothorax.[163]

02.25.10 FINAL DIAGNOSIS: SIGMOID COLON, PARTIAL RESECTION: DIVERTICULITIS. Microscopic Description: Sections of the grossly described diverticula demonstrate herniation of the mucosa through the muscularis and abutting the pericolonic adipose tissue. Sections of the grossly described area of fat necrosis show a broad area of microabscess formation with histologic features consistent with prior perforation. Histologic features of mucosal dysplasia and malignancy are not identified. The surgical margins of resection show uninflamed, histologically viable tissue.[164]

Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 499, 506, 509; Videotaped Deposition of Michael Perry, Vol IV, taken 13 October 2023, p. 878-879, 881, 883-884, 899.

[157] Videotaped Deposition of Michael Perry, Vol I, taken 10 October 2023, p. 97; Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 286; Videotaped Deposition of Michael Perry, Vol III, taken 12 October 2023, p. 423-424

[158] Summons and Complaint, p. 16.

[159] Summons and Complaint, p. 16.

[160] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 249.

[161] Videotaped Deposition of Michael Perry, Vol II, taken 11 October 2023, p. 256, 286-287.

[162] CT abd 02.08.03 Radiology reports pg 1 thru 2 of 59.

[163] AXR 02.08.03 Radiology reports pg 4 of 59.

[164] Surgical Pathology Report 02.25.10 OCRPathology reports; 02.25.10..pdf 1 thru 2 of 6

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12.27.11 Visit note. [Hiott] He still has reflux problems and uses Prevacid regularly. It is better since he lost some weight. Also, his asthma seems more related to his reflux so since that is better, his breathing is better and he has not had to use his inhaler.[165]

06.06.12 Visit note. [Hiott] He also has reflux and is on Prevacid daily. As long as he takes this he doesn't have a problem with his asthma. He thinks his asthma is allergy and reflux-induced. He does take Allegra over-the-counter for his allergies.[166]

06.24.13 Visit note. [Hiott] He does have underlying allergies but has not had to use the Allegra. His asthma has not flared as long as he keeps his reflux is ok. He does have reflux and uses generic Prevacid regularly. His reflux appears to be controlled. A/P: Asthma: Ventolin.[167]

07.29.15 Visit note. [Hiott] He does uses Ventolin inhaler when he feels short of breath particularly when he goes from cold to the heat and hynidity [sic] outside. He has a history of acid reflux and has used over-the-counter lansoprazole. This has not been a problem recently. A/P: Asthma: Ventolin stable.[168]04.07.15 Operative Report. POSTOPERATIVE DIAGNOSIS: Left lower quadrant ventral hernia. OPERATIVE PROCEDURE: Laparoscopic left lower quadrant ventral hernia repair with a 6 x 7 cm Prolene mesh in the retrorectus position. Examination of the abdomen revealed a left lower quadrant small ventral hernia with some omentum in it.[169]

12.27.16 Visit note. [Hiott] Patient does have allergies and will use over-the-counter Zyrtec or Allegra. Usually, spring and Fall are the worse. He does have asthma that is triggered by reflux and allergies. He has not had to use an inhaler recently because does [sic] have been controlled. A/P: Mild intermittent asthma without complication: stable, meds if needs has inhaler.[170]

08.09.17 Colonoscopy Report. [Schnell, MD] Impressions: Moderate diverticulosis of the sigmoid colon[171]

05.12.17 Visit note. [Hiott] SORE THROAT. sometimes [sic] hard to swallow. feels [sic] lump in neck. Felt like a really sore throat, gland sore. Std for the last three months he starts coughing and can’t stop. Clear mucas [sic]. He's concerned because his father recently was diagnosed with prostate cancer and there are other cancers in his family. A/P: Sore throat: Zithromax. Neck fullness: TSH, get US and if ok, send ENT.[172]

[165] Visit note 12.27.11 PERRY ROPER 5.19.17-7.1.23 pg 205 thru 206 of 225.
[166] Visit note 06.06.12 PERRY ROPER 5.19.17-7.1.23 pg 203 thru 204 of 225.
[167] Visit note 06.24.13 PERRY ROPER 5.19.17-7.1.23 pg 199 thru 200 of 225.
[168] Visit note 07.29.15 PERRY ROPER 5.19.17-7.1.23 pg 182 thru 183 of 225.
[169] Operative report 04.07.15 OCRPERRY -RSFP ROPER 2022-2023.pdf 131 thru 132 of 265
[170] Visit note 12.27.16 PERRY ROPER 5.19.17-7.1.23 pg 176 thru 177 of 225.
[171] Colonoscopy Report 08.09.17 OCRAdmission to Palmetto Digestive Health Specialists dated 08.09.17..pdf 1 thru 2 of 6
[172] Visit note 05.12.17 PERRY ROPER 5.19.17-7.1.23 pg 174 thru 175 of 225.

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06.11.17 CT Abdomen Pelvis. Lung bases: Minimal dependent atelectasis is seen at the lung bases. IMP: Acute diverticulitis of the midsigmoid colon without evidence of perforation or abscess formation.[173]

06.20.19 Visit note. [Hiott] He has mild asthma and can use his albuterol inhaler as needed. He has not had a problem with that recently. ROS: Respiratory: Shortness of breath denies. Asthma admits, mild intermittent affected by allergies/GERD. A/P: Mild intermittent asthma without complication: Ventolin.[174]

08.29.19 Visit note. [Hiott] HPI:49-year-old white male comes in today stating that he had fevers and had gone to the ER. His temperature was actually up to 102.7. He had no symptoms except a fever. No sore throat, sinus drainage, headache, dizziness, cough, nausea, vomiting, or diarrhea. At the ER his temperature was up and they did basic labs. Flu test and strep test were negative. They did a chest x-ray at the ER that was negative. He says he still feels funny and feels sweaty but his temperature will be normal. Temperature today is totally normal. ROS: Respiratory: Shortness of breath denies. Asthma admits, mild intermittent affected by allergies/GERD. Cough denies. Shortness of breath at rest denies. Shortness of breath with exertion denies. Wheezing denies. A/P: Fever. Follow Up: on labs.[175]

12.19.19 Visit note. [Hiott] Patient has had a cold and a hacking cough. He's only been sick for about 4 days and discussed is probably viral. He's had some greenish mucus and if it doesn't get better next week let us know. He had a fever but it's okay today he says. ROS: Respiratory: Shortness of breath denies. Asthma admits, mild intermittent affected by allergies/GERD. A/P: Mild intermittent asthma without complication: Ventolin, stable. Viral upper respiratory tract infection: treat symptoms. monitor.[176]

06.16.20 Visit note. [Hiott] Sts [sic] has been anxious with the covid19,and everything going on. sts in August he had fever that no one could figure out why. said he was very sick went to ER. No one could figure out what was causing fever. Hes wondering if he had covid 19. Fever went up to 104 and he missed 9 days of work. He does have allergies and has been having a lot of trouble with that recently. He gets really tight and short of breath and uses Ventolin inhaler. Does have low-grade asthma and has been on inhalers. If the allergies are better he probably won't need to use that as much. A/P: Mild intermittent asthma without complication: Ventolin. Allergic rhinitis, unspecified seasonality, unspecified trigger: Fluticasone Propionate, Montelukast.[177]

[173] CT Abd Pelvis 06.11.17 Radiology reports; 06.11.17 pg 1 thru 3 of 7.
[174] Visit note 06.20.19 PERRY ROPER 5.19.17-7.1.23 pg 148 thru 150 of 225.
[175] Visit note 08.29.19 PERRY ROPER 5.19.17-7.1.23 pg 142 thru 145 of 225.
[176] Visit note 12.19.19 PERRY ROPER 5.19.17-7.1.23 pg 136 thru 138 of 225.
[177] Visit note 06.16.20 PERRY ROPER 5.19.17-7.1.23 pg 132 thru 135 of 225.

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01.13.21 Virtual Visit. [Germinario, MD] Allergic rhinitis and mild intermittent asthma: Well-controlled on montelukast (as needed), fluticasone and ventolin (PRN). He uses his rescue inhaler when there are weather and temperature changes.[178]

03.01.21 CT Abdomen pelvis. Lower Thorax: Unremarkable.[179]

06.04.21 Progress note. [Germinario, MD] In November 2019 he was very sick, in Roper ER. He had fatigue, 104.7 F fever. He was told he had a virus, but it was unclear which one. No respiratory symptoms. He never ended up getting antibody tested. He wonders if he had Covid. Since then he gets waves of exhaustion, occasionally has to just go to bed. He never had these symptoms prior to this illness in November 2020. He does not feel depressed. He estimates an episode at least once per week, often multiple days per week. No obvious inciting triggers. No other symptoms besides just feeling totally weak and exhausted. No fevers or night sweats. No unintentional weight loss. Allergic rhinitis and mild intermittent asthma: Well-controlled on montelukast (as needed), fluticasone and ventolin (PRN). He uses his rescue inhaler when there are weather and temperature changes. 2. Fatigue, unspecified type – Etiology is unclear. He may have had a Covid illness, other viral illness such as Lyme or EBV. Continues to have waves of fatigue, will expand blood work.[180]

06.16.23 Visit note. [Germinario] he had COVID back in January and since then has had a fairly consistent persistent cough which is only sometimes productive of sputum with some development of intermittent shortness of breath, dyspnea on exertion and wheezing. He did not seek medical attention for this as he thought it was just a postviral cough and then he thought some of the symptoms might of been asthma related or allergy related as the pollen season came on. The persistence of his symptoms, however, it is concerning to him. He is not sure if he is actually having fevers but oftentimes at night he will woke [sic] up to quite a sweaty bed, not fully she [sic] soaking but he describes significant sweating. This is fairly new over the past 3 months. He has furthermore had unintentional weight loss of 14 pounds over the past 6 months. He reports decreased appetite but no significant abdominal pain or nausea or vomiting. A/P: Chronic cough: XR CHEST. Mild intermittent asthma with exacerbation: doxycycline, prednisone. Microcytic anemia. Rectal bleeding. Leukocytosis, unspecified type. Thrombocytosis. Night sweats. Unintentional weight loss. His symptoms are concerning, his physical exam is reassuring. I like to begin treatment/work-up with a chest x-ray which she [sic] can get today, and I am going to start him on a steroid dose as well as coverage for an asthma exacerbation given the ongoing cough following his COVID infection. His lungs are clear to auscultation bilaterally, there might be some slight decreased lung sounds at the left base. ADDENDUM 06/19/23: CXR reviewed, new hilar mass/density noted on CXR. CT w/ contrast ordered for better characterization.[181]

[178] Virtual Visit 01.13.21 Perry, Michael - Roper St. Francis Healthcare (Medical Vol 1 01.11.21 - 07.12.23) pg 28 thru 31 of 305.
[179] CT abd pelvis 03.01.21 Perry, Michael - Roper Hospital (Medical 03.01.21 - 06.30.23) pg 27 thru 28 of 333.
[180] Progress note 06.04.21 Perry, Michael - Roper St. Francis Healthcare (Medical Vol 1 01.11.21 - 07.12.23) pg 61 thru 66 of 305.
[181] Visit note 06.16.23 PERRY ROPER 5.19.17-7.1.23 pg 64 thru 84 of 225.

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06.16.23 CXR. FINDINGS: Slight left pleural fluid is present, with lobular small pleural-based densities over the left lateral chest wall at its mid portion, all new compared to prior study. No pleural fluid is seen on the right. Cardiac silhouette is not enlarged. No pulmonary vascular congestion. Ill-defined increased density is seen over the left hilar region, new compared to the prior study, especially projecting inferior to the left hilum. Impression: New slight left pleural fluid with lobular left pleural densities laterally and with new abnormal soft tissue density overlying the left hilum suspicious for mass or adenopathy. Follow-up chest CT with IV contrast would be useful for further investigation.[182]

06.21.23 Visit note. [Germinario] Since last visit, patient was treated with steroid and antibiotic. CXR was obtained showing new slight left pleural fluid with lobular left pleural densities laterally and with new abnormal soft tissue density overlying the left hilum suspicious for mass or adenopathy. This was discussed with patient over phone and a CT scan was ordered. CT was performed today. This showed numerous left sided pleural based lesions/deposits and enlarged left cardiophrenic lymphadenopathy. Findings are worrisome for malignancy. Recommended was further evaluation with tissue sampling. There was a small left pleural effusion. He is feeling a bit better, feels like his cough has improved. He reveals to me today that his mother has small cell carcinoma of the lung. A/P: Lung mass: Discussed findings with patient, concern for malignancy. Discussed that further diagnosis and treatment plan would be made with specialist. I have sent referral today to Dr. Kline for urgent appointment for further eval.[183]

06.21.23 CT chest. Lymph nodes: Numerous enlarged cardiophrenic nodes nodes [sic] include an index node measuring 1.6 x 1.3 cm. Airways: Central airways are patent. Lungs/Pleura: Several pleural deposits in the left lung with index deposit measuring 2.8 x 0.9 cm along the lateral left upper lobe and index implant along the anterior left upper lobe measuring 2.5-1.3 cm. Small left pleural effusion with associated pleural deposits including the index deposit along the left posterior lower lobe measuring 4.5 x 1.3 cm. No pneumothorax. Impression: Numerous left-sided pleural-based lesions/deposits and enlarged left cardiophrenic lymphadenopathy. Findings are worrisome for malignancy. Recommend further evaluation with tissue sampling. Follow PET/CT may also be considered to optimize tissue sampling target. Small left pleural effusion, suspected malignant.[184]

06.29.23 Visit note. [Kline] HPI: 53 y/o M never smoker with a PMH of asthma, chronic back pain. Mother had small cell lung cancer. He was seeing his PCP for chronic cough. Covid in January. Cough did not resolve. Treated with course of antibiotics and steroids. CXR revealed L pleural fluid with findings suspicious for mass or adenopathy on L. Subsequent chest CT revealed L sided pleural lesions and L pleural effusion. No history of known asbestos exposure. Reports recent weight loss and poor appetite. ROS: fever, fatigue, weakness, night sweats, change in appetite, weight change, cough, asthma. A/P: Pleural based nodules on left with small left pleural effusion. Concerning for malignancy

[182] CXR 06.16.23 Radiology reports pg 14 of 59.
[183] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[184] CT chest 06.21.23 Radiology reports pg 15 of 59.

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or aggressive benign disease. Plan for OR tomorrow for left thoracoscopy, pleural biopsies, PleurX catheter. No pleurodesis planned at this time in case he needs future intervention in chest.[185]

06.30.23 Operative Note. [Kline, MD] Pre-Op Diagnosis: Pleural mass. Pleural effusion, left. Post-Op Diagnosis: Malignancy. Procedures: 1-Bronchoscopy. 2-Left thoracoscopic pleural biopsies. 3-Left pleurx catheter insertion. Findings: 1-Multiple fleshy masses on parietal pleural surface, and fewer on the visceral pleural surface. 2-Full lung expansion (no trapping). 3-Malignancy per Dr. Hannay at FS.[186]

06.30.23 Surgical Pathology consultation report. Reported 7/5/2023. Diagnosis: A. PLEURA, LEFT, BIOPSIES: NON SMALL CELL MALIGNANCY, MOST COMPATIBLE WITH MALIGNANT MESOTHELIOMA. B. PLEURA, LEFT, BIOPSY FOR FROZEN SECTION: NON SMALL CELL MALIGNANCY, MOST COMPATIBLE WITH MALIGNANT MESOTHELIOMA. Microscopic description: A-B: Sections (including frozen section slides) demonstrate an infiltrative non-small cell malignancy comprised of moderate to markedly atypical cells arranged predominantly in infiltrative sheets with prominent nucleoli. Keratinization is absent. Gland formation is not identified. Overtly sarcomatoid differentiation or features of a high-grade sarcoma are not appreciated. To further differentiate the lineage of these malignant cells, a panel of qualitative immunohistochemical stains (with appropriate positive controls) was performed on block A2: Cytokeratin AE1/3: Positive, Cytokeratin 7: Positive, Cytokeratin 5/6: Positive, Calretinin: Positive, WT1: Positive, Desmin: Negative, PSA: Negative, CK20: Negative, SOX10: Negative, TTF-1: Negative. Overall, coexpression of cytokeratins and mesothelial markers favors mesothelioma with extensively epithelioid features. There is no evidence of a pulmonary non-small cell carcinoma or metastatic colorectal carcinoma. Despite the prominent nucleoli, findings argue against metastatic prostatic adenocarcinoma. There is no evidence of metastatic melanoma. The frozen section diagnosis is confirmed.[187]

07.07.23 Visit note. [Lingerfelt] Hematology/oncology; CC: Left malignant pleural mesothelioma, epithelioid type. Oncologic history: 1. Patient with COVID-19 in early 2023 and persistent cough. 2. Chest x-ray 6/16/2023 with a small left pleural effusion. 3. CT chest 6/21/2023 with numerous left-sided pleural-based lesions/deposits and left cardiophrenic lymphadenopathy with a small left pleural effusion. 4. Left Pleurx, thoracoscopy and biopsy 6/30/2023 showing malignant mesothelioma, epithelioid subtype. HPI: Patient presents today for initial consultation regarding mesothelioma. He drains his left Pleurx every other day, noting decreased output recently as well as some associated pain. He denies known asbestos exposure. Lungs: Diminished breath sounds on the left. Mr. Perry is a pleasant 53-year-old Caucasian gentleman with malignant pleural mesothelioma, epithelioid type, diagnosed 6/30/2023 status post thoracoscopy with biopsy and Pleurx placement. CT of the chest 6/21/2023 raise concern for left cardiophrenic lymphadenopathy. Patient has at least stage II disease, unclear if resectable

[185] Visit note 06.29.23 PERRY ROPER 5.19.17-7.1.23 pg 25 thru 39 of 225.
[186] Operative Note 06.30.23 Admission to Roper Hospital dated 06.30.23 pg 10 thru 12 of 12.
[187] Surgical pathology consultation report 06.30.23 Pages from Perry Complaint 8-11-2023 pg 1 thru 2 of 2.

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at this time. He also has mild hepatitis of unclear significance at this time. 1. Obtain PET/CT. 2. Referral to pulmonology for staging bronchoscopy/EBUS. 3. Present patient's case at multidisciplinary tumor conference. 4. Patient may warrant port placement. 5. Return to the office in 2 weeks for reassessment and review of the above-mentioned work-up. If she [sic] is a surgical candidate, could consider induction cisplatin plus pemetrexed. If not, would consider palliative ipilimumab plus nivolumab.[188]

07.11.23 Visit note. [Rangel] Hematology/oncology; Diagnosis: Suspected Malignant Pleural Mesothelioma, Epithelioid. Prior Treatments: VATS Thorocoscopy [sic] with Pleural biopsy and PleurX placement. HPI: presents to the thoracic oncology multidisciplinary clinic today for an initial consultation regarding his recently diagnosed malignant pleural mesothelioma. He saw Dr. Lungerfelt (Charleston Oncology Associates) on 7/7/2023. Plan was for PET/CT and pulmonology referred for mediastinal staging to determine resectability. He presents here for a second opinion. Today, he reports feeling "frail" but better since having the PleurX placed. He has been draining ~250cc every other day, and although still present his cough and chest tightness have improved. He reports 30 lb weight loss in the past 6 months with intentional dieting, along with metallic taste/poor appetite and some early satiety. He has had intermittent fevers and night sweats for 2 months. He does report a history of asbestos exposure while working at the old library/Hotel Bennet downtown, as well as talc exposure. A/P: Suspected Malignant Pleural Mesothelioma: As this is a very rare malignancy, we will plan to obtain his biopsy specimen for internal review/confirmation. PET/CT has also been ordered to complete staging. If this does prove to be epithelioid mesothelioma, I will discuss with Dr. Gibney whether he is a candidate for upfront resection vs neoadjuvant chemotherapy (cisplatin/pemetrexed).[189]

07.11.23 Cardiothoracic Surgery Consult. [Ramsden/Gibney] He was seen at Roper by Dr. Kline and was taken to the OR 6/30/23 for a left VATS pleural biopsy and pleur-x placement. His pathology returned most compatible with mesothelioma, favor epithelioid. He presents today for a second opinion regarding his diagnosis and treatment. He has not yet had a PET/CT but is scheduled for one 7/18/23. Mr. Perry denies any direct asbestos exposure however he did use a lot of talc throughout his life as a swimmer. He also use to work at embassy suites adjacent to the old county library which apparently had a lot of asbestos in the walls. A/P: epithelioid mesothelioma of the left pleura. We still need to have his pathology reviewed and confirmed here at MUSC as well as complete molecular testing. He needs to complete his staging with his PET scan 7/18/23. Should this be an epithelioid mesothelioma and be low volume we would consider proceeding with a pleurectomy. Should it be any other sub type then surgical resection would not be part of his treatment regimen.[190]

07.12.23 Surgical Pathology Consult Report. MUSC. Final Diagnosis: A) OUTSIDE CASE, SR23-3043 (6/30/23): A. PLEURA, LABELED AS “LEFT”, BIOPSY: EPITHELIOID MESOTHELIOMA, SEE COMMENT. IMMUNOHISTOCHEMICAL STAINS

[188] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[189] Visit note 07.11.23 Office notes of Medical University of South Carolina (reverse chron) pg 121 thru 125 of 128.
[190] Cardiothoracic Surgery Consult 07.11.23 Perry, Michael - MUSC Medical University of S. Carolina (Medical 07.08.23 - 08.18.23 Vol 1) pg 21 thru 24 of 437.

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(PERFORMED AT OUTSIDE INSTITUTION, AVAILABLE FOR REVIEW): CALRETININ: POSITIVE, CK5/6: POSITIVE, CK7: POSITIVE, AE1/AE3: POSITIVE, WT-1: POSITIVE, CD45: NEGATIVE, CK20: NEGATIVE, DESMIN: NEGATIVE, PSA: NEGATIVE, SOX-10: NEGATIVE, TTF-1: NEGATIVE. IMMUNOHISTOCHEMICAL STAINS (MUSC): P16: LOST IN CELLS OF INTEREST. BAP-1: INTACT. B. PLEURA, LABELED AS "LEFT", BIOPSY: EPITHELIOID MESOTHELIOMA, SEE COMMENT. COMMENT: The morphology and immunoprofile are consistent with epithelioid mesothelioma. Given the patient's young age, childhood asbestos exposure should be considered clinically.[191]

07.18.23 PET/CT. FINDINGS: Widespread hypermetabolic nodular left pleural thickening. For reference, there is a large retroaortic mass along the posterior aspect of the left lower lobe measuring up to 5.1 x 3.1 cm with a max SUV of 18.6. There is an ill-defined hypermetabolic soft tissue lesion between the left lateral fifth and sixth ribs with a max SUV of 5.8, also suggestive of disease involvement. Additionally, there are multiple hypermetabolic left paramediastinal and pericardial nodules as well as multiple left pericardiophrenic lymph nodes versus implants. For reference there is a left pericardiophrenic lesion measuring 2.1 x 1.7 cm with a max SUV of 14.8. Ill-defined hypermetabolic focus involving the left lateral seventh rib with a max SUV of 4.2. CT FINDINGS: THORAX: Small left pleural effusion with a left chest tube in place. Diffuse bronchial wall thickening. IMP: Widespread hypermetabolic nodular left pleural thickening with probable left paramediastinal, pericardial, and pericardiophrenic involvement. Additionally, a hypermetabolic chest wall lesion between the left lateral fifth and sixth ribs as well as a hypermetabolic focus in the left lateral seventh rib are also suspicious for disease involvement. Incidental small hiatal hernia with ill-defined hypermetabolic activity in the region of the distal thoracic esophagus, which is nonspecific and often associated with reflux esophagitis. Consider correlation with patient history and/or endoscopy for further evaluation. Extensive colonic diverticulosis with long segment hypermetabolic thickening throughout the rectum, which is nonspecific though may represent uncomplicated diverticulitis. Consider correlation with patient history and/or colonoscopy if not recently performed.[192]

07.24.23 Procedure report. [Gilbert, DO] Procedure: 11. Flexible bronchoscopy with airway exam. 12. EBUS TBNA station 4R. 13. EBUS TBNA station 7. 14. EBUS TBNA station 11L. Pre-operative Diagnosis: 1. Mesothelioma. 2. Abnormal CT. Post-operative Diagnosis: Same. Procedure: The flex bronchoscope was introduced and the vocal cords appeared gross within normal limits. We entered the trachea which appeared grossly within normal limits, as did the main carina. The right mainstem, right upper lobe, bronchus intermedius, right middle and right lower lobe all appeared grossly within normal limits. The left mainstem, left upper and left lower all appeared grossly within normal limits.[193]

07.24.23 FNA report. Specimens: A Lymph Node, 4R, Bronchoscopic Guided, Fine Needle

[191] Surgical Pathology Consult Report 07.12.23 Pathology reports; 02.25.10. pg 4 thru 6 of 6.
[192] FDG PET CT 07.18.23 Radiology reports pg 26 thru 29 of 59.
[193] Procedure report 07.24.23 Admission to Medical University of South Carolina dated 07.24.23 pg 1 thru 2 of 9.

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Aspiration. Final Diagnosis: NEGATIVE FOR MALIGNANT CELLS. Additional Findings: Benign polymorphous lymphocytes.[194]

07.24.23 FNA report. Specimens: A Lymph Node, Level 7, Bronchoscopic Guided, Fine Needle Aspiration. Final Diagnosis: NEGATIVE FOR MALIGNANT CELLS. Additional Findings: Mixed population of lymphocytes and bronchial epithelial cells are present with focal acute inflammation, minute fragments of cartilage, and blood. Cell block is scant with blood clot.[195]

07.24.23 FNA report. Specimens: A Lymph Node, 11 L, Bronchoscopic Guided, Fine Needle Aspiration. Final Diagnosis: SPECIMEN IS UNSATISFACTORY FOR EVALUATION. Additional Findings: Predominantly blood with rare bronchial epithelial cells. Cell block shows blood clot with minute fragments of cartilage.[196]

08.08.23 Operative Report. Pre-op diagnosis: Mesothelioma. Post-Op Diagnosis: Mesothelioma. Procedure: DECORTICATION, TOTAL. PLEURECTOMY, PARIETAL. DIAGNOSTIC BRONCHOSCOPY, RIGID OR FLEX. THORACENTESIS. CHEMOTHER, INTRACAVITARY, PLEURAL. EXCISION MALIGNANT LESION INCLUDING MARGINS, TRUNK, ARMS, OR LEGS; EXCISED DIAMETER 0.6 TO 1.0 CM. DIAPHRAGMATIC HERNIA REPAIR. THORACOTOMY WITH WEDGE RESECTION. Findings: moderate volume disease. Extended p/d with resection of portion of diaphragm with complex repair using patch. Complete macroscopic resection. Betadine heated therapy x 45 min. Excised previous port sites x 3, total diameter ~1 cm.[197]

08.08.23 Surgical pathology report. Final Diagnosis: A. SOFT TISSUE, LABELED AS "TUMOR IMPLANT," EXCISION: EPITHELIOID MESOTHELIOMA. B. FIBROADIPOSE TISSUE, LABELED AS "PORT SITE #1," EXCISION: MESOTHELIOMA PRESENT IN INFLAMED SKIN AND SUBCUTANEOUS TISSUE. C. RIB, LABELED AS "6TH," RESECTION: ONE OF TWO LYMPH NODES WITH METASTATIC MESOTHELIOMA (1/2), BENIGN MUSCLE, BENIGN BONE WITH TRILINEAGE HEMATOPOIESIS. D. LYMPH NODE, LABELED AS "LEVEL 10," LYMPHADENECTOMY: ONE BENIGN LYMPH NODE (0/1). E. LYMPH NODES, LABELED AS "LEVEL 9," LYMPHADENECTOMY: THREE BENIGN LYMPH NODES (0/3), MESOTHELIOMA PRESENT IN SURROUNDING SOFT TISSUE. F. DIAPHRAGM, LABELED AS "IMPLANT," EXCISION: INVASIVE MESOTHELIOMA, MESOTHELIOMA INVOLVES A CAUTERIZED MARGIN, TRANSDIAPHRAGMATIC EXTENSION NOT IDENTIFIED. G. LYMPH NODES, LABELED AS "LEVEL 7," LYMPHADENECTOMY: FOUR BENIGN LYMPH NODES (0/4). H. LUNG, LABELED AS "LEFT LOWER LOBE," LOBECTOMY: LUNG TISSUE WITH INVASIVE MESOTHELIOMA INVOLVEMENT OF VISCERAL PLEURA, ONE OF ONE INTRAPARENCHYMAL LYMPH NODE POSITIVE FOR METASTATIC

[194] FNA report 07.24.23 Pathology reports pg 3 thru 4 of 18.
[195] FNA report 07.24.23 Pathology reports pg 5 thru 7 of 18.
[196] FNA report 07.24.23 Pathology reports pg 8 thru 10 of 18.
[197] Operative report 08.08.23 Admission to Medical University of South Carolina dated 080823 pg 9 thru 12 of 32.

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MESOTHELIOMA (1/1), SURGICAL MARGINS NEGATIVE FOR MESOTHELIOMA. I. PLEURA, PLEURECTOMY: HISTOLOGIC TYPE: EPITHELIOID MESOTHELIOMA, HISTOLOGIC GRADE: HIGH GRADE (NUCLEAR ATYPIA SCORE: 2, MITOTIC COUNT SCORE: 3 (15 PER 2 MM2), NUCLEAR GRADE: 2, NECROSIS: PRESENT), TUMOR FOCALITY: DIFFUSE, TUMOR SITE: PARIETAL PLEURA, VISCERAL PLEURA, DIAPHRAGM, TUMOR SIZE: UNABLE TO BE DETERMINED, TUMOR EXTENT: DIFFUSE, INVOLVING LEFT LOWER LOBE, DIAPHRAGM, MARGIN STATUS: NEGATIVE IN THIS SPECIMEN, REGIONAL LYMPH NODE STATUS: UNINVOLVED BY INVASIVE MESOTHELIOMA (0/8), TREATMENT EFFECT: NO KNOWN PRESURGICAL THERAPY. J. LYMPH NODE. LABELED AS "LEVEL 5," LYMPHADENECTOMY: ONE BENIGN LYMPH NODE (0/1). K. SKIN, FIBROADIPOSE TISSUE, LABELED AS "PORT SITE #2," EXCISION: BENIGN SKIN WITH ACUTELY INFLAMED FIBROADIPOSE TISSUE WITH FIBROSIS. L. SKIN, FIBROADIPOSE TISSUE LABELED AS "PORT SITE #3," EXCISION: FOCAL MESOTHELIOMA PRESENT. PATHOLOGIC STAGE CLASSIFICATION (pTNM, AJCC 8TH EDITION): pT3 pN1, NUMBER OF LYMPH NODES EXAMINED: 12, NUMBER OF LYMPH NODES INVOLVED: 2. Synoptic Checklist: TUMOR – Tumor Focality: Diffuse, Tumor Site: Parietal pleura, Visceral pleura, Diaphragm, Tumor Size: Cannot be determined, Histologic Type: Epithelioid mesothelioma, Architectural Pattern: Tubulopapillary: 30 %, Solid: 70 %, Nuclear Atypia Score: 2 (moderate), Mitotic Count Score: 3 (high, 5 or more mitoses per 2 mm2), Nuclear Grade: 2, Necrosis: Present, Histologic Grade: High grade, Tumor Extent: Diaphragmatic muscle, Soft tissues of chest wall diffusely or in multiple foci, Treatment Effect: No known presurgical therapy. MARGINS – Margin Status: Mesothelioma present at margin, Margin(s) Involved by Mesothelioma: Diaphragm. REGIONAL LYMPH NODES - Regional Lymph Node Status: Tumor present in regional lymph node(s), Nodal Site(s) with Tumor: Bronchopulmonary: Intrapulmonary 6th rib soft tissue, Number of Lymph Nodes with Tumor: 2, Number of Lymph Nodes Examined: 12.[198]

08.10.23 Op Note. [Gibney, DO] PREOPERATIVE DIAGNOSIS: Left chest Mesothelioma. POSTOPERATIVE DIAGNOSIS: Left chest Mesothelioma. PROCEDURE(S) PERFORMED: 1) Bronchoscopy with therapeutic aspiration of secretions, 2) Resection of left 6th rib, 3) left extended pleurectomy and decortication, 4) mediastinal lymph node dissection of stations 5, 7, 9. 5) Intraoperative heated betadine x 45 min, 6) multiple pneumorrhaphy, 7) left lower lobe wedge resections, 8) reconstruction of diaphragm, 9) excision of old incision sites <1cm diameter. INDICATIONS FOR PROCEDURE: The patient has biopsy proven, epitheliod [sic] mesothelioma with a PS of 0. The tumor did not harbor a BAP-1 mutation. He was offered resection with betadine. Procedure in Detail: The pleura was easy to come off the chest wall, and there was no obvious chest wall invasion. The tumor came off the diaphragm with the exception of the lateral portion. With the tumor free from the chest wall, it was noted that additional deposits were present in the pericardial fat and on the phrenic nerve. The nerve was sacrificed. Then, the visceral pleura was then mobilized off the lung. The tumor was passed as specimen. Multiple pneumorrhaphy and wedge resections of the left lower lobe

[198] Surgical pathology report 08.08.23 Pathology reports pg 11 thru 18 of 18.

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performed for lung repair and removal of additional tumor deposits. toilet bronchosocopy [sic] was then performed - the carina was sharp, no endobronchial lesions and thin secretions primarily on the left were evacuated.[199]

09.08.23 Visit note. [Lally] Radiation oncology: Presents for discussion for treatment options. Patient appears to be halfway through his chemotherapy. ASSESSMENT: Cancer Staging Malignant pleural mesothelioma. Staging form: Malignant Pleural Mesothelioma, AJCC 8th Edition. Pathologic: Stage IIIA (pT3, pN1, cM0). RECOMMENDATIONS: He is at high risk for disease progression. I will offer him radiation therapy to the left pleural space. I plan on using IMRT to deliver treatment.[200]

04.29.24 CT Chest. IMPRESSION: Similar postsurgical changes in the left chest with trace pleural effusion. Pleural thickening in the left upper medial chest is slightly prominent compared to 12/5/2023 and is nonspecific. Short-term follow-up CT would be helpful.[201]

05.01.24 Oncology note. [Rangel, MD] Treated with IMRT to the Left Lung 45Gy/25fx from 2/8/2024- 3/14/2024. A/P: # Stage IIIA Malignant Pleural Mesothelioma, Pure Epithelioid: He has now been treated with 6 cycles of adjuvant Cisplatin and Pemetrexed from 9/13/23-12/27/2023. He saw Dr. Lally and completed IMRT which he tolerated relatively well. His interim CT Chest performed on 4/29/24 showed post-surgical changes and non-specific thickening in the medial LUL pleural which will be followed on surveillance scans.[202]

Radiology:

I have reviewed relevant radiological images of Mr. Perry. A detailed list of the studies received can be found in **Appendix C** at the conclusion of this report.

Past Medical History.

- Allergic rhinitis[203]
- Anxiety (2011)[204,205]
- Asthma (triggered by GERD)[206,207]

[199] Op Note 08.10.23 Perry, Michael - MUSC Medical University of S. Carolina (Medical 07.08.23 - 08.18.23 Vol 1) pg 316 thru 318 of 437.
[200] Visit note 09.08.23 Office notes of Medical University of South Carolina (reverse chron) pg 78 thru 88 of 128.
[201] CT Chest 04.29.24 OCRRadiology reports; 12.05.23..pdf 3 of 4.
[202] Oncology note 05.01.24 OCROffice notes of Medical University of South Carolina (reverse chron)..pdf 10 thru 20 of 98.
[203] Virtual Visit 01.13.21 Perry, Michael - Roper St. Francis Healthcare (Medical Vol 1 01.11.21 - 07.12.23) pg 28 thru 31 of 305.
[204] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[205] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[206] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[207] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.

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- GERD[208]
- Diverticulitis s/p colectomy[209]
- Hyperlipidemia[210]
- PTSD (2011)[211,212]
- Covid (1/2023)[213]
- Sigmoid diverticulosis and diverticular colitis (6/2023, 6/2017, 2001)[214,215,216]
- Kidney stones[217]
- Testicular cancer s/p orchiectomy and chemotherapy (1990)[218]
- Lipoma scalp and neck[219]
- Depression (2011)[220,221]
- Microcytic anemia[222]
- Shingles, periorbital (2011)[223,224]
- Skin lesion Lt wrist Junction Spitz's Nevus[225]
- Ruptured disc L4-L5 (1/2015)[226]
- Erectile dysfunction[227]
- Epidydimal cyst[228]

[208] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[209] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[210] Virtual Visit 01.13.21 Perry, Michael - Roper St. Francis Healthcare (Medical Vol 1 01.11.21 - 07.12.23) pg 28 thru 31 of 305.
[211] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[212] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[213] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[214] Visit note 06.26.23 Admission to Palmetto Digestive Health Specialists dated 062623 pg 1 of 1.
[215] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[216] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[217] Visit note 07.12.23 PERRY ROPER 5.19.17-7.1.23 pg 10 thru 24 of 225.
[218] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[219] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[220] Visit note 06.16.23 PERRY ROPER 5.19.17-7.1.23 pg 64 thru 84 of 225.
[221] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[222] Visit note 06.16.23 PERRY ROPER 5.19.17-7.1.23 pg 64 thru 84 of 225.
[223] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[224] Visit note 10.05.19 PERRY ROPER 5.19.17-7.1.23 pg 139 thru 141 of 225.
[225] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[226] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[227] Visit note 08.02.21 PERRY ROPER 5.19.17-7.1.23 pg 117 thru 118 of 225.
[228] Visit note 08.13.19 PERRY ROPER 5.19.17-7.1.23 pg 146 thru 147 of 225.

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- Precancerous skin lesions, sees dermatologist regularly[229]
- Mild aortoiliac atherosclerotic calcification[230]
- Benign thyroid cysts[231]
- Coronary artery calcifications[232]
- Lipid poor hemangioma[233]
- Left pectoralis muscle lipoma[234]
- Polypoid mucosal thickening of the right maxillary sinus[235]
- Small hiatal hernia[236]
- Bilateral gynecomastia[237]
- Small fat-containing L inguinal hernia[238]
- Multifocal degenerative joint disease[239]
- Multicompartmental Tarlov cyst at S2/S2-3[240]
- Vitamin D deficiency[241]

Past Surgical/Procedural History.

- Colectomy, laparoscopic sigmoid (3/2010)[242,243,244]
- Left ventral hernia repair with mesh, laparoscopic (4/2015)[245,246,247]
- Colonoscopy (6/2023)[248]

[229] Visit note 12.27.11 PERRY ROPER 5.19.17-7.1.23 pg 205 thru 206 of 225.
[230] CT Abdomen Pelvis w/o Contrast 03.01.21 PERRY ROPER 5.19.17-7.1.23 pg 217 of 225.
[231] US Thyroid 05.19.17 PERRY ROPER 5.19.17-7.1.23 pg 225 of 225.
[232] NM Lung Ventilation Perfusion VQ 07.14.23 Radiology reports pg 17 thru 19 of 59.
[233] MRI Chest w/wo Contrast 07.17.23 Radiology reports pg 20 thru 22 of 59.
[234] MRI Chest w/wo Contrast 07.17.23 Radiology reports pg 20 thru 22 of 59.
[235] MRI brain w/wo Contrast 07.17.23 Radiology reports pg 23 thru 25 of 59.
[236] FDG PET CT 07.18.23 Radiology reports pg 26 thru 29 of 59.
[237] FDG PET CT 07.18.23 Radiology reports pg 26 thru 29 of 59.
[238] FDG PET CT 07.18.23 Radiology reports pg 26 thru 29 of 59.
[239] FDG PET CT 07.18.23 Radiology reports pg 26 thru 29 of 59.
[240] MR sacrum PERRY -RSFP ROPER 2022-2023 pg 130 of 265.
[241] Progress note 06.28.22 Perry, Michael - Roper St. Francis Healthcare (Medical Vol 1 01.11.21 - 07.12.23) pg 164 thru 169 of 305.
[242] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[243] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[244] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[245] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[246] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[247] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[248] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.

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- L4-S1 lumbar fusion (2017)[249]
- Bilateral inguinal hernia repair (2007)[250]
- Colonoscopy 8/9/2017, 2014[251] History of colonoscopy 2001, 2007[252] Orchiectomy for testicular cancer (1990)[253]
- Lipoma of neck excised[254]
- Colonoscopy (diverticulosis, repeat in 5 years; 9/2007)[255]
- Removed skin lesion left wrist (12/2010)[256]

Social History.

- No direct asbestos exposure[257,258,259,260]
- Talc use throughout his life as a swimmer[261,262]
- Worked at Embassy Suites adjacent to old county library which apparently had a lot of asbestos in the walls[263,264]
- Married to male[265,266]
- Never a smoker[267]
- No passive exposure to tobacco[268]
- No smokeless tobacco[269]

[249] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[250] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[251] GI note 04.10.19 Admission to Palmetto Digestive Health Specialists dated 04.10.19 pg 1 thru 2 of 2.
[252] H&P Cardiothoracic 06.29.23 Admission to Roper Hospital dated 06.30.23 pg 6 thru 10 of 12.
[253] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[254] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[255] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[256] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[257] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[258] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[259] Visit note 06.29.23 PERRY ROPER 5.19.17-7.1.23 pg 25 thru 39 of 225.
[260] Visit note 07.11.23 Office notes of Medical University of South Carolina (reverse chron) pg 125 thru 128 of 128.
[261] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[262] Visit note 07.11.23 Office notes of Medical University of South Carolina (reverse chron) pg 125 thru 128 of 128.
[263] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[264] Visit note 07.11.23 Office notes of Medical University of South Carolina (reverse chron) pg 125 thru 128 of 128.
[265] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[266] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[267] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[268] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[269] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.

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- No drug use[270]
- No alcohol use currently[271]
- No children[272]
- College educated[273]
- Occupation: local developer[274]
- Engineer by trade[275]
- Works remotely for company doing sales and marketing[276]
- 1 dog[277]
- Travel in past 5 years (from 6/28/22) to Dominican Republic and South America[278]
- No caffeine[279]
- Diet: low fat, low cholesterol[280]
- Exercises 2-3 times per week[281]
- Occupation: full-time Hotelier[282]
- No pets[283]
- Asbestos exposure while working at the old library/Hotel Bennet downtown[284]

Family History.

- Heart disease (mother)[285]
- Ovarian cancer (mother)[286]

[270] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[271] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[272] Visit note 07.12.23 PERRY ROPER 5.19.17-7.1.23 pg 10 thru 24 of 225.
[273] Visit note 07.12.23 PERRY ROPER 5.19.17-7.1.23 pg 10 thru 24 of 225.
[274] Visit note 07.12.23 PERRY ROPER 5.19.17-7.1.23 pg 10 thru 24 of 225.
[275] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[276] Visit note 06.21.23 PERRY ROPER 5.19.17-7.1.23 pg 42 thru 63 of 225.
[277] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[278] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[279] Visit note 09.09.16 PERRY ROPER 5.19.17-7.1.23 pg 178 thru 179 of 225.
[280] Visit note 09.09.16 PERRY ROPER 5.19.17-7.1.23 pg 178 thru 179 of 225.
[281] Visit note 09.09.16 PERRY ROPER 5.19.17-7.1.23 pg 178 thru 179 of 225.
[282] Visit note 09.09.16 PERRY ROPER 5.19.17-7.1.23 pg 178 thru 179 of 225.
[283] Visit note 09.09.16 PERRY ROPER 5.19.17-7.1.23 pg 178 thru 179 of 225.
[284] Visit note 07.11.23 Office notes of Medical University of South Carolina (reverse chron) pg 121 thru 125 of 128.
[285] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[286] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.

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- Breast cancer (mother, paternal aunt)[287,288]
- Prostate cancer (father)[289]
- Lung cancer, small cell (mother)[290,291]
- Coronary artery disease (mother, paternal grandfather)[292,293]
- Elevated lipids (father)[294]
- MI (mother, paternal grandfather, maternal grandfather, paternal aunt, maternal uncle)[295]
- Uterine cancer (mother)[296]
- Mesothelioma (paternal grandfather)[297]
- Liver cancer (maternal grandfather)[298]
- Colon cancer (maternal grandmother)[299]
- Aortic valve issues (non-specific)[300]
- Aortic aneurysm (father, grandmother)[301]
- His uncle was recently diagnosed with lung cancer[302]

[287] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[288] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[289] Discharge summary 08.16.23 Admission to Medical University of South Carolina dated 080823 pg 1 thru 11 of 32.
[290] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[291] Visit note 06.29.23 PERRY ROPER 5.19.17-7.1.23 pg 25 thru 39 of 225.
[292] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[293] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[294] Visit note 07.07.23 Office notes of Charleston Oncology pg 1 thru 6 of 6.
[295] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[296] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[297] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[298] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[299] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[300] Visit note 06.28.22 PERRY ROPER 5.19.17-7.1.23 pg 104 thru 109 of 225.
[301] Visit note 02.25.19 PERRY ROPER 5.19.17-7.1.23 pg 159 thru 161 of 225.
[302] Palliative Care note 03.27.24 OCROffice notes of Medical University of South Carolina (reverse chron)..pdf 24 thru 34 of 98.

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SCIENTIFIC AND MEDICAL LITERATURE REVIEW.

Scientific Principles.

Epidemiologists and other scientists are often tasked with determining whether or not an exposure can cause an illness or condition. After an association has been demonstrated, criteria articulated by Austin Bradford Hill are often employed and considered the gold standard for assessing causation. Once an association has been established, these criteria to establish a causal inference include: consistency, strength of association, specificity, dose-response relationship, temporality, biologic plausibility, coherence of the association, and experimentation. Available evidence can be assessed and graded according to its sufficiency (or lack thereof) to establish a causal link. Evidence typically comes from research studies that involve humans, but can also include studies of animals or in vitro systems (toxicological and experimental) to provide supportive evidence, especially for plausibility.[303]

It is useful, when assessing causation, to consider non-causal explanations for the results of individual studies.[304] These other explanations can come from bias, confounding, and chance. These limitations can be quite important, as they can lead to risk estimates that are falsely higher or lower than the actual risk, and they can even lead to conclusions that an exposure causes disease when it does not, and vice versa. Such limitations regarding asbestos literature have been described as:

- "*Limitations in air measurements and other data available for characterizing historical exposures;*
- *Limitations in the manner that the character of exposure (i.e., the mineralogical types of fibers and the range and distribution of fiber dimensions) was delineated;*
- *Limitations in the accuracy of mortality determinations or incompleteness in the extent of tracing of cohort members;*
- *Limitations in the adequacy of the match between cohort subjects and the selected control population; and*
- *Inadequate characterization of confounding factors, such as smoking histories for individual workers.*"[305]

With regard to human studies, there is also a hierarchy of evidence to consider. For example, clinical trials are often considered the strongest type of evidence, followed by observational

[303] Hill AB. "The Environment and Disease: Association or Causation?" *Proceedings of the Royal Society of Medicine*. 1965;58:295-300.
[304] Elwood JM. "The diagnosis of causation." Chapter 8 in *Causal Relationships in Medicine: A Practical System for Critical Appraisal.* (New York, NY: Oxford University Press, 1988). 163-182.
[305] Berman DW, Crump KS. "Final Draft: Technical Support Document for a Protocol to Assess Asbestos-Related Risk." Environmental Protection Agency, 2003: EPA# 9345.4-06.

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cohort and case control studies. The lowest quality of evidence comes from case reports, case series, and descriptive studies, which cannot demonstrate causation.[306]

There are recent examples of case series, in which authors have erroneously stated that they have found a causal relationship between an exposure and cancer. Emory et al. report on 75 plaintiff cases, in which they served as expert witnesses and reported their medico-legal conclusions that mesothelioma was caused by asbestos in cosmetic talc.[307,308] Moline et al. similarly claims that their series of medico-legal plaintiff cases demonstrated causation.[309,310,311] Dragani published a paper in 2020 that discusses the difficulty of determining the real cause of a particular cancer in an individual.[312] Case reports and case series do not establish causation.

DIFFERENCES BETWEEN ASBESTOS AND TALC.

Asbestos.

Asbestos is a term that is used to describe several naturally occurring silicate mineral species when they are present in a fibrous form. Fibrous asbestos (known as asbestiform) has had commercial uses owing to certain physical properties including flexibility, separability, and weavability, as well as resistance to chemical and physical degradation. The major forms of commercial asbestos are known as amphibole and serpentine.[313] Certain industrial exposures to asbestos (e.g., amphibole-containing pipe insulation among insulators) are known causes of mesothelioma and lung cancer.[314]

Talc.

Talc refers to a type of mineral, as well as to industrial mineral products that contain talc. Talc is not asbestos. It occurs naturally in many regions of the world. Its commercial use is attributable to properties of softness, platyness, inertness, and ability to absorb organic matter. When talc

[306] Elwood JM. "The diagnosis of causation." Chapter 8 in *Causal Relationships in Medicine: A Practical System for Critical Appraisal.* (New York, NY: Oxford University Press, 1988). 163-182.
[307] Emory TS, Maddox JC, and Kradin RL. "Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients." *American Journal of Industrial Medicine.* 2020;63(6):484-489.
[308] Geyer SJ. "Evidence Does Not Support Exposure to Cosmetic Talc as Cause of Malignant Mesothelioma." *Journal of Occupational and Environmental Medicine.* 2020;62(2):e83-e84.
[309] Moline J, Bevilacqua K, Alexandri M, Gordon RE. "Mesothelioma Associated with the Use of Cosmetic Talc." *Journal of Occupational and Environmental Medicine.* 2020;62(1):11-17.
[310] Geyer SJ. "Evidence Does Not Support Exposure to Cosmetic Talc as Cause of Malignant Mesothelioma." *Journal of Occupational and Environmental Medicine.* 2020;62(2):e83-e84.
[311] Moline J, Bevilacqua K, Gordon RE. "Authors' Response to 'Evidence Does Not Support Exposure to Cosmetic Talc as a Cause of Malignant Mesothelioma." *Journal of Occupational and Environmental Medicine.* 2020;62(2):e85-e86.
[312] Dragani TA. "Difficulties in establishing a causal link between chemical exposures and cancer cannot be overcome by court assessments." *Human and Experimental Toxicology.* 2020;39(8):1095-1107
[313] Institute of Medicine (US). "Background Information on Asbestos," Chapter 3 in *Asbestos: Selected Cancers*. Committee on Asbestos: Selected Health Effects, Board on Population Health and Public Health Practices, Institute of Medicine of the National Academies. The National Academies Press (US). Washington, DC; 2006. 49-62.
[314] Selikoff IJ, Seidman H. "Asbestos-associated deaths among insulation workers in the United States and Canada, 1967-1987." *Annals of the New York Academy of Sciences*. 1991;643:1-14.

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particles are inhaled, it does not cause cancer in humans. Specifically, talc does not cause mesothelioma or lung cancer.[315]

DIFFUSE PLEURAL THICKENING.

Diffuse pleural thickening refers to fibrosis of the lining of the chest wall and the lung. Diffuse pleural thickening is recognized on chest imaging. On CT scanning, it characteristically extends over 25 percent of the chest wall and obliterates the costophrenic sulci. CT criteria to define diffuse pleural thickening include: 1) the pleural thickening extends more than 8 cm in the craniocaudal direction; 2) the pleural thickening extends along more than 5 cm of the chest wall when visualized in cross-section, and 3) the pleural thickness exceeds 3 mm.

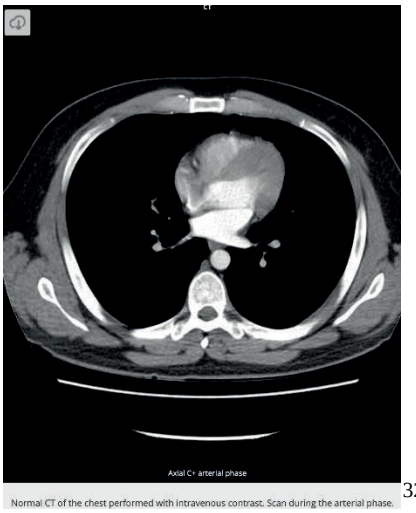
Diffuse pleural thickening often occurs from inflammation, as occurs with infection. There are other causes that include cancer, medications, radiation, trauma, environmental exposure (including asbestos and silica), bleeding, and treatment for tuberculosis.[316,317]

PLEURAL PLAQUES.

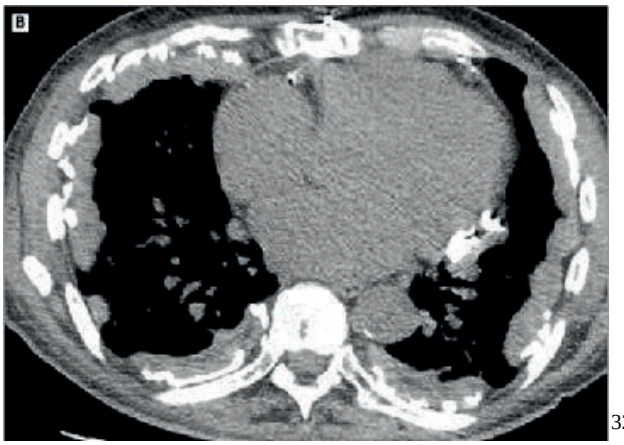
Pleural plaques are circumscribed areas of fibrous thickening that typically involve the parietal pleura. They are typically bilateral and most commonly found along the sixth to ninth ribs and along the diaphragm. They may or may not be calcified. Calcifications are identified by CT scan in 50% of cases and morphological examination in 80%. These plaques can result from low level asbestos exposures from work-related, household, or environmental sources. Approximately 60% of persons with work-related asbestos exposure have pleural plaques on low dose CT. Pleural plaques are benign, usually asymptomatic, are not a type of cancer, and do not become cancer.[318,319,320,321] In the example photos below, a normal image is on the left, and the image on the right shows an example of a patient with bilateral calcified pleural plaques.

[315] International Agency for Research on Cancer (IARC). "Carbon Black, Titanium Dioxide, and Talc." *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. World Health Organization, 2010: Volume 93.
[316] Stark P. "Imaging of pleural plaques, thickening and tumors." *UpToDate*. Last updated: 03 November 2017.
[317] Moon EK, Litzkey LA, Sterman DH. "Malignant Mesothelioma and Other Primary Pleural Tumors." Chapter 79 in *Fishman's Pulmonary Diseases and Disorders, 5th ed*. (McGraw-Hill Education, 2015).
[318] King TE Jr., "Asbestos-related pleuropulmonary disease." *UpToDate*. Last updated: 14 November 2018.
[319] Cowie RL, Becklake MR. "Pneumoconioses." In: Murray JF and Nadel JA, eds. *Textbook of Respiratory Medicine.* 6th ed. Philadelphia, PA: Elselvier Saunders; 2016.
[320] Churg A. "Asbestos-Related Disease in the Workplace and the Environment: Controversial Issues." Chapter 3 in *The Lung: Current Concepts.* Edited by Churg A, Katzenstein ALA. (Baltimore, MD: Williams & Wilkins, 1993), 54-77.
[321] American Thoracic Society (ATS). "Diagnosis and Initial Management of Nonmalignant Disease Related to Asbestos." *American Journal of Respiratory and Critical Care Medicine.* 2004;170:691-715.

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[322]



[323]

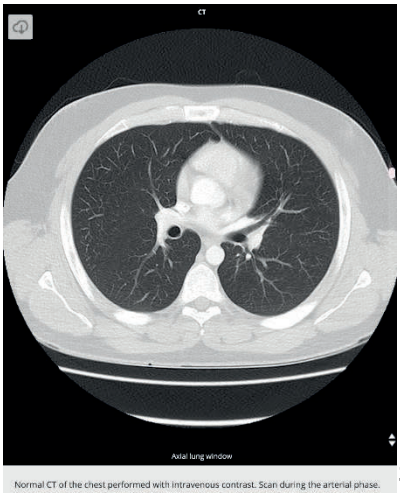
ASBESTOSIS.

Asbestosis is a pneumoconiosis that is caused by inhalation of asbestos fibers. A pneumoconiosis is a lung disease caused by inhaling dust. The development of asbestosis requires high exposure to asbestos and is usually found in workers with many years of high exposure, such as asbestos miners and millers, asbestos textile workers, and asbestos insulators.[324] A minimal exposure of 25 f/cc-yrs has been estimated to be needed to cause asbestosis.[325] Asbestosis causes a restrictive lung problem that arises from an interstitial or fibrotic disease. Restriction can be assessed with pulmonary function tests and interstitial lung disease can be recognized by chest imaging and on biopsy specimens. "*Clinical diagnosis depends on establishing the presence, extent and nature of pulmonary fibrosis and that the exposure has been of a duration and intensity sufficient to put the individual at risk for developing asbestosis.*"[326,327] Diagnosis of asbestosis also requires the exclusion of other diagnoses that would explain the pulmonary fibrosis. When there is uncertainty about the diagnosis, lung tissue from a surgical lung biopsy is needed to confirm the diagnosis. Symptoms of asbestosis typically include cough and shortness of breath, and a

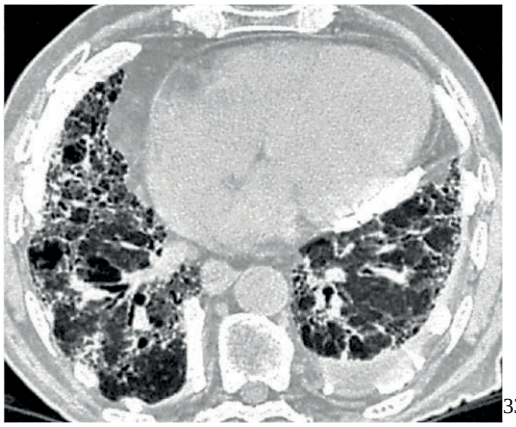
[322] Case courtesy of Dr. Andrew Dixon, Radiopaedia.org, rID: 36676.
[323] Stark P. "Imaging of pleural plaques, thickening and tumors." *UpToDate*. Last updated: 03 November 2017.
[324] Churg A. "Asbestos-Related Disease in the Workplace and the Environment: Controversial Issues." Chapter 3 in *The Lung: Current Concepts*, edited by Churg A, Katzenstein ALA. (Baltimore, MD: Williams & Wilkins, 1993), 54-77.
[325] Churg A. "Asbestos-Related Disease in the Workplace and the Environment: Controversial Issues." Chapter 3 in *The Lung: Current Concepts*, edited by Churg A, Katzenstein ALA. (Baltimore, MD: Williams & Wilkins, 1993), 54-77.
[326] Cowie RL, Murray J, Becklake M. "Pneumoconioses and Other Mineral Dust-Related Diseases." In *Murray and Nadel's Textbook of Respiratory Medicine, 5th ed.* Edited by Mason RJ, et al. (Philadelphia, PA: Saunders, 2010). 1554-1586.
[327] Selman M, Morrison LD, Noble PW, King Jr. TE. "Idiopathic Interstitial Pneumonias." Chapter 57 in *Murray and Nadel's Textbook of Respiratory Medicine, 5th ed.* Edited by Robert J. Mason, et al. (Philadelphia, PA: Saunders, 2010). 1356-1397.

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common physical exam finding is inspiratory crackles.[328,329,330] The example image on the left below shows normal lungs, and the example image on the right shows findings of asbestosis.



[331]


[332]

CAUSES OF MESOTHELIOMA.

While many cases of mesothelioma can be linked to heavy industrial exposures to asbestos, there are also cases of mesothelioma for which there was no significant asbestos exposure. Other causes of mesothelioma include exposure to radiation, thorotrast, chronic inflammation, after treatment for tuberculosis, erionite-type zeolite, fluoro-edenite, and probably

[328] American Thoracic Society (ATS). "Diagnosis and Initial Management of Nonmalignant Disease Related to Asbestos." *American Journal of Respiratory and Critical Care Medicine.* 2004;170:691-715.
[329] Cowie RL, Murray J, Becklake M. "Pneumoconioses and Other Mineral Dust-Related Diseases." In *Murray and Nadel's Textbook of Respiratory Medicine, 5th ed.* Edited by Mason RJ, et al. (Philadelphia, PA: Saunders, 2010). 1554-1586.
[330] Selman M, Morrison LD, Noble PW, King Jr. TE. "Idiopathic Interstitial Pneumonias." Chapter 57 in *Murray and Nadel's Textbook of Respiratory Medicine, 5th ed.* Edited by Robert J. Mason, et al. (Philadelphia, PA: Saunders, 2010). 1356-1397.
[331] Case courtesy of Dr. Andrew Dixon, Radiopaedia.org, rID: 36676.
[332] Stark P. "Imaging of occupational lung diseases." *UpToDate*. Last updated: 06 November 2020.

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balangeroite.[333,334,335,336,337,338,339,340,341,342,343,344,345,346,347,348,349,350,351,352,353,354,355,356,357,358,359,360] As concluded by Andrion et al., "*because asbestos fibers may be found in the lungs of the vast*

[333] Attanoos RL, Churg A, Galateau-Salle F, Gibbs AR, Roggli VL. "Malignant Mesothelioma and Its Non-Asbestos Causes." *Archives of Pathology & Laboratory Medicine*. 2018;142(6):753-760.
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[339] Oczypok EA, Sanchez MS, Van Orden DR, Berry GJ, Pourtabib, et al. "Case Report: Erionite-associated malignant pleural mesothelioma in Mexico." *International Journal of Experimental Pathology.* 2016;9(5):5722-5732.
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[355] Bani-Hani KE and Gharaibeh KA. "Malignant Peritoneal Mesothelioma." *Journal of Surgical Oncology*. 2005;91:17-25.

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majority of individuals living in industrialized countries one must be exceedingly cautious in establishing a cause and effect relationship between the mineral and the disease."[361]

Certain occupations have an elevated risk of mesothelioma, including pipe coverers and insulators. Some occupations have not been associated with an elevated risk of mesothelioma, including nurses and other health care workers, hairdressers, and barbers.[362,363,364,365,366,367,368,369,370,371,372,373,374,375]

Investigators suspect that there are predisposing factors in some people that allow cancer to develop. In a study by Ascoli et al., the authors listed evidence for the role of predisposing risk

[356] Ishak GE, Khoury NJ, Birjawi GA, et al. "Imaging finding of familial Mediterranean fever." *Clinical Imaging.* 2006;30:153-159.
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[361] Andrion A, Bosia S, Paoletti L, et al. "Malignant Peritoneal Mesothelioma in a 17-year-old Boy with Evidence of Previous Exposure to Chrysotile and Tremolite Asbestos." *Human Pathology.* 1994;25:617-622.
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[375] Lewis RC, Smith SJ, Krevanko CF, et al. "Occupational exposure to cosmetic talc and mesothelioma in barbers, hairdressers, and cosmetologists: A systematic review of the epidemiology." *Toxicology and Industrial Health.* 2023;39(10):564-582.

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factors for mesothelioma, including that mesothelioma patients are more likely than controls to have a family history of cancer, subjects with certain combinations of genetic defects are at higher risk of mesothelioma, and clusters of the disease have occurred among blood relatives. Several studies have examined familial clustering of mesothelioma.[376] These studies have provided evidence in some cases that there are shared heavy exposures, but in others, there is not a compelling exposure history, which suggests genetic susceptibilities.[377,378,379] Genetic mechanisms that have been implicated in the development of malignant mesothelioma include, but are not limited to, germline BRCA1 associated protein-1 (*BAP*-1) inactivation syndrome, structural gene rearrangements in Ewing sarcoma breakpoint region 1 (EWSR1), or fused in sarcoma (FUS) and anaplastic lymphoma kinase (ALK) rearrangements.[380] In a study by Panou et al.[381] of a series of patients with mesothelioma, they found that 12% had germline cancer susceptibility genes that included 13 different genes, some of which had not previously been identified [THEM127, CHEK2, MRE11A, VHL, WT1, and SDHA]. In this same study, the investigators found that cancer susceptibility genes were more common in people with minimal to no asbestos exposure, those who were younger, and those who had a second cancer.[382]

In another study by Panou et al., the authors identified numerous pathogenic or likely pathogenic germline mutations associated with malignant mesothelioma. Associated cancers included cancer of the breast, ovary, prostate, colon, pancreas, lung, brain, stomach, head and neck, bladder, liver, uterus, as well as melanoma, non-melanoma skin cancer, renal cell cancer, lymphoma, leukemia, cholangiocarcinoma, osteosarcoma, Wilm's tumor, rhabdomyosarcoma, glioma, adrenocortical carcinoma, and others.[383] In a paper by Betti et al.,[384] the authors listed eleven genes, besides BAP-1, involved in predisposition to malignant mesothelioma, including CDKN2A, PALB2, BRCA1, FANCI, ATM, SLX4, BRCA2, FANCC, FANCF, PMS1, and XPC. Another study[385] estimated the frequency of germline mutations in cancer susceptibility genes in malignant mesothelioma. Compared to controls without cancer, there was a significantly higher risk of carrying a BRCA2 mutation in those with mesothelioma [OR 5: 95% CI 1.0-14.7, p =0.03]. The authors noted that the prevalence of germline cancer susceptibility gene mutations in patients with mesothelioma were "*strikingly similar to the proportion found in other solid*

[376] Ascoli V, Cavone D, Merler E, et al. "Mesothelioma in blood related subjects: Report of 11 clusters among 1954 Italy cases and review of the literature." *American Journal of Industrial Medicine.* 2007;50(5):357-369.
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[383] Panou V, Røe OD. "Inherited genetic mutations and polymorphisms in malignant mesothelioma: A comprehensive review." *International Journal of Molecular Sciences.* 2020;21(4327):1-17.
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tumors, including ovarian, colon, metastatic prostate cancer, and diverse advanced solid tumors." Clinical characteristics associated with germline mutations included having minimal-to-no asbestos exposure (the most significant predictor) as well as young age and having a second cancer. A study examined 432 patients from the University of Chicago and the National Cancer Institute and found that loss of function mutations was more common in mesothelioma patients than controls.[386] The mutations were found in BAP1, BRCA2, CHEK2, MLH1, MRE11A, PALB2, and POT1. Significant associations were found for BRCA2 gene mutations [OR 2.80 (95% CI: 1.02, 7.66, p 0.036)] and [OR 5.67 (95% CI: 1.82, 17.65, p 0.0007)]. Additional studies have found BRCA2 gene mutations in association with mesothelioma.[387,388,389]

The Ataxia-telangiectasia-mutated (ATM) gene is a tumor suppressor gene that encodes a serine/threonine protein kinase involved in the repair and regulation of cellular pathways.[390] Pleural mesothelioma has been described in a child with a mutation in the ATM gene who had no history of asbestos exposure,[391] as well as in an infant who was homozygous for ATM mutations.[392] In a case series,[393] 14 "*asbestos-exposed*" people with malignant mesothelioma underwent whole genome sequencing. Ten people had cancer-related genes identified, including several genes involved in DNA repair. ATM was one of the genes identified in one person. A case series in Italy examined 93 pleural mesothelioma patients who lived in areas with past "*high asbestos exposure*."[394] ATM was one of the ten pathogenic truncating variants (PTVs) identified that are involved in DNA repair. A calculated estimate of asbestos exposure was lower in those with PTVs, than in those without PTVs, which suggested to the authors that those with a PTV may develop mesothelioma after lower exposures.[395]

Many types of tumors have been found in association with the *BAP*-1 mutation, including lung cancer, breast cancer, ovarian cancer, renal carcinoma, non-melanoma skin cancer (including basal cell and squamous), gastric cancer, meningioma, cholangiocarcinoma, leiomyosarcoma, neuroendocrine tumors, pancreatic cancer, paraganglioma, malignant fibrous histiocytoma,

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[395] This finding is also consistent with PTVs alone leading to development of mesothelioma.

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prostate cancer, leukemia, papillary thyroid cancer, thyroid adenoma, lymphoma, and multiple myeloma.[396,397,398,399,400,401,402,403,404,405,406,407,408,409,410,411,412,413,414,415,416,417,418,419,420,421,422]

[396] Attanoos RL, Churg A, Galateau-Salle F, Gibbs AR, Roggli VL. "Malignant Mesothelioma and Its Non-Asbestos Causes." *Archives of Pathology & Laboratory Medicine*. 2018;142(6):753-760.
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In patients with BAP-1 germline mutations, the prognosis may be much more favorable in mesothelioma than in those with sporadic mesothelioma. One study found a 7-fold increased long-term survival, with a median survival of 5 years with BAP-1 mutations vs. < 1 year in U.S. SEER data.[423,424,425]

Peritoneal mesothelioma has been also reported in association with Lynch syndrome (LS).[426,427,428,429,430,431,432,433,434] Lynch syndrome is an inherited cancer-prone syndrome and is characterized by a germline mutation in one of several DNA mismatch repair (MMR) genes (MSH2, MLH1, MSH6, PMS2, EPCAM) whose proteins function to maintain replications fidelity of DNA prior to mitosis.[435] The most common cancers associated with Lynch syndrome are colon and uterine. In addition to the risk of colon and uterine cancer, those with Lynch

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syndrome have higher risks for cancers of the ovary, stomach, small intestine, hepatobiliary system, pancreas (including serous cystadenoma, acinar cell carcinoma, and well differentiated neuroendocrine tumor), renal pelvis and ureter, brain, and sebaceous glands. Other cancers reported in association with Lynch syndrome include adrenocortical, prostate, breast, cervix, larynx, hematologic malignancy, malignant fibrous histiocytoma, leiomyosarcoma of the extremity or uterus, liposarcoma, malignant melanoma, lung adenocarcinoma, and anaplastic carcinoma of the thyroid.[436,437,438]

In a report by Karamurzin et al., a case of peritoneal mesothelioma was reported in a 56-year-old man with an MLH1 germline mutation, and whose tumor showed mutations in MLH1 and PMS2.[439] Latham et al. reported on the prevalence of Lynch syndrome Pan-Cancer among more than 15,000 patients. 165 cases of mesothelioma were found, of whom 6 (1.7%) had Lynch syndrome.[440] Lu and colleagues presented a case of a woman with Lynch syndrome who was diagnosed with peritoneal mesothelioma 10 months after being diagnosed with uterine endometrioid adenocarcinoma. The authors noted that the case raised the possibility that LS-associated primary peritoneal mesothelioma may present with more favorable histological features and carry a better prognosis than non-LS-associated peritoneal mesothelioma.[441] In the 2020 study by Rosenblum et al., a woman with LS was presented who had both pleural mesothelioma and endometrial cancer.[442] The paper by Shih and Kradin presented two cases from medicolegal litigation, both of whom had LS. One had peritoneal mesothelioma and one had well-differentiated papillary mesothelioma (WDPM) of the pleura.[443]

In support of a non-environmental role in causes of mesothelioma in the U.S., in a study published in 1994, the attributable risk of asbestos for both forms of mesothelioma in women combined was only 23%, meaning that 77% of mesotheliomas in women were not linked to asbestos exposure.[444]

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In some cases, called spontaneous cases, there are no known or suspected environmental causes, and these cases are considered to represent the background rate of mesothelioma. In women in the U.S., mesothelioma incidence rates have been fairly steady over several decades of observation, and, unlike the changing rates in men, they have not varied in relation to asbestos use patterns. These findings contrast with epidemic curves seen for diseases in women that followed an increase in tobacco use.[445] Thus, the background, or spontaneous, rate can be estimated based on the relatively constant incidence rate in women, who infrequently have mesotheliomas caused by asbestos exposure.[446,447,448,449,450,451,452,453,454,455]

Recent investigations have helped clinicians and scientists have a better understanding of how much cancer risk is from the environment, from heredity, and from errors in cell replication, informing multiple fields, including epidemiology. In a 2015 study, Tomasetti and Vogelstein demonstrated that the lifetime risk of many cancers is strongly correlated with the total number of divisions of the normal self-renewing cells. They estimated that about one-third of the variation in cancer risk was attributable to environmental factors or inherited predispositions, and that the remaining two-thirds were related to random mutations arising during replication in normal, non-cancerous stem cells.[456] In a follow-up study, Tomasetti et al.[457] pointed out that approximately three mutations occur every time a normal human stem cell divides, and they inferred that the reason for the previously reported correlation between stem cell divisions and cancer incidence was the driver gene mutations that randomly resulted from cell divisions. While their first study examined U.S. cancer rates, this newer study included data from 69 countries (4.8 billion people or 2/3 of the world population). As with the U.S. population alone, this worldwide study showed a very high correlation between the lifetime risk of multiple cancers and each tissue's lifetime number of stem cell divisions. The study further examined the

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proportion of driver mutations that result from the environment, heredity, and replication errors. Using a database from the UK of cancers that "*have been studied in depth through sophisticated epidemiological investigations and are reported in the Cancer Research UK database*," Tomasetti estimated that among the studied cancer types, 29% of driver gene mutations were caused by environmental factors and 5% were attributable to hereditary factors. About 66% of driver gene mutations were attributable to replication errors. The contribution of the environment varied, estimated as greater than 60% for cancers such as lung, esophagus, and skin and less than 15% for cancers such as prostate, brain, and breast. Regarding mesothelioma, driver gene mutations were estimated to be 65.7% attributed to the environment and 33.8% to replication errors. When examining women separately, the replication error contribution was 47% and the environment was 52.5%. Importantly, the contribution of the environment to cancer in the UK is markedly higher than that predicted in the U.S., as noted by Tomasetti, with Cancer Research UK estimating that 42% of cancers there are preventable, compared with only 21% in the U.S. estimated by the U.S. CDC. Such differences in the proportion of preventable cancers in different countries are related to different exposure circumstances, for example, in the UK (unlike the U.S.), women historically had heavy amphibole asbestos exposures in the workplace.[458,459,460] In sum, it is clear that, in addition to environmental exposures and heredity, replication errors play an important role in contributing to rates of driver gene mutations and cancers, even in cancers with historical links to suspected environmental causes.

ENVIRONMENTAL ASBESTOS EXPOSURE AND MESOTHELIOMA.

In a 2016 study by Baumann and Carbone, the authors sought to understand the potential role of "*environmental exposure*" to asbestos to explain cases of mesothelioma that are not related to occupational exposure. In that study, they referenced that occupational cases of mesothelioma predominate in males and those of older age (average of 8th decade of life), while there are clusters of mesotheliomas where there is no occupational asbestos exposure, and the patients are younger and equally likely to be male or female. They also noted that because the assessment of exposure is made retrospectively, the exposure related to the environment is likely to be underestimated. The authors performed an analysis of mesothelioma mortality in the U.S. by state and by county and concluded that in areas with high proportions of younger cases (<55 years old) and more females that there were probable environmental exposures. This study provides a potential explanation for the risk of mesothelioma in non-occupationally exposed people, in addition to genetic risk factors and spontaneously formed tumors.[461]

MESOTHELIOMA IN YOUNG PERSONS.

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Mesothelioma is a rare tumor and is especially rare in children and young adults. There are reported cases of mesothelioma in patients without significant asbestos exposure, who are also of younger age. Less is known about mesothelioma in the young, but the known long latency for asbestos-induced disease makes it more likely that genetic predisposition and/or environmental exposure plays a role.[462] Germline mutations in *BRCA1* associated protein-1 (*BAP1*) may account for some of these cases.[463] There are likely to be other genetic abnormalities linked to mesothelioma development in young people, as demonstrated in a study examining 25 cases of mesothelioma in adults younger than 40 years. That study found cases of *EWSR1* or *FUS-ATF1* gene fusions in people lacking a history of asbestos exposure, who also had retained expression of *BAP1*. Thus, there is emerging evidence for genetic contributions to the risk of mesothelioma, especially in those who are younger and who lack a history of asbestos exposure.[464]

TALC AND MESOTHELIOMA.

There is substantial evidence that talc is not a cause of mesothelioma. In 2010 IARC released a monograph that included their evaluation of talc not containing asbestiform fibers. The review by IARC included studies of cancer in humans with regard to cosmetic use of talc, occupational exposures, as well as talc in pleurodesis. The evaluation of the evidence led to an opinion that there is inadequate evidence in humans for the carcinogenicity of inhaled talc not containing asbestos or asbestiform fibers. IARC also noted that there is limited evidence for the carcinogenicity of perineal use of talc-based body powder. The overall evaluation resulted in perineal use as Group 2B (possibly carcinogenic) and inhaled talc as Group 3 (not classifiable as to its carcinogenicity). The working group considered the studies on talc miners and millers to be the "*best source of evidence*" but "*no consistent pattern was seen.*"[465]

Finley and colleagues performed an analysis in 2017 to determine if existing epidemiologic information supports the conclusion that cosmetic talc exposure can cause mesothelioma.[466] The systematic review sought studies of miners and millers of cosmetic talc as well as follow-up of patients who had had talc pleurodesis performed. There were three longitudinal studies of miners and millers that provided 99,022 person-years of observation. There were no cases of mesothelioma in these studies.

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Since the publication of the review by Finley et al., additional reports have been published about the Val Chisone and Norwegian miners and millers.[467,468] These studies found no deaths from pleural cancer or mesothelioma. In an update to the Finley 2017 analysis, Marsh et al. reported analyses of the pooled 113,344 person-years in the cohorts and concluded that "*the epidemiological evidence from the cosmetic talc miner/miller cohort studies does not support the hypothesis that exposure to cosmetic talc is associated with the development of pleural cancer/mesothelioma.*"[469]

The pooled analysis of studies examined the potential long-term health effects of talc pleurodesis, with follow-up durations of 14 to 40 years. No cases of mesothelioma were found. There have been multiple publications regarding the safety of talc pleurodesis that show that talc instilled into the pleural space causes the intended inflammation and scarring, and that it has not been found to cause cancer, including mesothelioma.[470,471,472,473,474,475] A recent article describing a review of published literature concluded that there is neither evidence for, nor reason to believe, that talc pleurodesis causes mesothelioma and that talc currently remains the gold standard agent for pleurodesis.[476] It is important to note that the miners and millers were chronically exposed to high doses of cosmetic talc and the pleurodesis patients had several grams of talc applied directly to their pleural cavities.

One study by NIOSH examined Vermont miners and millers of talc.[477,478] No asbestos was detected in the talc. No cases of mesothelioma were found in this study. Lung cancer mortality (not mesothelioma) was elevated in miners, but not millers "*despite probable higher dust exposures in mill operations.*" This finding by NIOSH investigators suggests that some factor(s)

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other than talc would possibly raise the risk of lung cancer, including differences in tobacco exposure (not assessed in the study).

In 2019 Fordyce et al.[479] published findings from an updated and expanded cohort of Vermont talc miners and millers that was originally studied and reported by Selevan et al.[480] While the original study examined workers employed between 1940 and 1969, the current updated cohort also includes workers employed from 1930 to 1940, as well as from 1970 to 1983. Mortality patterns were examined up through the end of 2012, rather than the original study's end of 1975. The updated study now included 427 workers with 17,170 person-years of observation. The Fordyce study showed that the cohort mortality rate was approximately 30% higher than the general U.S. population, while malignant neoplasms were not elevated. Significant elevations in mortality were found for non-malignant respiratory disease. As earlier versions of ICD coding did not include codes specific for mesothelioma, the authors employed a method of examining all ICD codes that could have potentially included cases of mesothelioma and employed a nosologist to examine the corresponding death certificates.[481] One case of mesothelioma was found by this method in a man whose death certificate stated that he had been exposed to asbestos. That worker had worked for less than five years in the talc industry, "*leaving open the possibility of exposure to asbestos in other occupations*." The standardized mortality ratios (SMRs) for diseases captured by these studied SMRs were not significantly elevated, whether examined with or without lung cancer deaths. In subsequent correspondence, Fordyce et al. articulates that the single case of mesothelioma does not represent a significantly elevated rate and that the individual had asbestos exposure outside the Vermont talc mines and mills.[482] Since the Fordyce publications, updated analyses of several worldwide cohorts have concluded "*that it is very unlikely that the true value of the SMR for mesothelioma for the pooled cosmetic talc miner/miller cohorts is 2.0 or greater*" and that "*despite the recent finding of one case of mesothelioma in the Vermont cohort (a case unlikely related to talc exposure), we continue to conclude that the epidemiological evidence from the cosmetic talc miner/miller cohort studies does not support the hypothesis that cosmetic talc exposures are associated with an increased risk of pleural mesothelioma.*" In fact, the authors estimated that the probability that the true mesothelioma SMR is at or above 2.0 or 3.0 is 0.0096 and 0.0005, respectively.[483,484]

[479] Fordyce TA, Leonhard MJ, Mowat FS, Moolgavkar SH. "A 37-year Update on Mortality Patterns in an Expanded Cohort of Vermont Talc Miners and Millers." *Journal of Occupational Environmental Medicine*. 2019;61(11):916-923.
[480] Selevan, SG, Dement, JM. "Mortality Patterns Among Miners and Millers of Non-Asbestiform Talc Preliminary Report." In *Dusts and Disease*, edited by Lemen R, Dement JM. (Park Forest South, IL: Pathotox Publishers, Inc., 1979). 379-388.
[481] Wojcik NC, Schnatter AR, Huebner WW. "Mesothelioma in Occupational Cohort Studies: Methodological Considerations." *Journal of Occupational and Environmental Medicine.* 2014;56(1):47-51.
[482] Fordyce TA, Leonhard MJ, Mowat FS, Moolgavkar SH. "Letter to the Editor: Response to Finkelstein Re: the Fordyce et al. Vermont Talc Miners and Millers Cohort Study Update." *Journal of Occupational and Environmental Medicine.* 2020;62(4):e172-e173.
[483] Ierardi AM, Marsh GM. "Absence of mesothelioma risk maintained in an expanded international cohort of cosmetic talc miners and millers." *Inhalation Toxicology.* 2020;32(6):257-264.
[484] Marsh GM, Ierardi AM. "Confidence interval function analysis to evaluate the risk of mesothelioma among an expanded international cohort of cosmetic talc miners and millers." *Regulatory Toxicology Pharmacology*. 2020;115:104696.

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As the Vermont talc mines were found to be free of asbestos,[485,486] if the talc worker with mesothelioma had had occupational asbestos exposure, it would have occurred in a different occupational setting. As made clear by Peto[487] and Rake,[488] when examining workers from low-risk settings, it is important to determine if those workers were also employed at other times in higher risk occupations. Otherwise, one can measure falsely elevated risks for mesothelioma that would be misattributed to the low-risk occupation. For example, in their case-control study, men in low-risk industrial jobs appeared to have an elevated risk of mesothelioma [OR(95% CI): 4.1 (2.6-6.4)], but there was no elevated risk after eliminating workers who had also had medium or high-risk industrial exposures [OR(95% CI): 1.1 (0.5-2.2)].[489,490]

There are also studies from the Val Chisone Italian mine that fail to show any cases of mesothelioma in the miners and millers of talc, including the most recently updated analysis from 2021.[491,492,493,494,495] Additional studies from talc mines in France, Norway, and Austria also failed to show any cases of mesothelioma among workers in those mines.[496,497,498,499,500] With regard to France, in the study by Leophonte and Didier, the authors noted that the only French talc deposit being exploited was located in Luzenac in the South of France. The study noted that

[485] Boundy MG, Gold K, Martin KP Jr, et al. "Occupational exposure to non-asbestiform talc in Vermont." In: Lemen R, Dement JM, eds, *Dusts and Disease,* (Park Forest South, IL: Pathotox Publishers, Inc., 1979.) 365-378.
[486] Rossner A, Williams PR, Mellas-Hulett E, Rahman MA. "Analysis of Historical Worker Exposures to Respirable Dust from Talc Mining and Milling Operations in Vermont." *Annuals of Work Exposures and Health.* 2020;64(4):416-429.
[487] Peto J, Rake C. Gilham C, Hatch J. "Occupational, domestic and environmental mesothelioma risks in Britain. A case-control study." *Health and Safety Executive (HSE), RR969 Research Report.* 2009.
[488] Rake C, Gilham C, Hatch J, et al. "Occupational, domestic and environmental mesothelioma risks in the British population: a case-control study." *British Journal of Cancer.* 2009;100:1175-1183.
[489] Peto J, Rake C. Gilham C, Hatch J. "Occupational, domestic and environmental mesothelioma risks in Britain. A case-control study." *Health and Safety Executive (HSE), RR969 Research Report.* 2009.
[490] Rake C, Gilham C, Hatch J, et al. "Occupational, domestic and environmental mesothelioma risks in the British population: a case-control study." *British Journal of Cancer.* 2009;100:1175-1183.
[491] Rubino GF, Scansetti G, Piolatto G, Romano CA. "Mortality Study of Talc Miners and Millers." *Journal of Occupational and Environmental Medicine*. 1976;18(3):186-193.
[492] Coggiola M, Bosio D, Pira E, et al. "An update of a mortality study of talc miners and millers in Italy." *American Journal of Industrial Medicine*. 2003;44(1):63-69.
[493] Pira E, Coggiola M, Ciocan C, et al. "Mortality of Talc Miners and Millers From Val Chisone, Northern Italy." *Journal of Occupational and Environmental Medicine*. 2017;59(7):659-664.
[494] Rubino GF, Scansetti G, Piolatto G, Gay G. "Mortality and Morbidity Among Talc Miners and Millers in Italy." In: Lemen R, Dement JM, Eds, *Dusts and Disease.* (Park Forest South, IL: Pathotox Publishers, Inc., 1979). 357-363.
[495] Ciocan C, Pira E, Coggiola M, et al. "Mortality in the cohort of talc miners and millers from Val Chisone, Northern Italy: 74 years of follow-up." *Environmental Research.* 2022;203:111865.
[496] Leophonte P, Didier A. "French Talc Pneumoconiosis." *Health Related Effects of Phyllosilicates*. NATO ASI Series, Springer, Berlin, Heidelberg. 1990;21:203-209.
[497] Wergeland E, Gjertsen F, Vos L, Grimsrud TK. "Cause-specific mortality and cancer morbidity in 390 male workers exposed to high purity talc, a six-decade follow-up." *American Journal of Industrial Medicine*. 2017;60(9):821-830.
[498] Wergeland E, Andersen A, Berheim A. "Morbidity and mortality in talc-exposed workers." *American Journal of Industrial Medicine*. 1990;17(4):505-513.
[499] Wild P, Leodolter K, Refregier M, Schmidt H, Bourgkard E. "Effects of talc dust on respiratory health: results of a longitudinal survey of 378 French and Austrian talc workers." *Occupational and Environmental Medicine*. 2008;65(4):261-267.
[500] Wild P. "A cohort mortality and nested case-control study of French and Austrian talc workers." *Occupational and Environmental Medicine*. 2002;59(2):98-105.

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the talc does not contain asbestos. The authors reported that pneumoconiosis was frequent among talc workers and related to dust overexposure, but there were no carcinogenic risks and no mesothelioma.[501] In Wild 2002, cohorts of talc workers were followed in France and Austria. The French cohort included 1,070 people contributing 28,849 person-years of observation. Mortality from pneumoconiosis was significantly elevated, while mesothelioma risk was not (0 cases observed).[502]

Airborne Dust Concentrations in Talc Mines and Mills.

Respirable dust particles are those that are small enough to penetrate deeply into the lungs. There are several studies that have assessed concentrations of respirable dust in talc mines and mills.[503] For example, samples from three Vermont mines evaluated from 1975 to 1976 showed mean exposures to respirable dust from 0.5 to 5.1 mg/m^3 in the mines and 0.5 to 2.9 mg/m^3 in the mills, with concentrations generally higher in the mills than the mines.[504,505]

Another study examined respirable dust from Vermont mining and milling operations in the time period from 1976 to 2003. By MSHA measures, the average concentration was 1.8 mg/m^3 and by company data 0.81 mg/m^3. The study showed that a number of job categories exceeded the ACGIH TLV of 2 mg/m^3 and the OSHA and MSHA PEL of approximately 3 mg/m^3.[506] In the studies of Italian talc miners and millers, high dust concentrations were documented at different time periods with steady reductions over a period of decades. Respirable dust was estimated at 100 to 1000 MPPCF before 1955 and less than 10 MPPCF between 1960 and 1975 (some conversions from MPPCF to mg/m^3 include for talc 1 MPPCF=0.1 mg/m^3 and for nuisance dust 1 MMPCF=0.33 mg/m^3).[507,508]

In a paper from 2003, more recent estimates were that mean respirable dust was 1.1 mg/m^3, ranging from 0.5 to 2.5 mg/m^3.[509,510] In the 2007 to 2014 time range, average respirable dust

[501] Leophonte P, Didier A. "French Talc Pneumoconiosis." *Health Related Effects of Phyllosilicates*. 1990:203-209.
[502] Wild P. "A cohort mortality and nested case-control study of French and Austrian talc workers." *Occupational and Environmental Medicine*. 2002;59(2):98-105.
[503] International Agency for Research on Cancer (IARC). "Carbon Black, Titanium Dioxide, and Talc." *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.* World Health Organization. 2010:Volume 93.
[504] International Agency for Research on Cancer (IARC). "Carbon Black, Titanium Dioxide, and Talc." *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.* World Health Organization. 2010:Volume 93.
[505] Boundy MG, Gold K, Martin KP Jr, et al. "Occupational exposure to non-asbestiform talc in Vermont." In: Lemen R, Dement JM, eds, *Dusts and Disease,* (Park Forest South, IL: Pathotox Publishers, Inc., 1979.) 365-378.
[506] Rossner A, Williams PR, Mellas-Hulett E, Rahman MA. "Analysis of Historical Worker Exposures to Respirable Dust from Talc Mining and Milling Operations in Vermont." *Annuals of Work Exposures and Health*. 2020;64(4):416-429.
[507] National Institute for Occupational Safety and Health (NIOSH). "Talc (containing no asbestos and less than 1% quartz)." *NIOSH Pocket Guide to Chemical Hazards.* 2018.
[508] Occupational Safety and Health Administration (OSHA). "Table Z-3 Mineral Dusts." *United States Department of Labor*. Available at: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ3. 2016.
[509] Rubino GF, Scansetti G, Piolatto G, Romano CA. "Mortality Study of Talc Miners and Millers." *Journal of Occupational and Environmental Medicine.* 1976;18(3):186-193.
[510] Coggiola M, Bosio D, Pira E, et al. "An update of a mortality study of talc miners and millers in Italy." *American Journal of Industrial Medicine.* 2003;44(1):63-69.

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varied with job and year but ranged from more than 0.2 to 1.6 mg/m^3.[511] In the study by Wild et al. of workers in a French talc-producing factory, respirable dust from 1986 to 1991 was measured as a mean of 0.5 to 15 mg/m^3, with estimates in the past up to 60 mg/m^3.[512] In the study of workers at a talc mine in northern Norway, investigators reported that personal air samples varied with job category and workplace with mean concentrations of 0.9 to 97 mg/m^3 and peak exposures during drilling of 319 mg/m^3.[513]

To put these very high dust concentrations into a more familiar context, one can consider the allowable dust concentrations in U.S. outdoor air. Airborne dust is also called particulate matter (PM), and PM comes from numerous natural and man-made sources.[514,515] For outdoor, or ambient air, the U.S. EPA specifies allowable limits to the respirable dust concentration, defined as $PM_{2.5}$, or particles that are less than or equal to 2.5 microns. The annual allowable concentration is 12 microns/m^3 (equivalent to 0.012 mg/m^3).[516] Notably, this maximum allowable limit is orders of magnitude less than the average exposure values of the studied talc miners and millers. Some perspective is apparent from visually observing days with dust concentrations of 0.032 and 0.004 mg/m^3, where the higher concentration is a hazy day and the lower one is clear.[517,518]

[511] Pira E, Coggiola M, Ciocan C, et al. "Mortality of Talc Miners and Millers From Val Chisone, Northern Italy." *Journal of Occupational and Environmental Medicine.* 2017;59(7):659-664.
[512] Wild P, Refregier, Auburtin G, et al. "Survey of the Respiratory health of the workers of a talc producing factory." *Occupational and Environmental Medicine.* 1995;52:470-477.
[513] Wergeland E, Andersen A, Berheim A. "Morbidity and mortality in talc-exposed workers." *American Journal of Industrial Medicine.* 1990;17(4):505-513.
[514] American Thoracic Society (ATS). "Health Effects of Outdoor Air Pollution." *American Journal of Respiratory and Critical Care Medicine.* 1996;153:3-50.
[515] James J, Clark C, Rice J. "Exploring the differences between ambient air data and emissions inventory." *Crustal Matter.* 18 March 2009.
[516] Environmental Protection Agency (EPA). "Revised Air Quality Standards for Particle Pollution and Updates to the Air Quality Index (AQI)." *The National Ambient Air Quality Standards for Particle Pollution.* 2012.
[517] AirNow.gov. AirNow Visibility Cameras. Available at: https://www.airnow.gov/index.cfm?action=airnow.webcams. Accessed: 06 September 2019.
[518] Breathe Project. Breathe Cam. Available at: https://breatheproject.org/learn/breathe-cam/. Published 2019. Accessed: 06 September 2019 (via AirNow.gov).

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Images of exact same location taken at 11:29AM on two separate dates – on a clear day (7/4) details on the horizon are clearly visible; on a hazy day (8/5) fine particle ($PM_{2.5}$) concentration is high and white haze covers the hillside.

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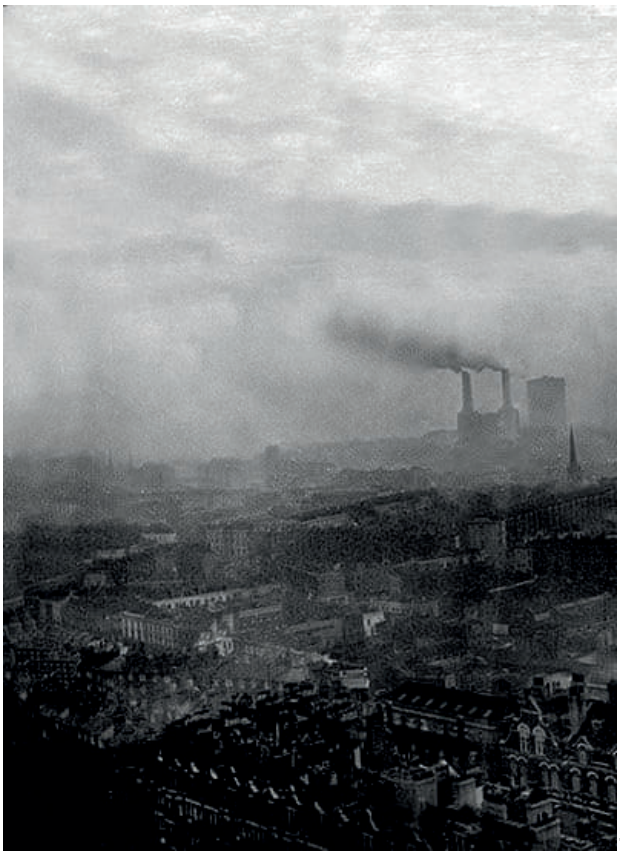
In the famous London Fog air pollution event, PM concentrations were estimated to be approximately 3 mg/m^3, and about 12,000 London residents died as a result. Images from the time period visibly show the appearance of dust of this magnitude.[519,520]



Neslon's column during the 1952 smog disaster. (Source: geograph.org.uk/N T Stobbs)

[519] Bell ML, Davis DL. "Reassessment of the Lethal London Fog of 1952: Novel Indicators of Acute and Chronic Consequences of Acute Exposure to Air Pollution." *Environmental Health Perspectives.* 2001;109(3):389-394.
[520] Davis DL, Bell ML, Fletcher T. "A Look back at the London Smog of 1952 and the Half Century Since." *Perspectives Guest Editorials.* 2002;110(12):A734-A735.

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[521]



[522]

[521] Associated Newspapers/Rex Fea/Rex Features. Guardian. Available at: https://www.theguardian.com/environment/gallery/2012/dec/05/60-years-great-smog-london-in-pictures. Published: 05 December 2012. Accessed: 25 October 2019.

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In contrast to heavy industrial exposures to talc in miners and millers, Burns et al.[523] demonstrated that potential exposures to asbestos in talc to consumers of talcum powder are quite low and below general population background airborne cumulative lifetime exposure. The authors used published and unpublished measurement data associated with talcum powder products and applied the "*EPA's current nonoccupational asbestos regulatory risk assessment methods and other important benchmarks.*" For four different use scenarios, authors estimated cumulative exposure potential ranging from 0.0000021 to 0.0096 f/cc-yr, which resulted in risk estimates that were within or below EPA's acceptable target risk levels. The authors concluded that their findings were consistent with the original EPA findings from 1985 and that exposure and corresponding health risk in this range were orders of magnitude below upper-bound estimates of cumulative asbestos exposure and risk at ambient levels, which have not been associated with increased incidence of asbestos-related disease. Lifetime ambient cumulative exposure to asbestos in the U.S. population ranges from approximately 0.002-0.4 f/cc-yr over a 70-year lifetime.[524,525]

EXPERT REPORTS & OPINIONS.

R. Mark Bailey, PG.[526,527,528,529,530,531,532,533,534,535,536]

Mr. Bailey is a geologist and mineralogist who performed transmission electron microscopy analysis on samples of Avon and Johnson & Johnson talcum powder products. The results of his studies showed tremolite, chrysotile, anthophyllite, serpentine, and actinolite fibers in some of the samples that he tested. One sample that Mr. Bailey tested was found to contain numerous

[522] PA. "Arsenal goalkeeper Jack Kelsey peers into the fog, searching for the elusive ball." *Guardian.* Available at: https://www.theguardian.com/environment/gallery/2012/dec/05/60-years-great-smog-london-in-pictures. Published: 05 December 2012. Accessed: 25 October 2019.
[523] Burns AM, Barlow CA, Banducci AM, et al. "Potential Airborne Asbestos Exposure and Risk Associated with the Historical Use of Cosmetic Talcum Powder Products." *Risk Analysis*. 2019;39(10):2272-2294.
[524] Burns AM, Barlow CA, Banducci AM, et al. "Potential Airborne Asbestos Exposure and Risk Associated with the Historical Use of Cosmetic Talcum Powder Products." *Risk Analysis*. 2019;39(10):2272-2294.
[525] Agency for Toxic Substances and Disease Registry (ATSDR). "Toxicological Profile for Asbestos: Potential for Human Exposure." *U.S. Department of Health and Human Services, Public Health Service* (2001).
[526] Expert Report of R. Mark Bailey, PG, Laboratory Test Results for Avon Pavi Elle Perfumed Talc, Floral Fantasy, and 2 Odesseys, dated 27 December 2021.
[527] Expert Report of R. Mark Bailey, PG, Montana Talc Report on behalf of Avon, dated 12 June 2015.
[528] Expert Report of R. Mark Bailey, PG, Analysis of Avon Cotillion, dated 17 December 2019.
[529] Expert Report of R. Mark Bailey, PG, Laboratory Test Results for Avon Soft Musk and Topaze Perfumed Talc, dated 13 October 2021.
[530] Expert Report of R. Mark Bailey, PG, Laboratory Test Results for Avon To a Wild Rose, dated 19 January 2024.
[531] Murphy, Noth Carolina Talc Chart of Documents for Mark Bailey, PG, dated 20 August 2021.
[532] Expert Report of R. Mark Bailey, PG, on Asbestos in Talc Products from the Fontane Mine, Val Germanasca, Italy for Avon, dated 12 June 2020.
[533] Expert Report of R. Mark Bailey, PG, on Asbestos in Talc Products from the Hammondsville Mine, Vermont, USA for Avon, 16 November 2020.
[534] Affidavit of R. Mark Bailey, on behalf of Johnson & Johnson, dated 30 October 2023, with exhibits 1 through 16.
[535] Expert Report of R. Mark Bailey, PG, Transmission Electron Microscopy Analytical Test Report of Johnson & Johnson Baby Powder, dated 06 May 2021.
[536] Expert Report of R. Mark Bailey, PG, Transmission Electron Microscopy Analytical results for 3 talc archive batch samples on behalf of Johnson & Johnson, dated 08 September 2021.

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richterite, and several aluminum-containing fibers which were designated as richterite/winchite, amphibole asbestos fibers; fibrous talc was also observed.

Mr. Bailey determined that commercial talc deposits from southwestern Montana, including the Regal and Treasure mines owned by Barretts Minerals, were produced by hydrothermal alteration of dolomitic rocks creating large asbestos-free talc deposits.

Mr. Bailey examined talc from the Fontane mine. He reports that the talc material derived from the Fontane mine is consistently contaminated with tremolite/actinolite minerals, ranging in form from prismatic to asbestiform and that chrysotile asbestos is also found in the mine at times as well.

Mr. Bailey examined talc from the Hammondsville Mine in Vermont. He reports that the talc from the Hammondsville mine consistently contained trace amounts of fibrous tremolite/actinolite, and for any given bottle, within the limits of statistical uncertainty, there exists an extremely high scientific likelihood that the amphibole minerals tremolite/actinolite and/or anthophyllite will be present when the talc came from the Hammondsville talc mine.

Mr. Bailey holds the opinion that Johnson & Johnson talc products containing talc sourced from the Fontane mine in Italy and the Vermont mines identified above consistently contained asbestos.

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William E. Longo, PhD.[537,538,539,540,541,542,543,544,545,546,547,548,549,550,551,552,553,554,555,556,557,558,559,560]

Dr. Longo provided opinions about various talcum powders and performed analyses of various talcum powders from Avon, Estée Lauder, and Johnson & Johnson.

Dr. Longo has the opinion that the application of talcum powder found in a number of samples of Avon talcum powder products would cause significant exposure, over background, to chrysotile asbestos to individuals who used Avon brand talcum powder products for their intended purpose. For two samples of Avon talcum powder products Dr. Longo has the opinion that when children were exposed to these types of Avon's talcum powder products, they would have had a significant exposure to chrysotile, over background levels. For one sample of Avon talcum powder, Dr. Longo has the opinion that the application of the talcum powder found in this

[537] MAS Talcum Powder Analysis, Jeannine Henderson- Avon Wild Country, prepared by William E. Longo, PhD, CEO dated 25 October 2023.
[538] MAS Report on Avon Talcum Powder Analysis with both Automated FESEM and ATEM, dated 12 March 2019.
[539] MAS Analysis Report of Chinese Talc Research Samples, prepared by William E. Longo, PhD, CEO dated 16 September 2020.
[540] MAS Analysis Report of Avon Occur Perfumed Talc, prepared by William E. Longo, PhD, dated 18 August 2021.
[541] MAS Talcum Powder Analysis of Avon and Clinique Containers, prepared by William E. Longo, PhD, dated 05 September 2021.
[542] MAS Talcum Powder Analysis of Montana Micro-Talc 1745 Retain Samples, prepared by William E. Longo, PhD, CEO dated 10 June 2022.
[543] MAS Talcum Powder Analysis of Avon Splits, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
[544] MAS Talcum Powder Analysis of Historical Avon Splits: Wild Rose 1965, Cotillion 1961, & Persian Wood 1958, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
[545] MAS Pfizer Treasure Mine Talc Analysis, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
[546] MAS Talc Ore Samples Collected from the Eclipse Mine in Death Valley: Analyzed for Amphibole Asbestos by Transmission Electron Microscopy, prepared by William E. Longo, PhD, CEO dated 12 June 2022.
[547] MAS Talcum Powder Analysis of Rita Chapman Avon Powder Containers, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
[548] MAS Supplemental Report Avon Talcum Powder Container Analysis for Asbestos, prepared by William E. Longo, PhD, CEO dated 30 September 2022.
[549] MAS Talcum Powder Analysis of Avon Powder Products, Project M71387 & M71587, prepared by William E. Longo, PhD, CEO dated 15 November 2022.
[550] MAS Talcum Powder Analysis of Avon Powder Products, Project M71560 & M71562, prepared by William E. Longo, PhD, CEO dated 15 November 2022.
[551] MAS Analysis Report of Avon Products, prepared by William E. Longo, PhD, dated 15 November 2022.
[552] MAS Supplemental Report Talcum Powder Analysis of Avon Powder Products, Project M71560 & M71562, prepared by William E. Longo, PhD, CEO dated 19 November 2022.
[553] MAS Talcum Powder Analysis of Avon Somewhere Powder, prepared by William E. Longo, PhD, CEO dated 20 September 2023.
[554] MAS Talcum Powder Analysis of Avon Split, prepared by William E. Longo, PhD, CEO dated 21 September 2023.
[555] MAS Avon Talcum Powder Analysis, prepared by William E. Longo, PhD, CEO dated 21 September 2023.
[556] MAS Talcum Powder Analysis of Solomon, Beth – Talc Splits, prepared by William E. Longo, PhD, CEO dated 16 February 2024.
[557] MAS Analysis Report of Avon Unforgettable Perfumed Talc, prepared by William E. Longo, PhD, dated 21 April 2017.
[558] MAS Expert Analysis Report of Estee Lauder Products by William E. Longo, PhD, CEO, dated 16 December 2022.
[559] MAS 4th Supplemental MDL Report, Analysis of Non-Historical J&J's Talcum Powder Consumer Product Containers and J&J Chinese Historical Talc Retain Samples, by William E. Longo, PhD, CEO, dated 29 April 2024.
[560] Declaration of William Longo, PhD, dated 21 September 2021.

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sample would cause significant exposure, over background, to chrysotile and tremolite asbestos to individuals who used Avon brand talcum powder products for their intended purpose.

Dr. Longo states that his opinion of the analytical results of 11 Guiguang Zhzhu, China Mine Source samples, is that the application of talcum powder from the Guiguang Zhzhu, China talc source, would have caused significant exposures over background to both chrysotile asbestos and fibrous talc.

Dr. Longo has the opinion that when individuals use cosmetic talc products that contain talcum powder from Pfizer's Montana Treasure Mine, it will cause these individuals to have significant exposure over background to chrysotile asbestos and potentially tremolite. It is his opinion that products that use talc sourced from the Eclipse talc mine would cause that product to contain significant amounts of amphibole asbestos and that individuals who use consumer products that contain talc from the Eclipse mine, where the product generates airborne dust during its use, will cause that individual to be exposed to significant levels of amphibole asbestos over background levels. He identified richterite asbestos and tremolite asbestos.

Dr. Longo has the opinion that the application of the talcum powder found in Estée Lauder body powder containers will cause significant exposure, over background, to tremolite asbestos and/or chrysotile to individuals, who used Estée Lauder brand talcum body powder products for their intended purpose, that used the same talcum powder mine source as the 12 Estée Lauder containers that were found to be positive for asbestos.

According to Dr. Longo, his analysis demonstrated that both the Italian and the Vermont mines that J&J sourced their talcum powder from contained significant amounts of amphibole asbestos (tremolite & anthophyllite/cummingtonite). Additionally, 15 talc ore samples sourced from their Vermont mine, were found to contain tremolite asbestos. He concludes that for the three talc mine sources that suppled J&J talcum powder for their two body powder products sold in the United States, Dr. Longo's company, MAS, has analyzed 96 containers of J&J talcum powder, He states that these products had detectable concentrations of asbestos in 82% of the containers and the 26 historical talc ore samples that MAS has analyzed, sourced from the Vermont and Chinese talc mines, found 73% positive for asbestos.

Dr. Longo reports that he tested Johnson & Johnson products that encompass the eras of all three sources for Johnson & Johnson talc products offered for sale in the United States (Italy, Vermont, China) as well as talc offered for sale in Asia, Australia, Argentina, and the United Kingdom. According to Dr. Longo, testing has shown regulated asbestos in containers sourced from each of these mines.

William E. Longo, PhD and Mark W. Rigler, PhD.[561]

Dr. Longo and Dr. Rigler used three principal analytical methods for the analysis of the one 1987 Avon Night Magic cosmetic talc sample was polarized light microscopy (PLM), analytical transmission electron microscopy (ATEM) and field emission scanning electron microscopy (FE-SEM). Drs. Longo and Rigler conclude that The Blount/PLM and ISO 22262-2 ATEM method demonstrated that actinolite asbestos was in the Avon Night Magic Container. The weight concentration of the actinolite asbestos was found to be <0.1% by Blount PLM and 4240

[561] MAS Analysis of Avon Night Magic Talcum Powder, prepared by William E. Longo, PhD, and Mark W. Rigler, PhD, dated January 2019.

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fiber/bundles by the 150- 22262-2 ATEM method and Cyprus's Olympic talc product, from the Beaverhead mine contains amphibole asbestos.

William E. Longo, PhD, Mark W. Rigler, PhD, and William B. Egeland, MS, PG.[562]

Dr. Longo, Dr. Rigler, and Mr. Egeland performed a study using both the NIOSH 7400 PCM method and the NIOSH 7402 TEM method to determine if any detectable amphibole asbestos fibers from a sample of Johnson's Baby Powder were released into the breathing zone of the investigator and immediate surrounding area in the exposure characterization lab. Dr. Longo, Dr. Rigler, and Mr. Egeland conclude that the four personal air samples that were collected in the breathing zone of the investigator showed an average mean tremolite asbestos fiber exposure of 2.57 f/cc and an average mean fibrous talc exposure of 1.95 f/cc. They explain that their results show that an individual, who uses asbestos-containing Johnson's talcum powder, can have a significant exposure to airborne amphibole fibers as shown in this study, and the magnitude of the asbestos fiber exposure levels will depend on the concentration level of the naturally occurring asbestos in the Johnson's Baby Powder product. They further state that their study showed that there was significant exposure to asbestiform talc fibers from the application of the Johnson's Baby Powder during the study.

William E. Longo, PhD, William B. Egeland, MS, PG, and Martin Bennett.[563,564]

Dr. Longo, Mr. Egeland, and Mr. Bennett performed a work practice study regarding Johnson's Baby Powder Application to baby during diaper change. Personal samples detected asbestos fibers.

Steven P. Compton, PhD.[565,566,567,568,569,570,571]

Dr. Compton investigated several talc/mineral samples for asbestos. According to Dr. Compton, amphibole fibers were detected in eleven of the thirteen Italian Talc samples. He states that aside from the talc itself, the primary fibrous contaminants in the sample set are anthophyllite and

[562] MAS Supplemental #2 Expert Report on Below the Waist Application of Johnson & Johnson Baby Powder by William E. Longo, PhD, Mark W. Rigler, PhD, and William B. Egeland, MS, PG, dated January 2018.
[563] MAS Expert Report Rev #1 on Talcum Powder Application to Baby and Diaper Change II: A Hygiene Study by William E. Longo, PhD, William B. Egeland, MS, PG, and Martin Bennett, dated 28 June 2019.
[564] MAS Expert Report on Johnson's Baby Powder Application to Baby and Diaper Change: A Hygiene Study Supplemental by William E. Longo, PhD, William B. Egeland, MS, PG, and Martin Bennett, dated May 2020.
[565] Expert Report of Steven P. Compton, PhD, Investigation of Italian Talc Samples for Asbestos, dated 01 August 2017.
[566] Expert Report of Steven P. Compton, PhD, Investigation of Vermont Talc Samples for Asbestos, dated 23 April 2018.
[567] Expert Report of Steven P. Compton, PhD, Investigation of Montana Talc (American International Industries Microtalc 1745) for Asbestos, dated 15 March 2019.
[568] Expert Report of Steven P. Compton, PhD, Examination of Avon Talcum Powder for Asbestos Gail Welch Case, dated 29 May 2020.
[569] Expert Report of Steven P. Compton, PhD, Examination of 907 Talc Powder for Asbestos, dated 26 January 2024.
[570] Expert Report of Steven P. Compton, PhD, Examination of Vintage Avon Bunny Fluffpuff Talc in Rabbit-shaped Puff container for Asbestos, dated 19 May 2023.
[571] Expert Report of Steven P. Compton, PhD, Examination of Vintage Avon Unforgettable Talc in Shaker Container for Asbestos, dated 19 May 2023.

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tremolite/actinolite, and the asbestos content of samples found to contain amphibole and chrysotile fibers range from approximately 1.7 to 660 million fibers per gram.

Dr. Compton also reported that amphibole fibers were detected in ten of the fifteen samples analyzed from the Argonaut Vermont mine, and aside from the talc itself, the primary fibrous contaminants in the sample set are anthophyllite and, in one sample, tremolite/actinolite. According to Dr. Compton, the asbestos content of samples found to contain amphibole fibers range from approximately 1.2 to 2,600 million fibers per gram.

Dr. Compton reported that asbestos fibers were detected by TEM in 6 of 53 Microtalc samples sourced from Montana that were collected from 2002 to 2017. According to Dr. Compton, aside from the talc itself, fibrous particles detected in the sample set include chrysotile, tremolite, and anthophyllite (including anthophyllite/gedrite), and for samples in which asbestos was detected, the asbestos content ranged from approximately 3.6 to 9.5 million fibers per gram.

Dr. Compton's investigation of a sample of Avon talcum powder showed that it contains platy talc as well as fibrous talc and chrysotile asbestos fibers/bundles. Dr. Compton investigated another sample of Avon talcum powder and determined that the analyzed sample of talcum powder product contains platy talc as well as elongate mineral fibers of talc and the amphibole minerals tremolite/actinolite, and the amphibole asbestos concentration can be expressed as less than 79.6 million fibers per gram of powder (the upper 95% confidence interval). Dr. Compton investigated a third sample of Avon talcum powder which he determined contains platy talc as well as elongate mineral fibers of talc, tremolite asbestos, and sodium calcium amphibole fibers. The tremolite asbestos concentration, based on the detection of fibrous tremolite structures via TEM, is approximately 1.95 billion fibers per gram.

Dr. Compton analyzed a sample of 907 talc powder which he determined contains platy and fibrous talc in addition to calcium-rich mineral fibers, like tremolite and possible diopside.

Alan M. Segrave, PG.[572]

Mr. Segrave provided opinions as a geologist and microscopist on the occurrence of asbestos in proximity to talc deposits, specifically, the talc deposits of Val Chisone, Italy; Murphy, North Carolina; southwest Montana; Alpine, Alabama; southern Vermont, southeast California, Canada, Brazil, and Guangxi, China. Mr. Segrave states that talc sourced by Avon did not contain asbestos. Mr. Segrave also states that there is no evidence that Vi-Jon talc used in the manufacture of Equate body powder, 2003-2016 was contaminated with asbestos and it is unknown what talc was specifically used in the manufacture of Equate body powder, 2003-2016 product Mr. Perry allegedly used or was in proximity to its use. Mr. Segrave also states that talc sourced by IMI Fabi in products Mr. Perry used did not contain asbestos.

It is his opinion that the testing program performed by mining companies and independent laboratories relied upon by distributors (such as IMI Fabi and Vi-Jon) as well as manufacturers was a proactive, forward-thinking program to characterize asbestos in talc. Mr. Seagrave's conclusions include that it is unlikely Mr. Perry would have been exposed to asbestos from the use of Avon Bird of Paradise, Cotillion, Skin So Soft, Soft Musk, Timeless, Topaze, Men's Musk, Deep Woods, and Spicy Talc body powders, and talc supplied by Vi-Jon or IMI Fabi. Mr.

[572] Expert Report of Alan M. Segrave, PG, dated 17 June 2024.

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Segrave's opinion is that there is no evidence that Mr. Perry used or was in proximity to talc that was contaminated with asbestos, and which allegedly may have been used the above products.

Matthew S. Sanchez, PhD.[573,574]

Dr. Sanchez provided opinions about the alleged contamination of asbestos in talc products manufactured by Estée Lauder using talc from a variety of sources. His opinion is that the Estée Lauder talcum-based products at issue in this case do not contain asbestos.

Dr. Sanchez also provided an analysis in this case and concluded that Johnson & Johnson talcum powder and talc from the source mines were and is free of asbestos. Dr. Sanchez's opinions are based on his review, analysis, and interpretation of the available analytical testing data on Johnson & Johnson talcum powder and talc from its three source mines: Val Germanesca Italy, southern Vermont USA, and Guangxi China.

Paul A. Nony, PhD, CIH, CSP.[575]

Dr. Nony calculated a hypothetical estimate, 0.000014 f/cc-yr, of Mr. Perry's cumulative exposure to asbestos as a result of his mother's described use of talc products manufactured by Estée Lauder. Comparatively, Dr. Nony figured Mr. Perry's estimated cumulative exposure from breathing asbestos present in ambient air through his date of disease diagnosis. He concluded that any hypothetical cumulative exposure to asbestos experienced by Mr. Perry associated with his mother's use of ELC talcum powder products was approximately 379 times less than his cumulative exposure resulting from ambient exposures in the environment.

Dr. Nony concluded the hypothetical exposure experienced by Mr. Perry did not present any significant risk toward his development of pleural mesothelioma. Any hypothetical exposure from ELC talcum powders would be substantially less than Mr. Perry's ambient exposure and of no significance towards his risk of developing disease.

Christy A. Barlow, PhD.[576]

Dr. Barlow reviewed case materials pertaining to Mr. Perry. Her opinion is that the chemistry, geometry, and biological reactivity of talc particles in cosmetic talcs are different from asbestos fibers. Likewise, cleavage fragments are not reactive and are distinctly and functionally different from asbestos fibers. Dr. Barlow has the opinion that increased rates in the development of mesothelioma associated with exposure to cosmetic talc have not been reported in the numerous experimental and epidemiological studies that have evaluated the carcinogenic potential of cosmetic talc. Dr. Barlow determined that based on the available evidence, Mr. Perry was unlikely to have been exposed to any measurable asbestos from his use of Johnson & Johnson talcum powders. Dr. Barlow further stated that using a worst-case assumption that trace asbestos could theoretically have been found in the Johnson & Johnson talcum powders, any associated asbestos exposure potential would have been well within (or below) the corresponding cumulative background or ambient levels of asbestos found in the air in the U.S., and below the cumulative asbestos exposure potential associated with working at the current OSHA PEL for asbestos over 45 years. Dr. Barlow estimated that the cumulative, worst-case asbestos fiber

[573] Expert Report of Matthew S. Sanchez, on behalf of Johnson & Johnson, dated 06 June 2024.
[574] Expert Report of Matthew S. Sanchez, on behalf of Estée Lauder, dated 06 June 2024.
[575] Expert Report of Paul A. Nony, PhD, CIH, CSP, on behalf of Estée Lauder, dated 26 June 2024.
[576] Expert Report of Christy A. Barlow, PhD, on behalf of Johnson & Johnson, dated 18 June 2024.

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exposure estimate for Mr. Perry's consumer use of Johnson & Johnson talcum powders ranged from 0.0002 to 0.04 f/cc-yr.

Dr. Barlow also opined that Mr. Perry was unlikely to have been exposed to any measurable asbestos from his use of cosmetic talcum powder distributed by IMI Fabi LLC and IMI Fabi (Diana) LLC. Dr. Barlow further stated that using a worst-case assumption that trace asbestos could theoretically have been found in the cosmetic talcum powder distributed by IMI Fabi LLC and IMI Fabi (Diana) LLC, any associated asbestos exposure potential would have been well within (or below) the corresponding cumulative background or ambient levels of asbestos found in the air in the U.S., and below the cumulative asbestos exposure potential associated with working at the current OSHA PEL for asbestos over 45 years. Dr. Barlow estimated that the cumulative, worst-case asbestos fiber exposure estimate for Mr. Perry's consumer use of cosmetic talcum powder distributed by IMI Fabi LLC and IMI Fabi (Diana) LLC beginning in 2001, ranged from 0.0001 to 0.03 f/cc-yr.

Jennifer S. Pierce, MS, PhD.[577]

Dr. Pierce reviewed legal and medical materials pertaining to Mr. Perry, as well as materials pertaining to Avon in this matter. Dr. Pierce has the opinion that the weight of the evidence does not support that cosmetic talcum powders contain asbestiform minerals. She states that it is generally accepted that the development of asbestos-related cancer is not associated with exposure to talc that does not contain asbestiform minerals; however, if one were to assume that a cosmetic talcum powder product contained asbestiform minerals, the asbestos-related disease risk associated with that product is dependent on the chemical and physical properties of the asbestiform minerals present. She explained that even if one assumed that Avon cosmetic talcum powder products contained a trace level of asbestiform minerals, Mr. Perry's hypothetical exposure would have been well below the cumulative asbestos exposure that is permitted by the federal government (in the occupational setting), below that associated with breathing ambient air, and far too low to increase his risk of asbestos-related disease. Dr. Pierce's opinion is that Mr. Perry's disease may be unrelated to asbestos, and if asbestos-related, any hypothetical asbestos exposure that Mr. Perry may have experienced as a result of Avon products would not have increased his risk of developing mesothelioma.

Dr. Pierce calculated Mr. Perry's total hypothetical bystander exposure to asbestos from his mother's puff applications of Avon talcum powder to a range from 0.000099 f/cc-years to 0.0023 f/cc-years. She calculated Mr. Perry's total hypothetical bystander exposure to asbestos from his mother's personal shaker applications of Avon talcum powders (assuming a trace level of contamination) to a range from 0.00017 f/cc-years to 0.0049 f/cc-years. Dr. Pierce calculated that, overall, assuming a trace level of contamination in every Avon talcum powder product that Mr. Perry's mother ever applied in his vicinity, Mr. Perry's total hypothetical exposure to asbestos fibers resulting from this product would range from 0.00027 f/cc-years to 0.0072 f/cc-years. Dr. Pierce explains that the cumulative exposure over a working lifetime at the current Permissible Exposure Limit is 4.5 f/cc-years (i.e., 0.1 f/cc x 45 years), and Mr. Perry's hypothetical cumulative exposure to asbestos associated with Avon products is between approximately 625- and 16,729-fold below the cumulative occupational exposure that is currently acceptable in the United States. According to Dr. Pierce, Mr. Perry's total hypothetical

[577] Expert Report of Jennifer S. Pierce, MS, PhD, in the matter of Michael Perry regarding Avon, Inc., dated 19 June 2024.

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cumulative exposure to asbestos associated with Avon products throughout his lifetime is lower than the cumulative exposure associated with a lifetime of breathing ambient air; lower than the NOAELs for chrysotile, amosite, and crocidolite; and lower than the NOAEL for anthophyllite and tremolite asbestos.

Jennifer Sahmel, PhD, CIH, CSP, FAIHA.[578]

Dr. Sahmel evaluated case-specific materials pertaining to Mr. Perry. Dr. Sahmel indicated that her understanding that the relevant period during which Walmart-brand Equate baby powder could have been manufactured by Vi-Jon was between January of 2003 and August of 2016. Her opinion is that Mr. Perry was unlikely to have had the opportunity for exposure to any measurable asbestos from consumer use of powder products associated with Vi-Jon. According to Dr. Sahmel, even using an upper bound assumption that trace asbestos could theoretically have been found in Equate baby powder to which Mr. Perry was exposed between 2003 and 2016, according to any available data, any associated asbestos exposure potential would have been well within the corresponding cumulative background or ambient levels of asbestos found in the air in the U.S. However, Dr. Sahmel notes that Mr. Perry's actual cumulative asbestos exposure potential associated with the use of Equate baby powder potentially associated with Vi-Jon could have been below the limit of detection, if not zero. This is well below the cumulative asbestos exposure associated with a working lifetime at the current OSHA PEL for asbestos. She further notes that exposures to asbestos to the general U.S. population across a wide range of measured background airborne fiber concentrations have not been shown to be associated with a statistically significant increased risk of asbestos-related disease, including mesothelioma. Mr. Perry's total estimated cumulative lifetime exposure from Equate baby powder potentially associated with Vi-Jon could have been 0 f/cc-year or up to as much as a theoretical upper bound of 0.0086 f/cc-year, which is well below the range of reported lifetime ambient asbestos exposures in the U.S, if not below the limit of detection. Dr. Sahmel also states that any asbestos exposure potential associated with the use of cosmetic talc under more realistic scenarios is likely to be even further within or below the range of general cumulative ambient exposure, and orders of magnitude below the current OSHA PEL for asbestos.

ASSESSMENT.

The allegation in this case is that Mr. Perry has pleural mesothelioma that was caused by cosmetic talc believed to also contain asbestos. I have assumed that the diagnosis of pleural mesothelioma is correct. Based on the materials available in this case, Mr. Perry does not have conditions such as diffuse pleural thickening or bilateral calcified pleural plaques which, if present, could be compatible with prior asbestos exposure. He does not have asbestosis.

In particular, I assessed the evidence in this case that asbestos as a potential contaminant of cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon, Estée Lauder, Gold Bond, Ammens IMI-Fabi, LLC, IMI Fabi (USA), LLC, and/or IMI-Fabi (Diana) could have been responsible for causing pleural mesothelioma in Mr. Perry. In this case, there is no objective evidence available that shows that Mr. Perry had any asbestos exposure from his alleged use of cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon,

[578] Expert Report of Jennifer Sahmel, PhD, CIH, CSP, FAIHA, on behalf of Vi-Jon, dated 20 June 2024.

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Estée Lauder, Gold Bond, Ammens, IMI-Fabi, LLC, and/or IMI-Fabi (Diana) . There is no epidemiological evidence that the use of cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon, Estée Lauder, Gold Bond, Ammens, IMI-Fabi, LLC, IMI Fabi (USA), LLC, and/or IMI-Fabi (Diana) causes mesothelioma.

According to the testimony of Mr. Perry, his exposure to Johnson's Baby Powder was from his own personal use, his application to his husband, his husband's application to himself in his proximity, his mother's application to herself in his proximity, and his mother's application directly to him. Mr. Perry's exposure to Avon cosmetic talcum powder products was from playing with his father's container of powder and from being in proximity to his mother while she applied powder to herself. Mr. Perry's exposure to Vi-Jon cosmetic talcum powder products was from his application to himself and his application to his husband, and his husband's application to himself in Mr. Perry's proximity. Mr. Perry's exposure to Estée Lauder cosmetic talcum powder products was from being in proximity to his mother while she applied powder to herself. Mr. Perry's exposure to Gold Bond and Ammens cosmetic talcum powder products was from his own personal use and from applying powder to his shoes. Mr. Perry's exposure to cosmetic talc allegedly produced by IMI-Fabi, LLC, IMI Fabi (USA), LLC, and/or IMI Fabi (Diana), LLC was from talcum powder products since 2001.

Mr. Perry likely had no asbestos exposure from cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon, Estée Lauder, IMI-Fabi, LLC, and/or IMI-Fabi (Diana), but even worst-case estimated exposures would have been to a dose too low to elevate his risk for mesothelioma. It is not plausible that his alleged exposures from cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon, Estée Lauder, Gold Bond, Ammens, IMI-Fabi, LLC, IMI Fabi (USA), LLC, and/or IMI-Fabi (Diana) caused his mesothelioma.

I have not seen evidence in this case of any significant exogenous exposure (including asbestos) that would raise his risk of developing pleural mesothelioma, though I cannot rule out a contribution from his claimed occupational exposures. If Mr. Perry did not have significant exogenous exposure from commercial amphibole asbestos, it is most likely that his mesothelioma developed spontaneously or was naturally occurring.

It is possible that Mr. Perry had an inherited genetic risk factor for cancer especially given his young age, and personal and family history of malignancies. However, there is no germline testing result available to confirm that.

CONCLUSIONS.

Based on the review of case materials and medical and scientific literature relevant to this case, I express my opinions with a reasonable degree of medical certainty, including that:

- Mr. Perry was diagnosed with pleural mesothelioma in July 2023.
- Talc is not a carcinogen. Talc does not cause mesothelioma.

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- There is no objective evidence that Mr. Perry had any exposure to asbestos from cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon, Estée Lauder, Gold Bond, Ammens, IMI-Fabi, LLC, IMI Fabi (USA), LLC, and/or IMI-Fabi (Diana).

- Based on the available medical and scientific literature, it is not plausible that asbestos as a potential contaminant of cosmetic talc produced and/or distributed by Johnson & Johnson, Avon, Vi-Jon, Estée Lauder, Gold Bond, Ammens, IMI-Fabi, LLC, IMI Fabi (USA), LLC, and/or IMI-Fabi (Diana), could have caused Mr. Perry to develop pleural mesothelioma.

- I cannot rule out a contribution to his mesothelioma from his reported asbestos exposures at work. If Mr. Perry did not have significant asbestos exposure from his work or any other source, it is most likely that his mesothelioma developed spontaneously or was naturally occurring.

- It is possible that Mr. Perry has a hereditary risk for developing cancer. However, there is no available germline testing to confirm whether or not he has a hereditary risk factor.

This report is based on the information available to me at this time. Should additional information become available, I reserve the right to determine the impact, if any, of the new information on my opinions and conclusions, to revise my opinions and conclusions if necessary, and to rebut the opinions of any other experts that formulate an opinion in this matter.

Respectfully submitted,



Gregory B. Diette, M.D., M.H.S.

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APPENDIX A: CASE MATERIALS AND OTHER DOCUMENTS RECEIVED.

Legal Documents/Materials:

- Summons and Complaint
- First Amended Summons and Complaint
- Second Amended Summons and Complaint
- Plaintiff's Responses to Defendants' Master Set of Interrogatories and Requests for Production (Ex. 2)
- Plaintiffs' Responses to Defendants' Standard Interrogatories
- Plaintiffs' First Supplemental Responses to Defendants' Standard Interrogatories
- Plaintiffs' First Supplemental Responses to Defendants' Master Set of Interrogatories and Requests for Production (Ex. 2)

Depositions:

- Video-recorded Deposition of Michael L. Perry, Volume I, taken 10 October 2023, *with* Exhibits 1 through 14.
- Video-recorded Deposition of Michael L. Perry, Volume II, taken 11 October 2023, *with* Exhibits A through D.
- Video-recorded Deposition of Michael L. Perry, Volume III, taken 12 October 2023.
- Video-recorded Deposition of Michael L. Perry, Volume IV, taken 13 October 2023.

Expert Reports & Materials:

- Expert Report of Matthew S. Sanchez, on behalf of Johnson & Johnson, dated 06 June 2024.
- Expert Report of Matthew S. Sanchez, on behalf of Estée Lauder, dated 06 June 2024.
- Expert Report of Alan M. Segrave, PG, dated 17 June 2024.
- Expert Report of Christy A. Barlow, PhD, on behalf of Johnson & Johnson, dated 18 June 2024.
- Expert Report of R. Mark Bailey, PG, Laboratory Test Results for Avon Pavi Elle Perfumed Talc, Floral Fantasy, and 2 Odesseys, dated 27 December 2021.
- Expert Report of R. Mark Bailey, PG, Montana Talc Report on behalf of Avon, dated 12 June 2015.
- Expert Report of R. Mark Bailey, PG, Analysis of Avon Cotillion, dated 17 December 2019.
- Expert Report of R. Mark Bailey, PG, Laboratory Test Results for Avon Soft Musk and Topaze Perfumed Talc, dated 13 October 2021.
- Expert Report of R. Mark Bailey, PG, Laboratory Test Results for Avon To a Wild Rose, dated 19 January 2024.

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- Murphy, Noth Carolina Talc Chart of Documents for Mark Bailey, PG, dated 20 August 2021.
- Expert Report of R. Mark Bailey, PG, on Asbestos in Talc Products from the Fontane Mine, Val Germanasca, Italy for Avon, dated 12 June 2020.
- Expert Report of R. Mark Bailey, PG, on Asbestos in Talc Products from the Hammondsville Mine, Vermont, USA for Avon, 16 November 2020.
- MAS Talcum Powder Analysis, Jeannine Henderson- Avon Wild Country, prepared by William E. Longo, PhD, CEO dated 25 October 2023.
- MAS Analysis of Avon Night Magic Talcum Powder, prepared by William E. Longo, PhD, and Mark W. Rigler, PhD, dated January 2019.
- MAS Report on Avon Talcum Powder Analysis with both Automated FESEM and ATEM, dated 12 March 2019.
- MAS Analysis Report of Chinese Talc Research Samples, prepared by William E. Longo, PhD, CEO dated 16 September 2020.
- MAS Analysis Report of Avon Occur Perfumed Talc, prepared by William E. Longo, PhD, dated 18 August 2021.
- MAS Talcum Powder Analysis of Avon and Clinique Containers, prepared by William E. Longo, PhD, dated 05 September 2021.
- MAS Talcum Powder Analysis of Montana Micro-Talc 1745 Retain Samples, prepared by William E. Longo, PhD, CEO dated 10 June 2022.
- MAS Talcum Powder Analysis of Avon Splits, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
- MAS Talcum Powder Analysis of Historical Avon Splits: Wild Rose 1965, Cotillion 1961, & Persian Wood 1958, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
- MAS Pfizer Treasure Mine Talc Analysis, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
- MAS Talc Ore Samples Collected from the Eclipse Mine in Death Valley: Analyzed for Amphibole Asbestos by Transmission Electron Microscopy, prepared by William E. Longo, PhD, CEO dated 12 June 2022.
- MAS Talcum Powder Analysis of Rita Chapman Avon Powder Containers, prepared by William E. Longo, PhD, CEO dated 01 June 2022.
- MAS Supplemental Report Avon Talcum Powder Container Analysis for Asbestos, prepared by William E. Longo, PhD, CEO dated 30 September 2022.
- MAS Talcum Powder Analysis of Avon Powder Products, Project M71387 & M71587, prepared by William E. Longo, PhD, CEO dated 15 November 2022.
- MAS Talcum Powder Analysis of Avon Powder Products, Project M71560 & M71562, prepared by William E. Longo, PhD, CEO dated 15 November 2022.