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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.

In the Matter Of:
MICHAEL L. PERRY, et al.
VS
AMERICAN INTERNATIONAL INDUSTRIES, et al.

David Weill, M.D.
July 18, 2024



David Weill, M.D.

July 18, 2024

STATE OF SOUTH CAROLINA IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND FOR THE FIFTH JUDICIAL COURT

X

MICHAEL L. PERRY and LONNIE L.

C/A NO.

LONG,

2023-CP-40-04072

Plaintiffs,

v.

AMERICAN INTERNATIONAL

INDUSTRIES, et al.

CERTIFIED COPY

Defendants.

X

VIDEOCONFERENCE DEPOSITION
OF
DAVID WEILL, M.D.

* * *

Taken by Plaintiff
July 18, 2024

* * *

Reported in Stenotype by: Peter DeCrescenzo,
Registered Professional Reporter

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David Weill, M.D.

July 18, 2024

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REPORTER'S NOTES:

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* * *

P R O C E E D I N G S

On July 18, 2024, commencing at 2:01 p.m., the deposition of David Weill, M.D. was taken pursuant to notice and pursuant to the South Carolina Rules of Civil Procedure, on behalf of the Plaintiff, all parties participating remotely.

THE REPORTER: I am Pete DeCrescenzo, RPR, the reporter for today s deposition.

Do counsel stipulate and agree that I may administer the oath remotely and that the oath so given is valid for all purposes of this deposition?

ALL COUNSEL: Yes.

Whereupon, David Weill, M.D., having been duly sworn, was examined and testified as follows:

MS. FORBES-KING: Before we begin, I'd like to offer the following stipulation: That an objection by one counsel is good for all present, and you can opt out of any objection at trial, and your appearance at today's deposition does not waive any pending motions for -- based on personal jurisdiction.

Is that agreeable?

MS. BUENO: YES
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MS. FORBES-KING: Okay.

EXAMINATION

BY MS. FORBES-KING:

Q. Doctor, can you please state your name for the record.

A. David Weill.

Q. And where are you calling in from today?

A. New Orleans.

Q. And anyone in the room with you?

A. No.

Q. Okay. I am well aware that you've had your deposition taken before. So are you okay moving forward without going over the rules of the road, the difference between guessing and estimating, and things of that nature?

A. Yes.

Q. Okay. And you're still a pulmonologist; correct?

A. I am.

Q. And you understand that you're here testifying in the Michael Perry case today?

A. Yes.

Q. Okay. My notes have been that you've been retained by Avon and Johnson & Johnson in this case; is that correct?

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1 A. Yes.

2 Q. Anyone else?

3 A. No.

4 Q. I'm going to mark today's deposition
5 notice as Exhibit 1. I assume that you've seen your
6 deposition notice?

7 (Plaintiffs' Exhibit 1 was introduced.)

8 A. Yes.

9 Q. Have you provided your entire file in the
10 Perry case?

11 A. The attorneys mentioned it to me, that
12 they would provide that to you.

13 Q. And we'll go through -- I have two
14 reports, an initial report, and a supplemental
15 report.

16 Are there any other reports or notes that
17 you issued in this case?

18 A. No.

19 Q. Perfect. I'm going to attach as Exhibit 2
20 your CV that I have as dated January 25th of 2024.

21 Is that your most recent?

22 (Plaintiffs' Exhibit 2 was introduced.)

23 A. Yes.

24 Q. Anything to add or change to make that up
25 to date?

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David Weill, M.D.

July 18, 2024

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1 A. No.

2 Q. Okay. I'm going to attach a list of
3 expert testimony that I have for you as Exhibit 3.
4 The last thing I have dated on this, and I might
5 mess up the name, but it's the Nucklos,
6 N-U-C-K-O-L-S, depo on June 28th as the last
7 deposition that you gave.

8 Is that the most up to date list of prior
9 testimony you have?

10 A. No. I actually gave a deposition on
11 Monday that we put on our updated list, so I'm happy
12 to provide that for you if you would like.

13 Q. So why don't we, as Exhibit 3, attach the
14 updated list.

15 I'm going to attach your reference list as
16 Exhibit 4. I have the most recent one as dated
17 July 10th, 2024.

18 Is that the most recent reference list?
19 (Plaintiffs' Exhibits 3 and 4 were introduced.)

20 A. Yes.

21 Q. Anything that needs to be added or updated
22 for that?

23 A. No.

24 Q. Okay. And I think you previously noted
25 that the reference list **GPS LLC** is not an exhaustive list of
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1 everything.

2 How do you decide what reference
3 literature makes it onto this list versus what might
4 not make this reference list?

5 A. It really doesn't reflect everything that
6 I've read, but if the study is sufficiently high
7 quality and seems to be the basis of my core
8 opinions, I put it on. Otherwise I don't.

9 Q. And would it be fair to say that the
10 publications on your reference list are publications
11 that you've reviewed and considered in preparation
12 for your opinions in this case?

13 A. Yes.

14 Q. I'm going to mark -- I have two letters in
15 this case that I've received, that are addressed to
16 you with attention Pete Tafaro. I'm going to attach
17 these as Exhibit 5.

18 Mr. Tafaro is the business manager of your
19 consulting group; right?

20 (Plaintiffs' Exhibit 5 was introduced.)

21 A. Yes.

22 Q. Perfect. I have one invoice in this case
23 that's dated May 23rd, 2024.

24 Are you familiar with that invoice?

25 A. I'm not familiar with which one you're
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David Weill, M.D.

July 18, 2024

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1 talking about just because I don't have it in front
2 of me, but if you tell me what it says, I can maybe
3 answer the question.

4 Q. Here, I'll share it with you. Can you see
5 this invoice?

6 A. Yes.

7 Q. This is the one invoice I have for this
8 case.

9 Are you aware of any other invoices
10 related to this case?

11 A. I don't know if there were any other than
12 that, but I can certainly provide them for you, if
13 there were.

14 Q. Okay. Based on this invoice, it has the
15 hours that you spent working on this case as six
16 hours at a rate of \$725.

17 Do you see that?

18 A. Yes.

19 Q. Can you estimate for the entirety of the
20 Perry case the total number of hours that you've
21 spent on the case?

22 A. I would imagine it's probably an
23 additional six, since this was invoiced for a total
24 of 12, and that would include the deposition
25 preparation.

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1 Q. And then the other people indicated here,
2 a litigation consultant, senior litigation
3 consultant, those are individuals that help review
4 materials and get things ready for you then to
5 review the materials and create the report?

6 A. Correct.

7 Q. And you wouldn't know how much additional
8 time they've spent on this case outside of what was
9 listed in the invoice?

10 A. No, I wouldn't, without looking at
11 additional invoices, if there are any.

12 Q. Okay. I'm going to attach this I think
13 as -- I think I'm on Exhibit 6 -- as Exhibit 6. I'm
14 going to attach the July 11th, 2024 report as
15 Exhibit 6.

16 In that original report, there's a list of
17 case specific documents you reviewed in the Perry
18 case listed on the first, second, third, and fourth
19 pages of the report; is that correct?

20 (Plaintiffs' Exhibit 6 was introduced.)

21 A. Yes.

22 Q. And then I'm going to attach the
23 supplemental report dated July 12th, 2024 as
24 Exhibit 7.

25 And the first page of that report lists
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1 additional case specific documents you reviewed in
2 the Perry case; is that correct?

3 (Plaintiffs' Exhibit 7 was introduced.)

4 A. Yes.

5 Q. Okay. Great. Have you reviewed any other
6 case specific materials outside of the materials
7 listed in the first -- the original and supplemental
8 report?

9 A. No.

10 Q. Did you ever talk to any of Mr. Perry's
11 physicians?

12 A. No.

13 Q. Any witnesses in the case?

14 A. No.

15 Q. Everything you know about the facts of the
16 Perry case from the documents listed in the two
17 reports; correct?

18 A. Yes.

19 Q. What did you understand to be your
20 assignment in this case when you were retained?

21 A. It was not explicitly told to me, but I
22 understood it to mean, first, to determine whether
23 or not this gentleman, in fact, suffered from a
24 pleural mesothelioma, which I think he did.

25 And then secondly, to determine whether or
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1 not any exposure he would have gotten to talcum
2 powder would have elevated his risk.

3 Q. Okay. And so based on your review, it's
4 your opinion that Mr. Perry does, in fact, have
5 pleural mesothelioma?

6 A. Yes.

7 Q. Do you have any opinions as to the cause
8 of Mr. Perry's mesothelioma, based on your review of
9 the materials?

10 A. I think that this was a naturally
11 occurring disease due to intrinsic factors specific
12 to Mr. Perry. I don't think that there was an
13 exposure that caused his disease.

14 Q. And you said based on intrinsic factors.
15 Are there any specific intrinsic factors
16 that you believe caused his mesothelioma?

17 A. I can only say that there was a series of
18 genetic mutations that occurred, but I can't be any
19 more specific than that, or be able to name them
20 without any additional testing that was performed.

21 Q. And when you say naturally occurring is
22 that the same as spontaneous mesothelioma?

23 A. I'm using those terms interchangeably with
24 also the idiopathic mesothelioma.

25 Q. Got it. Just wanted to make sure. Did
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1 you find anything in Mr. Perry's medical records
2 indicating evidence of genetic change or mutation?

3 A. No.

4 Q. Did you see that Mr. Perry had genetic
5 testing for BAP1?

6 A. I saw that the tumor was tested for BAP1,
7 and I mentioned that in my report as well. And the
8 BAP1 was said to be intact then, so no mutation.

9 Q. And what does it mean to you when you see
10 a mesothelioma patient where the BAP1 was intact?

11 A. Well, if it's tumor testing, that is
12 tissue testing, I don't have a -- I don't believe it
13 has any implication one way or the other. The
14 testing that I would be looking for would be blood
15 testing for germline mutations.

16 Q. So a finding of an intact BAP1 in the
17 tumor is not indicative one way or the other whether
18 or not the individual has any germline mutation to
19 their BAP1?

20 A. Yes. Correct.

21 Q. So then based on that, the fact that the
22 BAP1 was intact in Mr. Perry's tumor would not
23 factor into your opinion --

24 A. Correct.

25 Q. -- because -- GPS LLC
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1 A. Yeah. Sorry. I answered before you were
2 done.

3 Q. No. My question was done. I was adding
4 on unnecessarily, so thank you.

5 And then I believe, based on your
6 statement that you didn't see any intrinsic
7 exposures that would have increased Mr. Perry's risk
8 of developing mesothelioma, causing him to develop
9 it, you weren't able to identify any asbestos
10 exposure that Mr. Perry had that would've
11 contributed to his development of mesothelioma?

12 MS. BUENO: Objection. Form.

13 A. I actually --

14 Q. I'm going to take that question back
15 because it's very, very wordy.

16 A. Okay.

17 Q. Based on your review of Mr. Perry's
18 records, were you able to identify any exposure to
19 asbestos?

20 A. None that I thought elevated his risk for
21 the disease, no.

22 Q. You noted in your review Mr. Perry's
23 family history of colon cancer, and that his father
24 had prostate cancer?

25 A. Yes. GPS LLC
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1 Q. Did either of those have any relevance to
2 your opinions in this case?

3 A. No.

4 Q. Do you intend to testify at trial that
5 Mr. Perry had a family history of cancer that you
6 considered in forming your opinion that his
7 mesothelioma was spontaneous?

8 A. I'll answer that question this way. I'll
9 note that he had a family history of it. If you're
10 asking whether or not I'm going to point to this as
11 a family cancer syndrome, if you'll use that
12 terminology, then the answer is no, I won't.

13 Q. How, if at all, does Mr. Perry's family
14 history of cancer factor into your opinions in this
15 case?

16 A. It doesn't. I just noted it for
17 completeness sake in my report, but it doesn't.

18 Q. Okay. Did you see any evidence in the
19 medical records that any doctor believed that
20 Mr. Perry's mesothelioma was spontaneous?

21 A. I -- I didn't see that any of the doctors
22 commented on the cause of it one way or the other.

23 Q. Other than not having any external risk
24 factors, is there anything else that you would
25 identify that indicates

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1 mesothelioma was spontaneous?

2 A. That's the definition of a spontaneous
3 tumor, not being able to identify any external
4 factors which elevated the risk, and I didn't see
5 those in this case, unless one of these exposures or
6 any exposure becomes more further characterized.

7 At this time I can't say more likely than
8 not that any exposure he would have gotten would
9 have elevated his risk of disease.

10 Q. And I just wanted to make sure that the
11 only thing, from your review of the medical records,
12 is there anything else you saw or didn't see that
13 indicates Mr. Perry's mesothelioma was spontaneous,
14 beyond there being no external factors?

15 MS. BUENO: Objection. Form.

16 A. I'm not sure I understand the question.
17 Do you mind rephrasing?

18 Q. From your review of the materials, was
19 there anything -- other than the fact that you were
20 unable to identify an external risk factor or
21 risk -- I want to make this clean, and I think I'm
22 kind of putting the same question that's going to
23 give you the same response.

24 A. I think I know where you're headed, but
25 I --

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1 Q. Yeah.

2 A. -- I'm reluctant to answer the question
3 until you pose it.

4 Q. Outside of the fact that you were unable
5 to identify any external exposure that put Mr. Perry
6 at risk for developing mesothelioma, was there
7 anything else, in your review of materials that you
8 either saw or didn't see, that would indicate to you
9 that Mr. Perry's mesothelioma was spontaneous?

10 MS. BUENO: Objection. Form.

11 A. No.

12 Q. And you said there was no exposure that
13 you could say, to a reasonable degree of medical
14 certainty, caused his mesothelioma. I want to ask
15 you a similar question.

16 Is it your opinion, to a reasonable degree
17 of medical certainty, that Mr. Perry's mesothelioma
18 was spontaneous?

19 A. That is my opinion.

20 MS. BUENO: Objection. Form.

21 A. Yeah.

22 Q. As far as external risk factors or risk
23 factors for mesothelioma, what did you look for and
24 see in Mr. Perry's records?

25 A. The same things that I would identify
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as -- as established risk factors for mesothelioma development, namely significant amphibole exposure, number one; number two, erionite exposure; and, number three, therapeutic radiation exposure.

Q. That's what I anticipated. The first one I want to talk about is you didn't see any significant history of amphibole exposure.

What type of exposure would you need to see in order to attribute it to somebody's mesothelioma?

A. Depending on the particular asbestiform amphibole that we would be talking about, I would have to see exposure types that were consistent with what's been reported in the medical literature as elevating the risk of the disease.

And so when one talks about amosite, tremolite, or crocidolite, I consider what's in the medical literature, and what's been shown to increase the risk for mesothelioma, and I didn't see that in this case.

Q. And for tremolite, what level, based on your review of the medical literature, would you be looking for?

A. So tremolite exposures have been best characterized I think by GPS LLC Finley, Brent Finley's
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1 study from 2011, when he saw a no observed effect
2 level anywhere from 25 to 75 fiber years. And I
3 would also, for tremolite, look to those exposures
4 that were present in the vermiculite mines, where
5 the average exposure was upwards of 80 fiber years
6 of tremolite in order to see a prevalence of disease
7 in that mining community.

8 Q. And then I want to ask you about
9 chrysotile. I anticipate it's your opinion that an
10 individual could breathe chrysotile dust every day
11 and their risk of developing mesothelioma would not
12 be increased at all; correct?

13 A. So if we're talking about chrysotile
14 that's uncontaminated with an asbestiform amphibole,
15 my answer would be that I don't think that elevates
16 risk. If we're talking about chrysotile that's
17 contaminated with asbestiform tremolite, then
18 that -- that risk exists in the -- in mining
19 communities when there's hundreds to thousands of
20 fiber years of exposure.

21 Q. And you were talking about amphibole
22 asbestos. It appears to me that you were talking
23 about commercial amphibole asbestos forms; correct?

24 A. Yes.

25 Q. Well, you also talked about tremolite.

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1 A. Yes.

2 Q. How do you define commercial asbestos?

3 A. Well, I don't -- I don't define it because
4 that's -- that's something that's defined by
5 industry, and so I -- I really don't define it.

6 I look at, when I think about amphiboles
7 and asbestiform amphiboles, I consider all the
8 identified amphiboles that are out there. I -- I
9 don't define whether or not they're commercially
10 exploited or not.

11 Q. We talked about tremolite. Do you have a
12 fiber level exposure that you need to see to
13 attribute somebody's mesothelioma to anthophyllite
14 or actinolite?

15 A. I think those -- those two fiber types are
16 less well characterized when it comes to levels that
17 have been associated with mesothelioma. I think, at
18 best, both are very weakly mesotheliomagenic,
19 more -- more on the order of chrysotile than the
20 other asbestiform amphiboles.

21 The only information that's -- I'm aware
22 of in terms of anthophyllite is in the Finnish
23 mining communities where there were very high
24 exposure levels were required to demonstrate disease
25 incidents, and I'm not aware of any with regard to

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1 actinolite that show if there is any risk, how --
2 where is that risk -- where does the risk begin.

3 Q. And those were the Finland mining studies,
4 so studies regarding an actinolite mining in
5 Finland?

6 A. Anthophyllite mines in Finland.
7 Actinolite, I'm not aware of any -- any studies that
8 have looked at that specifically with regards to
9 mesothelioma risk.

10 By the way, are you guys hearing all of
11 this back here or not?

12 MR. BISHOP: Yeah.

13 Q. Yes.

14 A. Okay.

15 Q. I was just -- I was like somebody is in a
16 massive storm it sounds like.

17 A. No. It's south Louisiana in the summer.
18 I'm having to like scream to be heard, so I
19 apologize. I'm not yelling or purposely yelling,
20 let's put it that way.

21 Q. I got you. You're totally fine.

22 You did not do a dose reconstruction in
23 this case; correct?

24 A. No.

25 Q. You did review the expert reports in
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1 this case?

2 A. I did.

3 Q. Did you review other expert opinions in
4 this case who did a dose reconstruction?

5 A. Yes. There were -- there were --
6 specifically Barlow and Pierce came up with
7 accumulative exposure levels, or at least a range of
8 accumulative exposure levels.

9 Q. And did those dose reconstructions factor
10 into your opinions at all?

11 A. I -- I considered them. I don't know that
12 they change my opinion any, but I considered them
13 certainly. And consistent with what my opinion has
14 been in the past or what my understanding of the
15 exposure levels has been in the past.

16 Q. Got it. So even without having reviewed
17 those reports, your opinions would be the same?

18 A. Yes.

19 Q. Is it possible that any of the talcum
20 powder products Mr. Perry used had amphibole
21 asbestos in them?

22 A. I -- I don't weigh in on the topic about
23 what's present in the materials. I think that
24 that's outside of my scope of expertise. I --
25 I actually instead look at the risk, so the medical risk
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1 of developing the disease. It -- assuming that
2 there's even a small amount of amphibole asbestos
3 present, although I -- I can't testify that there is
4 or there isn't.

5 Q. Have you ever reviewed testing results of
6 Avon talc powder products for the presence of
7 asbestos?

8 A. No.

9 Q. Have you ever reviewed testing results of
10 J&J talc powder products for the presence of
11 asbestos?

12 A. No.

13 Q. Okay. I want you to assume for me that
14 Mr. Perry used talc body powder every day, and
15 assume for me that the specific powder that he used
16 had been tested for the presence of asbestos, and
17 amphibole asbestos had been found in the same
18 product Mr. Perry used repeatedly.

19 Are you with me?

20 A. Yes.

21 Q. Would that change your analysis in forming
22 your opinions in this case?

23 A. No.

24 MS. BUENO: Objection. Form.

25 A. No, it wouldn't.
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1 Q. Did you review Mr. Perry's deposition
2 yourself in its entirety?

3 A. I did.

4 Q. Okay. Have you reviewed Dr. Haber's
5 testimony in this case?

6 A. No, I haven't.

7 Q. Same true for Dr. Longo?

8 A. And you're talking about their testimony
9 as opposed to their expert reports?

10 Q. Correct.

11 A. No, I haven't.

12 Q. And do you intend to offer any opinions
13 regarding Dr. Haber's report itself?

14 A. I didn't -- I didn't review his report.

15 Q. What about Dr. Longo's report? Did you
16 review that?

17 A. Yes.

18 Q. Do you intend to offer any criticisms or
19 critiques or opinions based on his report?

20 A. To the extent that that involves testing
21 of the product, I won't be offering any opinions
22 about the validity or lack thereof of his testing.

23 Q. Outside of his testing, was there any
24 critiques or opinions that you intend to give
25 regarding Dr. Longo's report?

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1 A. Well, he -- he issued several reports in
2 this case and all -- they were pretty lengthy, so I
3 don't want to endorse all of them, all of the
4 opinions he had. If you have a specific one that
5 you want to ask me about, that's fine.

6 Q. I'm just asking if you anticipate coming
7 in to testify at trial, intending to give opinions
8 critiquing Dr. Longo or his reports in some manner
9 as you sit here --

10 A. I -- Yeah. I haven't done that in the
11 past just because the bulk of his report is directed
12 toward testing, and I don't testify in that area.

13 Q. That's what I anticipated. I just wanted
14 to make sure.

15 As a pulmonologist, what is asbestos in
16 terms of what has been demonstrated to cause
17 disease?

18 MS. BUENO: Objection. Form.

19 A. What is the definition of asbestos?

20 Q. Correct.

21 A. Well, so the -- as a non geologist, my
22 understanding of it is informed by geologists. And
23 the distinction between asbestiform and non
24 asbestiform minerals is based on the habit, so
25 where -- where and how ~~GPS LLC~~ formed in nature.

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1 And to the extent that those can be
2 identified and classified as either asbestiform or
3 non asbestiform, that's important to me as a
4 pulmonologist, because I think the one handles them
5 rather differently and one has the potential to
6 cause disease and one doesn't.

7 Q. In differentiating asbestiform and non
8 asbestiform based on the habit, what is your basis
9 for the habit being the factor in determining
10 whether something is asbestiform or non asbestiform?

11 A. That is based on my understanding of the
12 geology. Again, as a non geologist, that's what my
13 understanding has become from reading their
14 literature.

15 Q. Outside of the specific geology reports
16 that you've read in this case, is there anything
17 that you can cite to specifically for the opinion
18 that asbestiform and non asbestiform is determined
19 by the habit?

20 A. I think I would point to the work on my
21 reference list by Dr. Ann Wylie. I would also point
22 to the work that is also on my reference list by
23 Graham Gibbs, who references geologic papers to talk
24 about the differences between non asbestiform and
25 asbestiform minerals.

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1 Q. And for Ann Wylie, is this a geology
2 publication or is it medical literature?

3 A. Well, she's a geologist, so she would be
4 publishing geology kind of papers.

5 Q. And what about Graham Gibbs? Is this
6 another geologist or would this be in the medical
7 literature?

8 A. He's a medical doctor. And so he looks at
9 the geologic differences, but also looks at how
10 they're handled differently in the body.

11 Q. Let me see if I can find this just so that
12 we can make sure that we're talking about the same
13 thing.

14 I am only seeing a Graham -- or a Gibbs A.
15 And it's Gibbs, A.R.

16 Is there anything else that you could give
17 me to identify this publication or publications?

18 A. Let me get to that on my reference list.
19 Yeah. Actually the Gibbs -- the Gibbs article is
20 going to be under Gamble. Go to page -- the bottom
21 of page 25. Gibbs was actually the senior author on
22 that 2008 paper, 2007 paper by those two authors.

23 Q. I got it. So it's this 2007 Evaluation of
24 the Risks of -- it says lunch cancer, but I'm
25 guessing it might be Lung Cancer, Mesothelioma from

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Exposure to Amphibole Cleavage Fragments?

A. Good help is hard to get these days, yeah. Yeah. It's lung, not lunch.

Q. Okay. And then the second publication is An Evaluation of the Risk of Lung Cancer and Mesothelioma From Exposure to Amphibole Cleavage Fragments.

Did I read that correctly?

A. Yes.

Q. Okay. Outside of the publications by Ann Wylie, Graham Gibbs, that we just discussed, are there any other publications that you rely on that it is the habit that determines whether or not something's asbestiform versus non asbestiform?

A. None come to mind right now.

Q. Do you make any distinction between industrial talc and cosmetic talc?

A. There is a distinction. And again, it's the -- how they're -- how they're mined. So it has to do with more of the purity of the material in the mining and milling process.

Q. And when making your opinions in these cases, do you make any distinction between industrial talc and cosmetic talc?

A. Just for the purposes of this work, I
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1 assume that these are cosmetic talc issues.

2 Q. And what would make something a cosmetic
3 talc, other than how it's mined? What would be the
4 difference between industrial talc and cosmetic
5 talc?

6 A. I'm not an expert in this, but I'll tell
7 you what I know. The purity requirements that
8 differ between cosmetic talc and industrial talc,
9 based on how they're used differently in the public.
10 So aside from that, I can't tell you.

11 Q. What purity level do you think a talc
12 needs to have in order to be cosmetic talc?

13 A. I don't know what the regulatory
14 requirements are on that, if they are --

15 Q. That was going to be my follow up
16 question.

17 Are you aware of any regulatory
18 requirements on the purity level of cosmetic talc?

19 A. I've seen it said that there is
20 0.1 percent amphibole or less as a regulatory
21 requirement, but that's my only vague recollection
22 of any commentary one way or the other.

23 Q. And, in your opinion, are any talc mines
24 contaminated with asbestos?

25 A. The talc mines GPS and SCI understand them, that
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1 are pertinent to cosmetic talc, the answer is no. I
2 haven't seen any literature that shows any
3 contamination.

4 Q. And you're still a practicing
5 pulmonologist; correct?

6 A. I am.

7 Q. Do you ever treat patients with
8 mesothelioma?

9 A. I don't have a patient right now with
10 mesothelioma. I have in the past, but not right
11 now.

12 Q. And you would agree with me that taking a
13 patient's history of asbestos exposure when they
14 have mesothelioma is important; correct?

15 A. Yes.

16 Q. Do you ever ask any of your patients, or
17 have you ever asked -- I know you don't currently
18 have any, but have you ever asked any of your
19 patients with mesothelioma if they've been exposed
20 to cosmetic talc?

21 A. No. Just because it's not a known risk
22 factor, in my opinion, for developing the disease.

23 Q. Have you ever diagnosed a patient with a
24 spontaneous mesothelioma in your practice as opposed
25 to any litigation work?

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1 A. Yes.

2 Q. And when was that?

3 A. I --

4 Q. Or like what would happen that you would
5 do that?

6 A. What would happen? It would be the same
7 way I would diagnose somebody in the medical-legal
8 context.

9 Q. Got it. So if you couldn't identify an
10 external risk for the development of mesothelioma,
11 you would diagnose them with a spontaneous
12 mesothelioma?

13 A. Correct.

14 MS. BUENO: Objection. Form.

15 A. Correct.

16 Q. And back to the opinion that the talcum
17 powder products, the cosmetic talcum powder products
18 didn't contain asbestos, it's your testimony that
19 Mr. Perry's use of those products did not expose him
20 to asbestos; correct?

21 A. Well, I -- I don't get into the issue
22 about whether or not there's a small amount of
23 amphibole asbestos contamination or not, or whether
24 or not -- if there is amphibole, whether it's
25 cleavage fragments or not. GPS LLC is not able to make
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1 that determination.

2 What I can say is that regardless, there's
3 no excess risk of disease, if he was exposed.

4 Q. And when you're making that opinion,
5 you're not going to testify at trial whether or not
6 the mines or those products at issue were actually
7 contaminated with asbestos; correct?

8 A. The only thing I'll be able to say at
9 trial is if we're talking about a specific mine, and
10 there happens to be medical literature related to
11 that mine, whether or not it says there's asbestos
12 contamination or not, I can certainly testify about
13 that.

14 But beyond that, if there's actual testing
15 done in an expert witness kind of fashion, then I
16 don't do that.

17 Q. Do you know what mines are at issue in
18 this case, which talc mines?

19 A. Well, I -- I make the assumption that --
20 the ones that are traditionally associated with J&J
21 and Avon, but I -- I can't say in this particular
22 case what they would be.

23 Q. And which talc mines are typically
24 associated with Avon and J&J?

25 A. Well, as I mentioned in my report, it
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1 would be the Italian mines, as well as the Vermont
2 and Chinese mine for J&J; and the Italian mine,
3 Montana, and North Carolina for Avon. That's my
4 understanding.

5 Q. And what is your understanding based on?

6 A. Just having worked on these cases for some
7 years, I -- I came to know that.

8 Q. Was that by being told by people? Was it
9 based on --

10 A. I think most --

11 Q. -- other expert reports?

12 A. Yeah. I think most of it was not so much
13 being told by anybody, but reading other expert
14 reports.

15 Q. And even if Mr. Perry's talcum powder
16 products were contaminated with asbestos, your
17 opinion is that it wouldn't be a sufficient enough
18 of an exposure level to cause his mesothelioma;
19 correct?

20 A. Correct.

21 Q. Anything else, from a causation
22 standpoint, that you're going to opine and testify
23 about that we haven't talked about?

24 MS. BUENO: Objection. Form.

25 A. Yeah. The only thing that we haven't
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1 talked about is it's my understanding also that
2 there's lung tissue that's being analyzed. And to
3 the extent that that lung tissue is available, I'd
4 like to review that as well.

5 Q. Well, I'm not aware of any testing having
6 been completed. If you are provided with additional
7 materials, we would want to be informed, that you
8 have been informed of any additional opinions that
9 you have, based on materials that you review, and
10 then I'm sure counsel can discuss whether or not
11 further deposition needs to take place, based on any
12 additional review for testing or documents that you
13 receive. I'm going to make that statement on the
14 record.

15 Are all of the opinions you intend to
16 offer at trial either found within your report, the
17 supplemental report, or something that we've talked
18 about today?

19 A. Yes. With the usual caveat I give, that I
20 can't predict what I'm going to be asked at trial,
21 but you certainly have my core opinions.

22 Q. Right. And I'm just talking about as you
23 sit here today, beyond what you might be asked, is
24 there anything that you can think of that you
25 anticipate testifying about at trial, as you sit

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1 here today, that we either haven't discussed or you
2 haven't provided in either of your reports?

3 A. No.

4 Q. So the trial in this case is set in the
5 beginning of August in Columbia, South Carolina.
6 Are you planning to attend live and in person and
7 testify in this case?

8 A. That's certainly my intention, yes.

9 Q. Anything you have that would prohibit you
10 from being able to go to South Carolina in the -- I
11 think it's August 5th is the start date.

12 So those two weeks of August. Anything
13 prohibiting you from going to South Carolina?

14 A. I'll make it work.

15 Q. I'm just making sure you don't have some
16 big trip or something.

17 A. No. I'm dropping my daughter off at
18 college during that time period. But, again, I'll
19 make it work.

20 Q. Okay. I want to go back to your
21 overarching opinion that we've talked about, that
22 the talcum powder products didn't contain asbestos,
23 and Mr. Perry's use of those products did not expose
24 him to asbestos.

25 That's based on other expert reports, the
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1 case specific materials that you reviewed in this
2 case.

3 Any other materials that you would be
4 relying on for that particular opinion?

5 A. No.

6 Q. And when we're talking about case specific
7 materials, that would be when it comes to that the
8 product didn't contain asbestos, and Mr. Perry's use
9 of those products didn't expose him to asbestos, we
10 would be talking about the expert reports of other
11 folks.

12 Anything else?

13 A. With my report and the -- and the
14 reference list, that you have the universe of what I
15 rely on.

16 Q. Got it. And that may have been where it
17 was a poor question. I just want to talk
18 specifically about the fact that the talcum powder
19 products didn't contain asbestos --

20 A. Yeah.

21 Q. -- and therefore Mr. Perry's use of those
22 products didn't expose him to asbestos, that
23 particular opinion --

24 A. That's -- can I interrupt?

25 Q. Uh-huh. GPS LLC
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1 A. That's not exactly my -- that's not
2 exactly my opinion. So I don't testify about
3 whether or not there's asbestiform minerals present
4 in the talcum powder or not. That's outside of my
5 realm of expertise.

6 I make the assumption that there might be
7 a small amount, just worst case scenario. I'm not
8 testifying that there is a small amount. I'm just
9 using that as worst case scenario to determine
10 whether or not there's excess risk, even if that's
11 present.

12 So I don't testify about whether there is
13 or there isn't asbestiform amphibole present in the
14 talcum powder.

15 Q. What are you assuming as a worst case
16 scenario level of asbestos in talcum powders that
17 Mr. Perry was exposed to?

18 A. Well, I -- first, I -- I consider the
19 epidemiology when I'm looking at disease causation,
20 so I'm not looking so much at the levels that are
21 present.

22 In other words, I look to see if there is
23 any indication from human epidemiology whether
24 there's a risk present to exposure of this type. I
25 certainly consider the ~~case~~ **GPS** that Pierce and Barlow
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1 and -- have determined, and the medical literature
2 has shown, the exposure levels to be at or below
3 background. But when it -- when it gets to
4 causation, I'm looking at human epidemiology to make
5 that opinion, not so much a level.

6 Q. And when you say human epidemiology, when
7 it comes to talc cases, what specific studies would
8 you be pointing to?

9 A. Well, again, using worst case scenario,
10 which would be at the source, which would be the
11 mine, there's no indication that that elevates the
12 risk, even the people that mine the talc.

13 And, secondly, there's -- there's not any
14 epidemiology to show that talcum powder elevates the
15 risk of the disease.

16 Q. So we've got the epidemiological studies
17 regarding talc miners.

18 Are there any other studies or
19 publications related to epidemiological studies of
20 talc exposure that you would rely on?

21 A. No. Those are the most important ones.

22 MS. FORBES-KING: Sir, I think those are
23 all of my questions that I have for you.

24 I'm not sure if anybody else on the line
25 has any questions for ~~David Weill~~.

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MS. BUENO: This is Kim Bueno. I have a couple of quick follow ups, but I'm happy to let somebody else proceed, if you have questions first.

Okay. Hearing no one.

EXAMINATION

BY MS. BUENO:

Q. Dr. Weill, just a couple of questions for you. I'm looking at your report, the very first one, which was marked for the record as Exhibit Number 6.

And if you'll turn with me to page two of that report, am I correct that this is a list of materials that you reviewed and considered before authoring your opinions in this case?

A. Yes.

Q. And starting on number 23 on page two, it looks like you reviewed reports of Dr. Sanchez and Dr. Segrave; is that correct?

A. Yes.

Q. And you understand that those experts are testing experts for Johnson & Johnson and Avon respectively; correct?

A. Yes.

MS. FORBES-KING: Objection.

Q. You also reviewed reports, starting at
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1 number 27, for Dr. Mark Bailey who is a geologist,
2 mineralogist for plaintiffs.

3 You understand that?

4 A. Yes.

5 Q. And then it looks like you also reviewed a
6 series of reports from Dr. Longo, that's starting --
7 it appears at number 35 on page two and going into
8 page three, that's up through number 55; is that
9 correct?

10 A. Yes.

11 Q. And is it your understanding that
12 Dr. Longo is a testing expert for the plaintiffs?

13 A. Yes.

14 Q. And you were asked a question by
15 plaintiff's counsel about whether or not you had
16 reviewed testing of Johnson & Johnson talc products
17 for asbestos, and I believe you answered no to that.

18 Just to clarify, did you indeed review
19 expert reports where testing of Johnson & Johnson
20 products was discussed and considered?

21 A. I -- I took that question to mean -- the
22 company testing of the -- of the product, not so
23 much expert testing of the product. So if I
24 misunderstood the question, then that's what I --
25 that's how I answered

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1 Q. Okay. Great. I just want to make sure
2 there's no confusion.

3 So is it true to say then that you did
4 consider testing of Johnson & Johnson products for
5 asbestos by both plaintiffs' and defendants' experts
6 in this particular matter?

7 A. Yes.

8 Q. Same question as it relates to Avon, so
9 there's no confusion. You were asked whether or not
10 you had reviewed testing of Avon talc products for
11 asbestos.

12 If we consider the expert reports that you
13 reviewed, would the answer to that question be yes
14 or no?

15 A. I -- I reviewed that testing by expert
16 witnesses.

17 Q. And did you take into account, as part of
18 your opinions, the findings of plaintiffs' experts
19 indicating that they found trace amounts of asbestos
20 in talcum products manufactured by both Johnson &
21 Johnson and Avon?

22 MS. FORBES-KING: Objection.

23 A. Yes.

24 Q. Will you turn with me now to the invoice
25 that was discussed in the GPS LLC case. I don't think it
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David Weill, M.D.
July 18, 2024

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1 was marked as an exhibit, but do you have that in
2 front of you, Dr. Weill?

3 A. No.

4 Q. Okay. At the bottom of the invoice
5 there's a note, and it says this represents one half
6 of total bill in this matter.

7 A. Uh-huh.

8 Q. Are you familiar with those kind of
9 annotations in your billing?

10 A. Yes.

11 Q. And tell us what that means.

12 A. That just means likely that their -- their
13 half of the bill went to Avon, and half of the bill
14 went to Johnson & Johnson.

15 Q. And so to be clear, if it indicates on the
16 bill that you submitted to Johnson & Johnson that
17 there was six hours of time by you on this matter,
18 would it be fair to say that the amount of work you
19 had done as of the date of this invoice, May 23rd,
20 would actually be double that?

21 A. Yes.

22 Q. Okay. Just to make sure we're clear.

23 So if there had been 12 hours of time then
24 from May 23rd of 2024, how much additional time
25 since then do you believe you spent on Mr. Perry's

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case?

A. Six, as I answered.

Q. Okay. So then the total amount would more likely be 18 than 12 that we discussed previously?

A. Yes.

Q. All right. Terrific.

MS. BUENO: Those are my only questions.
Thank you, Dr. Weill.

THE WITNESS: Thank you.

MS. BUENO: Does anybody else have anything else?

MR. BISHOP: No questions for me.

MS. FORBES-KING: I have a couple. I don't hear anybody else.

EXAMINATION

BY MS. FORBES-KING:

Q. First, I want to mark, and I had made a note while you were speaking that I did forget to mark the invoice as an exhibit, so I'm going to go ahead and mark it next in order, which I believe is 8. If not, it will be 9.

And I did want to clarify, when you were talking about testing earlier, just to make it clear, since we're talking about what testing you did review, your assumption was correct about what I

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1 was asking about, but I just want to make it clear
2 for the record.

3 You haven't seen any of Johnson &
4 Johnson's corporate records about asbestos testing
5 of its talc; correct?

6 (Plaintiffs' Exhibit 8 was introduced.)

7 A. Correct.

8 Q. And that for Avon, you haven't seen any
9 company records regarding any of the testing for
10 asbestos they did on talc; correct?

11 A. Correct.

12 Q. Got it.

13 MS. FORBES-KING: And I think those are
14 the only additions that I have.

15 I think we can go off the record, unless
16 somebody has something else.

17 MS. BUENO: Yeah. I think we're good. I
18 agree.

19 (There was a discussion off the record.)

20 THE REPORTER: And, lastly, can we get
21 orders on the record, please, or if you haven't
22 already emailed me.

23 MS. BUENO: Johnson & Johnson has a
24 standing order.

25 You may drop ~~GPS~~ Dr. Weill, in the
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1 rainstorm.

2 THE WITNESS: Yeah. I'm going to go get
3 my boat.

4 MS. FORBES-KING: And I think we have a
5 standing order as well. Since my car has turned off
6 and it's getting hot, I'm going to go ahead and
7 leave, unless somebody needs something.

8 MS. BUENO: No. Thank you, Shawna. Take
9 care.

10 MS. FORBES-KING: Thank you. Bye-bye.

11 MR. BISHOP: Hey, Alicia, if you're still
12 on, do you want a -- or would you like me to order?

13 MS. RITCHIE: I am on. Sorry. I was just
14 trying to get unmuted. You can go ahead, Bruce.
15 Y'all can just keep doing what you're doing.

16 And, Mr. DeCrescenzo, I'm on for Avon as
17 well.

18 THE REPORTER: Okay. Great.

19 MR. BISHOP: So, Pete, if you could -- you
20 have my contact information, but we'd like an
21 E-transcript, and a scanned copy of the exhibits but
22 it's not a rush.

23 THE REPORTER: Okay. Thank you. Great.
24 Thank you.

25 And, Ms. Nahata, GPS LLC did get your
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1 information as well.

2 And the person joining as D. Addison, if
3 they are here --

4 MR. ADDISON: I'll -- I'll put mine in.
5 Sorry.

6 THE REPORTER: Thank you.

7 MS. BUENO: All right. Pete, you have
8 everything you need?

9 THE REPORTER: I think so.

10 And, sir, can you confirm whether or not
11 you'd like a copy, or email me your order, please?

12 MS. BUENO: All right. Thank you all so
13 much again.

14 MR. BISHOP: Thank you. Bye, everybody.

15 THE REPORTER: Bye. Take care.

16 (Concluded at 2:58 p.m.)
17
18
19
20
21
22
23
24

25 GPS LLC
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David Weill, M.D.

July 18, 2024

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STATE OF NORTH CAROLINA

MECKLENBURG COUNTY

C E R T I F I C A T E

I, Peter DeCrescenzo, Registered Professional Reporter and Notary in and for the aforesaid county and state, do hereby certify that the foregoing pages are an accurate transcript of the deposition of David Weill, M.D., which was taken on behalf of plaintiff by me in machine shorthand and transcribed by computer-aided transcription.

The witness and parties did not reserve the signing of the deposition by the witness.

I further certify that I am not financially interested in the outcome of this action, a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of such attorney or counsel.

This 18th day of July, 2024

Peter DeCrescenzo, Registered Professional Reporter

GPS LLC
gpscalendar@gps.llc ~ 214.347.4781

Johnson & Johnson
CONSUMER PRODUCTS, INC.

Page 1 of 7

SPEC NO: RM08006

DOC TYPE: RAW MATERIAL
SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC
LOCATION: Royston

REVISION	AUTHORIZATION	DESCRIPTION OF CHANGE
03/01/90	CR012001	Specification converted to CPI numbering system (was 8-006).
06/28/90	CR012201	Arsenic Content changed from NMT 2 ppm to NMT 2.5 ppm. PCA, Puerto Rico and Baby Lotion w/Powder deleted.
09/26/90	CR012330	Sec. 5, Acceptance, Hamm Mine (Windham) added. (V. McCluskey)
01/07/92	CR013276	Specification revised making IS76906 standard (R. Corder).

J&J-0023847

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JNJ 000315350



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SPEC NO: RM08006

DOC TYPE: RAW MATERIAL

SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC

LOCATION: Royston

PRODUCT(S): BABY POWDER
BABY POWDER CORNSTARCH

J&J-0023848

Johnson & Johnson
CONSUMER PRODUCTS, INC.

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SPEC NO: RM08006

DOC TYPE: RAW MATERIAL
SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC
LOCATION: Royston

1.0 DESCRIPTION

A hydrous magnesium silicate (also called magnesium acid metasilicate), a fine white lustrous powder, slippery, adherent to skin with no foreign odor or grittiness.

2.0 PROPERTIES & REQUIREMENTS

2.1 Asbestos (CTFA/J4-1) (TM7024)

None detected. Asbestos is defined to be the fibrous serpentine, chrysotile and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite and actinolite.

2.2 Moisture (TM7164)

NMT 0.15%

2.3 Solubility by Acid (TM7165)

NMT 2.0%

2.4 Magnesite (MgCO₃)% (TM7171 or TM7077 or TM7716)

NMT 1.10% MgCO₃

2.5 Bulk Density (TM7166)

20.5 to 25.5 lb./cu. ft. or metric equivalent at Cyprus Windsor Minerals.

2.6 Color (TM7170 or TM7071)

White as compared to a previously accepted lot or minimum of 85.5 reflectance reading.

2.7 Fineness (TM7070 or TM7167)

Through 60 mesh, 100%. Through 100 mesh, at least 99.7%, through 200 mesh, at least 98.5%.

2.8 Heavy Metals (TM7168)

NMT 10 ppm

2.9 Arsenic (TM7169 or TM7717)

NMT 2.5 ppm

J&J-0023849

Johnson & Johnson
CONSUMER PRODUCTS, INC.

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SPEC NO: RM08006

DOC TYPE: RAW MATERIAL
SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC
LOCATION: Royston

2.10 Water Soluble Iron (USP)

Pass Test

2.11 Microbial Requirement (TM7807)

Samples taken from Cyprus Windsor silos, trucks or bags shall contain no detectable harmful microorganisms and the total count shall be no greater than 50 microorganisms per gram of product. (See section 7 for details of testing)

3.0 CERTIFICATE OF ANALYSIS

A silo source analytical certificate will provide numerical analytical results required in Secs. 2.2, 2.3, 2.4, 2.5, 2.6, 2.7 and 2.11 of this specification. Secs. 2.8 and 2.10 will be reported as pass/fail. These results are obtained from a silo composite sample which is comprised from samples taken at eight hour intervals during the filling of the silo. The silo source analytical certificate will reference the railcar or trailer number (if a trailer is used to ship directly to Royston).

The certificate of analysis and the railcar/ or trailer seal log required as per SOP-B30 will accompany the preshipment samples to Royston and will be sent to the Royston Microbiology Laboratory.

The Certificate of Analysis is an Acceptance/Rejection criteria.

4.0 PACKING, MARKING & STORAGE

4.1 Packing

In suitable bags to protect contents from loss, contamination and deterioration in normal shipment and storage. Pallets of bagged material must be either stretch wrapped or covered with corrugated and secured with straps. Each bag shall contain 50 lbs. or metric equivalent. Bulk shipments will be made in CFI approved railcars and trailers.

4.2 Marking

Each bag shall be marked with:
Contents Name, Supplier
Name, Supplier Lot No.
Net Weights
Purchaser's Code

Bulk shipments are identified by the individual number of the particular trailer or railcar.

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DOC TYPE: RAW MATERIAL
SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC
LOCATION: Royston

4.3 Storage

If stored in bags, keep in dry area. Suitable bulk silos (for CPI): Buttlar electro-fused polymer utilizing white flint-flex powder #531-7010 manufactured by DuPont.

5.0 ACCEPTANCE

There shall be no change in the supplier's process or composition of the material without prior notification to and approval of JOHNSON & JOHNSON. Any non-conformance to the specified Description/Properties & Requirements, shall be cause for rejection.

The following mine properties in Vermont are qualified and approved to provide ore for processing into Grade 66 talc: Hammondsville Mine, Argonaut Mine, Rainbow Mine, Hamm Mine (Windham).

6.0 RAILCAR LOADING & SAMPLING

Railcar loading, unloading and sampling shall be in accordance with the approved J&J Consumer Products Procedure SOP-B30.

7.0 FREQUENCY OF CHARACTERISTICS TO BE TESTED

<u>No.</u>	<u>Characteristic</u>	<u>T.M.</u>	<u>Frequency</u>
2.1	Asbestos(a)	CTFA/J4-1	Per Note 1A
2.1	(b)	TM7024	Per Note 1B
2.2	Moisture	TM7164	Certified per 2a
2.3	Solubility by Acid	TM7165	Certified per 2a
2.4	Magnesite (MgCO ₃)%	TM7171/TM7077/ TM7716	Certified per 2b
2.5	Bulk Density	TM7166	Certified per 2b
2.6	Color	TM7170 or TM7071	Certified per 2b
2.7	Fineness	TM7167 or TM7070	Certified per 2b
2.8	Heavy Metals	TM7168	Certified per 2a
2.9	Arsenic	TM7169 or TM7717	Certified per 2a
2.10	Water Soluble Iron	USP	Certified per 2a
2.11	Microbial Requirement	TM7807	Every silo-See 3a Every railcar 3b

Johnson & Johnson
CONSUMER PRODUCTS, INC.

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SPEC NO: RM08006

DOC TYPE: RAW MATERIAL
SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC
LOCATION: Royston

NOTE:

- 1A. A composite sample is made from every two completed silos, labeled with silo numbers and production dates and forwarded to J & J Consumer Products for x-ray diffraction. Results are reported to Windsor Minerals.
- 1B. Quarterly composite samples of above silo samples will be evaluated by TM 7024 by CPI and data reported to Windsor Minerals.
2. Certificates of Analysis are received from Windsor Minerals with each pre-shipment microbial sample. Analytical testing frequencies.
 - a. Tested on silo composite after each silo is filled.
 - b. Tested in two hour composite samples. Each silo is released on the average result of all the two hour composite sample results.
3. Microbial
 - a. Microbial testing performed on flash dried samples taken as the silo is being filled to represent a stratified sampling of at least 30 samples. (Royston is used as the testing lab.)
 - b. Microbial testing will be conducted on the pre-shipment composite sample of each railcar taken as per SOP-B30.

NOTE: TM7807 using only 1 gram for Aerobic Microorganism Enrichment Diagnostic testing.

J&J-0023852

Johnson & Johnson
CONSUMER PRODUCTS, INC.

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SPEC NO: RM08006

DOC TYPE: RAW MATERIAL
SUBJECT: CYPRUS WINDSOR MINERALS CORPORATION GRADE 66 TALC
LOCATION: Royston

QUALITY ASSURANCE INFORMATION

1.0 FREQUENCY OF CHARACTERISTICS TO BE TESTED

<u>No.</u>	<u>Characteristic</u>	<u>T.M.</u>	<u>Frequency</u>
2.1	Asbestos(a)	CTFA/J4-1	Per Note 1A
2.1	(b)	TM7024	Per Note 1B
2.2	Moisture	TM7164	Certified per 2a
2.3	Solubility by Acid	TM7165	Certified per 2a
2.4	Magnesite (MgCO ₃)%	TM7171/TM7077/ TM7716	Certified per 2b
2.5	Bulk Density	TM7166	Certified per 2b
2.6	Color	TM7170 or TM7071	Certified per 2b
2.7	Fineness	TM7167 or TM7070	Certified per 2b
2.8	Heavy Metals	TM7168	Certified per 2a
2.9	Arsenic	TM7169 or TM7717	Certified per 2a
2.10	Water Soluble Iron	USP	Certified per 2a
2.11	Microbial Requirement	TM7807	Every silo-See 3a Every railcar 3b

NOTE:

- 1A. A composite sample is made from every two completed silos, labeled with silo numbers and production dates and forwarded to JJCPI for x-ray diffraction. Results are reported to Windsor Minerals.
- 1B. Quarterly composite samples of above silo samples will be evaluated by TM7024 by CPI and data reported to Windsor Minerals.
2. Certificates of Analysis are received from Windsor Minerals with each pre-shipment microbial sample. Analytical testing frequencies.
 - a. Tested on silo composite after each silo is filled.
 - b. Tested in 2 hour composite samples. Each silo is released on the average result of all the 2 hour composite sample results.
3. Microbial
 - a. Microbial testing performed on flash dried samples taken as the silo is being filled to represent a stratified sampling of at least 30 samples. (Royston is used as the testing lab.)
 - b. Microbial testing will be conducted on the pre-shipment composite sample of each railcar taken as per SOP-B30.
(NOTE: TM7807 using only 1 gram for Aerobic Microorganism Enrichment Diagnostic testing.)
4. JJCPI acceptable limit on samples taken from railcars or trucks at the receiving point is between 20.5 to 27.0 lb./cu. ft.
5. All tests should be accepted under Certificate of Analysis.

J&J-0023853

Johnson & Johnson

EXHIBIT I

June 28, 1977

SUBJECT: Audit Testing of Windsor 66 Talc for Asbestos

TO: Mr. G. Lee

FROM: Mr. A. Frank

To formalize the audit testing currently performed to ensure the absence of asbestos in Windsor 66 Talc, the following protocol is currently being used:

1) Scope

Windsor 66 talc is manufactured from a previously approved mine site known to contain an acceptable cosmetic grade talc ore which has been tested by and has met the requirements for detectable asbestos by the test methods and sampling plan described below. Windsor Minerals will assure mine site evaluation data to include analysis of diamond drill core samples, and deposit testing of composite ore samples removed from the mine site during the development phase prior to production of cosmetic talc to be used for JOHNSON'S* Baby Powder.

Asbestos is defined to be the fibrous serpentine, chrysotile and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite asbestos and actinolite.

2) Testing Requirements

<u>CHARACTERISTIC</u>	<u>TEST METHOD</u>	<u>REQUIREMENT</u>
Fibrous Amphibole Forms	CTFA J4-1	None detected
Serpentine Forms (Chrysotile)	TM 7019	None detected
Asbestiform Minerals (fibrous forms) (Transmission Electron Microscopy)	TM 7024	None detected

-continued-

22-213

J&J-0086339

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3) Testing Procedure/Frequency

The following sample types are tested on an audit basis according to the test procedures and frequencies noted.

<u>SAMPLE TYPE</u>	<u>TESTS</u>	<u>FREQUENCY</u>
Raymond Grind	TM 7024	bi-weekly composite sample
Flash Dried Talc	CTFA J4-1 TM 7019	weekly composite samples
Finished Talc	TM 7024	quarterly audit of random sample



A. M. Frank

AMF:eap

cc: H. Cohen
L. Orlando
J. Runnells

J&J-0086340

MEMORANDUM

TO: Dick Wiles, John Shipp
FROM: Lenore McKenna
DATED: 10/16/97
RE: Coker v. Johnson & Johnson
54.2121
Mesothelioma/Talc Medical Research

According to the literature, most of the research done on mesothelioma closely links it to exposure to asbestos. However, mesothelioma was inducible in rats by intrapleural inoculation of nonasbestos fibrous materials such as synthetic aluminium silicate (ceramic fibers), fibrous glass and aramid. Although most patients with mesothelioma have had occupational exposure, spontaneous mesotheliomas do occur. (1) Since mesothelioma is considered to be closely related to exposure to asbestos, mortality from mesothelioma can be taken as an index of past exposure to asbestos in the population. (Lancet 1995 Mar 4;345(8949):535-9.). In fact, the incidence of mesothelioma in populations unexposed to asbestos is only 1-2 per million. (2)

Mesothelioma is usually malignant although it may be benign. Benign mesotheliomas are less frequent than malignant ones and they are not associated with asbestos exposure. (3) About 2/3 of all benign mesotheliomas occur in females. (3)

The majority of mesotheliomas are located in the pleura. (1) One study found that 72% of mesotheliomas were located in the pleura, 13% in the peritoneum and 11% in the lung. (1) This study also found that smoking was more prevalent in patients with mesothelioma of the peritoneum and lung compared with patients with mesothelioma of the pleura. (1)

Asbestos is divided into two main classes: the serpentines (chrysotile) and the amphiboles (crocidolite, amosite, anthophyllite, tremolite and actinolite). (2) The association between asbestos and both pleural and peritoneal mesothelioma has clearly been established since the 1960's. (2) Still, mesothelioma is an uncommon disease, even among asbestos-exposed populations. (2)

The carcinogenic effects of asbestos are related to the physical properties of size and shape of the fibers, and to their quantity. (2) In order for the fibers to cause mesothelioma, they must be less than 0.25 um in diameter and more than 5 um in length. (2) If the fiber is larger than 0.5 um in diameter and shorter than 5 um in length, then such fibers are not going to

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produce mesotheliomas. (1) It must be remembered that there is also a natural incidence of mesotheliomas of the pleura and the peritoneum in both humans and experimental animals. (1)

Some researchers have argued that it is only in very large quantities that chrysotile causes mesothelioma, however, others have suggested that it is only the amphibole contaminant in chrysotile (such as the tremolite in Canadian chrysotile deposits) that causes mesothelioma and that chrysotile itself is relatively harmless. (2) Still others have reached different conclusions. (2) The most recent literature suggests that uncontaminated chrysotile fibers will not cause mesotheliomas (although most chrysotile is contaminated with tremolite). (1)

In all occupationally exposed studies of mesotheliomas, none have occurred in patients where amphibole asbestos has never been used or detected. (2) Chrysotile asbestos has not been directly implicated in any cases of peritoneal mesothelioma although there is good evidence from lung studies that chrysotile alone can cause mesothelioma. (2) It is generally accepted that the numbers and length of fibers are much more relevant to the development of mesothelioma than particle counts or total dust collection levels. (2)

The relationship between exposure to asbestos and incidence of mesothelioma is uncertain, but there is a positive correlation between the dose of asbestos and the probability of contracting mesothelioma. (2) However, there have been isolated cases of mesothelioma in people whose only exposure appears to have been from buildings with asbestos insulation. (2)

Most reports of patients with mesothelioma contain a proportion of patients with no documented exposure to asbestos. However, later analysis of fiber counts in the patients' lungs showed the histories to be inaccurate. (2) Some mesotheliomas do occur in the absence of detectable fibers in the lungs and there are causes of mesothelioma other than asbestos. (2) That mesothelioma can be caused by nonoccupational exposure to mineral fibers is not in doubt and the highest documented incidence of mesothelioma in the world is in Karain in Turkey where naturally occurring erionite, a fibrous zeolite, has been used in building. (1) In addition, communities built around natural sources of tremolite have experienced incidence of the disease through nonoccupational exposure. (1) Erionite is considered the most potent mesothelioma producer followed by tremolite. (2) Although tremolite is a cause of mesothelioma, testing in animals has revealed that it was only the very fine tremolite (longer than 8.0 um and smaller than 0.25 um in diameter) that caused mesotheliomas. (1)

Mesothelioma may occur after brief or indirect exposure to asbestos. (2) Some studies have shown a longer latency period for peritoneal rather than pleural mesothelioma although others

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have shown no difference. (2) In most reports, pleural mesothelioma remains the most prevalent with the pleural to peritoneal ratio at 3:1. (2) The high rate of peritoneal mesothelioma among insulation workers should be looked on as the exception. (2) An hereditary predisposition to mesothelioma has been suggested although most clustering of mesothelioma are linked to exposure to asbestos in the home. (2) Rare cases of mesothelioma may be related to therapeutic radiation or chronic pleuritis and fibrosis. (2)

Even with today's technology, there are still enormous problems in estimating actual levels of environmental exposure to asbestos.

Talc

Some studies made between asbestos and other fibers such as glass fibers, calcium phosphate, talc and kaolin show that they have similar effects to asbestos, but yet are not carcinogenic in humans. (2) However, in several mesothelioma patients studied, both talc fibers and tremolite were detected. (2) In fact, the majority of asbestos bodies isolated from the lungs of women in the general population have tremolite or anthophyllite and because tremolite and anthophyllite are known contaminants of talc, this data suggests that rare cases of mesothelioma among women with no other identifiable exposure might be related to exposure to cosmetic talc. ((2) at p. 215).

Possible Environmental Exposure to Asbestos

Environmental factors must be given the major consideration in the incidence of Mesothelioma. (1)

1. Cigarette manufacturers who used crocidolite for making filter-tips had extremely high cancer rates
2. Rochdale Textile Workers
3. Ontario Cement manufacturers
4. American insulations workers
5. Naval dockyard workers
6. Wittenoon crocidolite workers
7. Inhabitants of Karain, Turkey (erionite in local environment)
8. Asbestos
9. Household contact with asbestos workers
10. Living in the neighborhood of asbestos mines and factories (especially: Wittenoon, East London, Bohlig, Hain, Hamburg)
11. Areas with naturally occurring asbestos or asbestos-like deposits
12. Railroad workers
13. Manual laborers (plumbers, carpenters, electricians)
14. Vermiculite miners
15. Talc miners (tremolite asbestos is a known contaminant of some deposits of talc)
16. Mines in Turkey, Cyprus and Quebec

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17. Auto mechanics (especially break repair)
18. School teachers (exposed to ceiling and pipe insulation over many years)

Some letters to the various journals also indicate that the following may be risk factors for the development of Mesothelioma:

1. Exposure to asbestos in dental practice (Lancet Vol 338, p. 696)
2. Clustering of Peritoneal Mesothelioma in the Midlands, UK (Lancet 1995 Jan 7;345:66-7)
3. Tremolite containing white-wash (Lancet 1987 Apr 25;1:965-7)
4. Diapers contaminated with asbestos (Lancet 1989 Apr 22;1:909-10)
5. Mesothelioma among sugar refinery workers (Lancet 1983 Dec 24-31;2:1503)
6. Chlorinated phenols (Lancet 1981 Jul 4;2:40)
7. Prenatal exposure to isoniazid (a medication) (Lancet 1980 Aug 16;2:362)
8. Mesothelioma among shoeworkers (Lancet 1980 Feb 2;1:259)

Other Possible Causes of Mesothelioma

1. Chronic inflammation and old pleural scars (may only be a risk for pleural mesothelioma)
2. Radiation treatment of Wilms' tumor in childhood
3. Erionite (a fibrous zeolite) used in building, especially in Karain in Turkey.(1)

Signs and Symptoms and Prognosis

Peritoneal mesothelioma usually presents late with dull pain, abdominal swelling, weight loss and ascites. (1) The outlook of malignant mesothelioma is poor with few patients living for 2 years; the time from diagnosis to death is usually about 6 months. (1) No chemotherapy has been of value and treatment remains symptomatic.(1)

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1. The Mesothelial Cell and Mesothelioma, edited by Marie-Claude Jaurand, Jean Bignon, 1994
2. Malignant Mesothelioma, edited by Douglas W. Henderson, Keith B. Shilkin, Suzanne Le P. Langlois, Darrel Whitaker, 1992
3. Mesothelioma: Diagnosis and Management, edited by C. Frederick Kittle, 1987
4. Longo, D.L., Young, R.C.: Cosmetic Talc and Ovarian Cancer. Lancet 1979 Aug 18;2(8138):349-51
5. Philippe Chahinian, M.D., et al: Diffuse Malignant Mesothelioma. Ann Intern Med 1982 Jun;96(6 Pt 1):746-55

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RoA_20829

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
1	10/6/48	US Public Health Service	Vermont	ASBESTOS	1
2	10/15/57	J&J Hired Lab (Battelle)	Italian	Amphiboles	2
3	5/9/58	J&J Hired Lab (Battelle)	Italian	Tremolite 24 samples	26
4	5/23/58	J&J Hired Lab (Battelle)	Italian	Tremolite 30 samples	56
5	7/31/59	J&J Hired Lab (Battelle)	Italian	Tremolite 63 samples	119
6	8/31/59	J&J Hired Lab (Battelle)	Italian	Tremolite 4 samples	123
7	9/15/59	J&J Hired Lab (Battelle)	Italian	Tremolite	124
8	12/31/59	J&J Hired Lab (Battelle)	Italian	Tremolite 25 samples	149
9	1/31/60	J&J Hired Lab (Battelle)	Italian	Tremolite 44 samples	193
10	3/8/60	J&J Hired Lab (Battelle)	Italian	Tremolite 7 samples	200
11	3/8/60	J&J Hired Lab (Battelle)	J&J Baby Powder	Tremolite	200
12	4/12/60	J&J Hired Lab (Battelle)	Italian	Tremolite 20 samples	220
13	6/6/61	J&J Hired Lab (Battelle)	Vermont	Altered Amphiboles (at least 2 samples)	222
14	8/25/61	J&J Hired Lab (Battelle)	Vermont	Amphibole - altered amphiboles 3 samples	225

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
15	10/13/61	J&J Hired Lab (Battelle)	J&J Baby Powder Standard	Tremolite & Amphiboles "usual contaminants" Trace amphiboles are part of J&J standard for Johnson's Baby Powder	225
16	5/27/63	J&J Hired Lab (Battelle)	Vermont	Amphibole	226
17	3/1964	Schimmel Briefs	Italian	"Tremolite is a mineral of fibrous character which is often present in talc." Tremolite is often an impurity in Italian talc.	226
18	4/7/66	J&J Hired Lab (Battelle)	Vermont	Serpentine Altered Amphibole	227
19	7/13/66	J&J	Johnson's Baby Powder	Tremolite	229
20	1/30/67	J&J	Competitor baby powder Italian Talc Vermont Talc	Tremolite Fibrous	230
21	11/1/67	J&J	Vermont Italian	Tremolite - 3 samples Serpentine - 2 samples	233
22	1/24/68	J&J Hired Lab (Battelle)	Italian	Tremolite 6 samples	239
23	12/4/70	J&J Hired Lab (Colorado School of Mines)	Vermont	Tremolite-Actinolite 8 samples	247
24	4/14/71	J&J Hired Lab (Colorado School of Mines)	Vermont Product Sample	Tremolite-Actinolite Needles 2 samples	249
25	5/14/71	Internal testing by Dr. Ashton	Johnson's Baby Powder (Lot 344-L) Vermont	ASBESTOS Tremolite-Actinolite Needles	250
26	6/30/71	J&J Hired Lab (Colorado School of Mines)	Johnson's Baby Powder (Lot 344-L) Vermont	ASBESTOS Tremolite-Actinolite	251

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
27	7/7/71	J&J Hired Lab (Colorado School of Mines)	Vermont	Tremolite/Actinolite 6 samples	257
28	7/8/71	J&J Hired Lab (Colorado School of Mines)	Vermont	Tremolite and Actinolite (less than 1%)	259
29	7/9/71	Mt Sinai (Dr. Langer)	Johnson's Baby Powder	ASBESTOS	260
30	7/23/71	J&J Hired Lab (Colorado School of Mines)	Vermont	Amphiboles	261
31	7/29/71	J&J letter Subject: Talc/Asbestos Reports testing from Colorado School of Mines (344-L)	Vermont	Tremolite/Actinolite Fibrous Minerals	262
32	8/6/71	J&J letter	Italian	Tremolite Actinolite Chrysotile	263
33	8/9/71	J&J letter	Johnson's Baby Powder	Fines in baby powder implicated in asbestos toxicology	264
34	8/9/71	J&J Admission	Johnson's Baby Powder	"It would seem more than appropriate that we upgrade the quality control on our talc and baby powder, particularly as to the potential asbestos content."	264
35	9/3/71	J&J Hired Lab (McCrone)	Johnson's Medicated Powder & Johnson's Shower to Shower	ASBESTOS Chrysotile	266
36	10/12/71	J&J Hired Lab "looking at problems of talc & asbestos minerals" (McCrone)	Johnson's Shower-to-Shower	Chrysotile	267
37	10/21/71	J&J Hired Lab (McCrone)	Vermont	Chrysotile suspected Substantial similarity to the morphology of Chrysotile Several Fibers	270

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
38	11/10/71	Letter from Mt Sinai to J&J	Johnson's Baby Powder	ASBESTOS	271
39	1972	J&J admission + external lab confirmation	Johnson's Baby Powder	Tremolite repeatedly seen "This is not new"	273
40	1/1972	Article J&J Files	Johnson's Baby Powder	ASBESTOS	274
41	2/16/72	Turin Polytechnic	Italian	Asbestos minerals	275
42	4/27/72	NIOSH	Johnson's Baby Powder and Johnson's Medicated Powder	Fiber Count performed in standard manner used for asbestos samples 10,000s fibers per Mg. 2 samples	277
43	6/12/72	Outside ES Laboratories	Italian	ASBESTOS	278
44	8/3/72	FDA Testing Dr. Lewin - NYU	Johnson's Shower-to-Shower	ASBESTOS	279
45	8/9/1972 - 8/10/1972	Johnson & Johnson Internal Testing of FDA samples	Johnson's Shower-to-Shower	Tremolite Rods 4 samples	283
46	8/18/72	Letter from a Company (EMTAL) J&J bought	Vermont	ASBESTOS	287
47	8/24/72	J&J Letter Talc/Asbestos Sperry Rand Lab's Results (not hired or paid by J&J)	Shower-to-Shower (FDA/Lewin sample)	ASBESTOS	288
48	8/24/72	J&J Letter Talc/Asbestos J&J Scientist	Johnson's talc products	J&J admits tremolite fibers could be present in J&J Shower to Shower	288
49	8/31/72	Outside Lab (Sperry Rand) Expertise in examining Chrysotile Asbestos	Shower-to-Shower (FDA/Lewin sample)	Chrysotile fibers multiple fibers of chrysotile - provided J&J photographs of the fibers	289
50	9/5/72	Testing from a talc competitor to a Company (EMTAL) J&J bought	Vermont	Tremolite fibers	291
51	9/25/72	Johnson & Johnson Memo Asbestos in Talc Shower-to-Shower/Asbestos	Italian Mine	Tremolite	292
52	9/26/72	Dr. Lewin	Johnson's Baby Powder + Medicated Power + Shower to Shower	Over half the samples sold in J&J's cosmetic products were industrial grade talc	292
53	9/30/72	New York University	Italian Talc	Tremolite & Chrysotile	293
54	10/19/72	NYU (Lewin)	Johnson's Baby Powder Shower to Shower	Chrysotile & Tremolite	299

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
55	10/27/72	J&J Hired Lab (McCrone)	Johnson's Baby Powder (re-testing samples FDA/Lewin tested)	Tremolite Rods 2 samples 0.2 or .3% tremolite in sample 109T 0.5% tremolite in sample 108T	301
56	Nov 1972	J&J Hired Lab (University of Minnesota)	Johnson's Baby Powder + Shower to Shower (re-testing samples FDA/Lewin tested)	ASBESTOS 2 samples	303
57	2/26/73	J&J Hired Lab (Colorado School of Mines)	5 Talc Samples	Tremolite-Actinolite Anthophyllite Serpentine which may be chrysotile	306
58	3/14/73	J&J Mine	Vermont	Tremolite	308
59	4/2/73	J&J	Vermont	Chrysotile	309
60	4/6/73	Member of J&J industry group (Avon)	Italian Talc	1% Tremolite	310
61	4/17/73	Avon	Chinese	1-2% Tremolite ASBESTOS	311
62	4/19/73	J&J testing	Johnson's Baby Powder	Tremolite Fibers 4 samples	315
63	4/26/73	J&J Admissions	Johnson's Baby Powder	ASBESTOS repeatedly found in baby powder	317
64	4/27/73	Analysis of Johnson's Baby Powder	Johnson's Baby Powder (Lot 285-S, Lot 397-R, Lot 068-Z, Lot 086-Z)	Tremolite/Actinolite parallel sided rods .01-.001% by weight	321
65	4/30/73	Talco e Grafite (Dr. Stefano)	Italian	ASBESTOS 0.02%	322
66	5/1/73	J&J Admission	Vermont	Actinolite	323
67	5/8/73	J&J Admission	Vermont	Actinolite	325
68	5/16/73	Proposed Specs for Analyzing Talc for Asbestos (Pooley Method)	Vermont	ASBESTOS 0.05%	326
69	5/25/73	Testing from a talc competitor to a Company (Engelhard) that mined Vermont Talc	Vermont	ASBESTOS	330
70	6/4/73	J&J Admissions	Vermont	Tremolite	330

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
71	6/12/73	Testing from a talc competitor to a Company (EMTAL) J&J bought	Vermont	ASBESTOS	334
72	7/31/73	FDA	Johnson & Johnson Consumer Talc products	Tremolite + a question about Chrysotile	336
73	8/28/73	Johns-Manville - another company's internal testing	Italian and Vermont	Chrysotile + suspect Tremolite	338
74	8/28/73	Johns-Manville - another company's internal testing	Johnson's Baby Powder	Chrysotile	339
75	9/4/73	Johns-Manville - another company's internal testing	Italian	Chrysotile 1880 f/mg	340
76	9/6/73	FDA (Stuart) Asbestos and other contaminants in talc	Johnson's Shower-to-Shower	Tremolite/Actinolite	341
77	9/13/73	J&J Consultant Dr. Pooley	Vermont	Actinolite	342
78	9/13/73	J&J Consultant Dr. Pooley	Italian	Tremolite	343
79	9/14/73	McCrone	Italian	ASBESTOS 0.1-2%	345
80	9/14/73	Columbia University	Italian	ASBESTOS 0.1-2%	347
81	10/29/73	Outside lab (not hired by J&J) Hazen Research, Inc.	Johnson's Baby Powder	Chrysotile	348
82	10/29/73	Outside lab (not hired by J&J) Hazen Research, Inc.	Italian	"Italian talc has an appreciable chrysotile content"	349
83	11/20/73	NY Lab hired by Talc Supplier - WCD	Italian	Chrysotile fibers (hundreds of thousands of fibers per gram) Amphibole fibers (millions of fibers per gram)	350
84	11/20/73	NY Lab hired by Talc Supplier - WCD	Vermont	Chrysotile fibers (hundreds of thousands of fibers per gram) Amphibole fibers (millions of fibers per gram)	351
85	12/13/73	J&J Letter Re: asbestos in baby powder Outside Testing	Johnson's Baby Powder (Italian)	ASBESTOS 2 samples	353
86	12/27/73	Colorado School of Mines (lab hired by J&J)	Vermont	Chrysotile & Tremolite	357

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
87	1974	NIOSH Sponsored Multi-lab research	Italian	"Commercial talc is generally not monomineralic material, but rather a mixture of mineral phases. Some of these minerals may pose occupational or even consumer risk of disease" Common mineral impurities: Major: Tremolite + Anthophyllite Minor: Actinolite + Chrysotile 4 samples "These minerals are known to have disease potential"	361
88	2/11/1974	J&J Hired Lab (McCrone)	J&J samples	Chrysotile	362
89	3/11/2014	J&J Hired Lab (McCrone)	Talc Sample for Johnson & Johnson Baby Products Co.	Chrysotile	363
90	4/4/74	J&J visit to outside lab - admissions (Colorado School of Mines)	Vermont	Fibrous Tremolite Fibrous Chrysotile Goal: "establish destruction of tremolite in presence of Vermont talc." + "establish destruction of chrysotile in presence of Vermont talc."	365
91	4/24/74	J&J Hired Lab (McCrone)	Vermont	Chrysotile 15 samples	380
92	4/24/74	J&J Hired Lab (McCrone)	Vermont	Amphiboles 4 samples	384
93	5/9/74	J&J Hired Lab (McCrone)	Vermont	Chrysotile fibers 2 samples	386
94	5/14/74	J&J Vermont Mine Confidential findings (McCrone)	Vermont	Chrysotile 4 samples Subject: use of system to attempt to remove chrysotile "The use of these systems is strongly urged by this writer, to provide the protection against what are currently considered to be materials presenting a severe health hazard and are potentially present in all talc ore in use at this time"	390
95	5/14/74	J&J Vermont Mine Confidential findings (Dartmouth College)	Vermont	Amphibole Minerals 8 samples	396
96	5/16/74	J&J Hired Lab (McCrone)	Vermont	ASBESTOS - Chrysotile 2 samples	398

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
97	7/8/74	J&J Hired Lab (McCrone)	Vermont	Chrysotile 6 samples	404
98	7/8/74	J&J Hired Lab (McCrone)	Vermont	ASBESTOS - Tremolite	405
99	7/17/74	J&J external lab (McCrone)	Talc Sample	Chrysotile	406
100	9/24/74	Confidential J&J Letter Re "damaging" talc/asbestos release on Italian talc (Societa Talco e Grafite)	Italian	ASBESTOS - Chrysotile	407
101	10/10/74	J&J Hired Lab (McCrone)	Vermont	Chrysotile Fibers ~ 0.006%	408
102	11/26/74	J&J	Vermont	Tremolite asbestos	409
103	12/9/74	J&J Hired Lab (McCrone)	Johnson & Johnson Baby Powder	ASBESTOS - Chrysotile	410
104	1/31/75	Member of J&J industry group (Avon)	Italian Talc	Tremolite	411
105	2/24/75	J&J Supplier discussing EPA findings	Vermont Talc	"The EPA claims talc from Windsor Minerals, obtained from various manufacturing plants, contains asbestos"	412
106	2/24/75	J&J Supplier's Findings	Vermont Talc	ASBESTOS repeatedly found Tremolite + possible Chrysotile Tremolite was mainly in massive form although "further processing would likely result in additional fibrous tremolite being liberated"	412
107	3/26/75	Member of J&J industry group (Avon)	Italian Talc	Chrysotile	413
108	4/30/75	Member of J&J industry group (Avon)	Italian Talc	Tremolite	414
109	6/11/75	J&J Hired Lab (McCrone)	Talc samples sent by J&J to be tested	Amphibole fibers/bundles 2 samples	416
110	7/1/75	J&J Hired Lab (McCrone)	Vermont	ASBESTOS 9 samples Low and Medium levels of confirmed asbestos	425

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
111	9/9/75	Johnson & Johnson letter Langer's Findings	Johnson's Baby Powder + off-the-shelf talc products	Chrysotile + Amphiboles - tremolite & anthophyllite	426
112	9/9/75	Johnson & Johnson reaction to Langer findings	Johnson's Baby Powder + off-the-shelf talc products	The chrysotile finding contradicts what Dr. Pooley (one scientist) had reported - no claim it contradicts the finding about the tremolite or anthophyllite J&J immediate response: "refute the data" "prepare our strategy"	426
113	9/11/75	J&J Hired Lab (McCrone)	Vermont	Chrysotile	427
114	11/1/75	Competitor's Analysis of Italian Talc	Italian	Fibrous Tremolite 4 samples	431
115	11/5/75	J&J Hired Lab (McCrone)	Vermont	ASBESTOS 13 samples some are "rather high" most are "bundles" of fibers	444
116	11/19/75	J&J Hired Lab (McCrone)	Vermont	ASBESTIFORM - amphiboles 2 samples	446
117	3/1/76	Italian Researchers (Rubino, et al.)	Italian	Tremolite	447
118	3/30/76 - 7/16/92	Pfizer	Italian	Fibers and Bundles of Asbestos 115 samples TEM/SAED Individual samples had from 1 to 150 fibers	562
119	7/5/76	J&J Hired Lab (Colorado School of Mines)	Vermont	Amphibole Needles	564
120	2/23/77	Testing from Vermont Mining Company	Vermont	ASBESTOS	566
121	4/1/77	Geochemist Report to J&J + Certificate of Microanalysis for Asbestos (EMV Associates)	Talc Samples with new preparation and examination techniques	ASBESTOS - 4 samples "Tremolite is often present" including a bundle Composite sample: "both large and small fibrous tremolite particles found"	570
122	5/1977	NIOSH	J&J Product Vermont	Tremolite-actinolite	571
123	5/24/77	NIOSH	Vermont	Chrysotile	572

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
124	6/27/77	Testing from Vermont Mining Company done by J&J outside lab (McCrone)	Vermont	Asbestos - actinolite	573
125	8/18/77	Testing from Vermont Mining Company	Vermont	Actinolite-tremolite fibers	575
126	12/15/77	Outside Mineralogist for J&J's Vermont Mine Mountain States Research	Vermont	Tremolite-Actinolite long needles 2 samples	577
127	2/20/78	Report on Ore Reserves for Hammondsville Ore Body	Vermont	Actinolite needles	578
128	10/5/78	J&J Hired Lab (McCrone)	Vermont	CHRYSTILE 2 samples	580
129	10/27/78	Testing from Vermont Mining Company	Vermont	Asbestos Type Found in Sample included Chrysotile	581
130	11/14/78	J&J Hired Lab (McCrone)	Vermont	Chrysotile & Tremolite asbestos	582
131	2/1/79	Testing from Vermont Mining Company	Vermont	chrysotile	583
132	2/9/79	DOC Analytical Research Quality Control for Vermont Talc	Vermont	"found massive amphiboles" specifically Tremolite + Actinolite Samples may be "indicative of a coming problem"	584
133	3/23/79	Testing from Vermont Mining Company	Vermont	ASBESTOS	586
134	4/11/79	Testing from Vermont Mining Company	Vermont	ASBESTOS	586
135	4/30/79	Testing from Vermont Mining Company done by J&J outside lab (McCrone)	Vermont	Chrysotile 0.1%- 1% range of sample	587
136	5/17/79	Vermont Mining Company admission	Vermont	Vermont Talc: "Asbestos fiber is present."	587
137	5/22/79	Testing from Vermont Mining Company	Vermont	Chrysotile	591
138	7/17/79	Testing from Vermont Mining Company	Vermont	Asbestos	594
139	9/29/80	J&J Admission + external lab confirmation (McCrone)	Vermont	Chrysotile	595

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
140	11/6/80	J&J external lab (McCrone)	Vermont	ASBESTOS - Chrysotile	596
141	3/11/82	Testing from Vermont Mining Company	Vermont	Asbestos	598
142	8/24/82	Mine Safety and Health Administration	Exposures to asbestos at the South Plainfield Mill (Italian)	ASBESTOS 14 samples	612
143	2/24/84	J&J Hired Lab (McCrone)	Composite Sample	ASBESTOS - Chrysotile 2 grids	614
144	5/15/84	Mine Safety and Health Administration	Air filter samples South Plainfield Mill (Italian)	ASBESTOS - Anthophyllite ~0.6% by weight	619
145	9/26/84	J&J letter Subject: Talc Asbestos Findings by Paoletti published by reputable organization in Italy + Paoletti article	Italian	ASBESTOS - Chrysotile 1 sample	620
146	9/26/84	J&J letter Subject: Talc Asbestos Findings by Paoletti published by reputable organization in Italy + Paoletti article	Italian	ASBESTOS - Tremolite 7 samples	627
147	11/2/84	J&J Hired Lab (McCrone)	Air filter samples	ASBESTOS - Chrysotile 4 sample	631
148	2/26/85	J&J	Chinese	Sample of Cosmetic Grade Talc Results "Asbestiforms Positive"	632
149	8/22/85	J&J Hired Lab (McCrone)	California	ASBESTOS - Chrysotile 2 samples Multiple asbestos fibers seen and counted. J&J to complain about the lab's failure to use "substantially different language" and "couch" results as in earlier reports. Report changed to claim testing "did not find any quantifiable amount of asbestiform minerals in any samples."	632
150	11/18/85	American Chemical Society (from J&J internal files)	Italian	Fibrous Amphiboles/Tremolite	633
151	1/30/87	Johnson & Johnson	Vermont + Johnson's Baby Powder	Amphiboles	634
152	3/30/87	Johnson & Johnson	Vermont	Amphiboles 23 samples	657

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
153	7/1/87	ES Labs	Vermont	Talc Analysis (ASBESTOS) Tremolite Less than 90% talc	658
154	10/1/87	Johnson & Johnson	Vermont	Hammondsville and Rainbow mines found Amphiboles 4 samples	662
155	3/14/88	J&J Hired Lab (RJ Lee)	Johnson's Baby Powder using Chinese Talc	Chrysotile: .0024% by weight Fibrous tremolite: .014% tremolite by weight	663
156	4/15/88	Skyline Laboratories	Vermont	Actinolite	665
157	10/13/88	Windsor Minerals (J&J's talc mine)	Vermont	Sub-trace Amphiboles found - passes industry standards	666
158	5/23/89	J&J Hired Lab (RJ Lee)	Talc Sample for Johnson & Johnson Baby Products Co.	Chrysotile	667
159	11/26/90	J&J Hired Lab (McCrone)	Talc Samples sent to Quality Control Manager for Vermont Mine	Anthophyllite fiber + Chrysotile fiber 2 samples Results verified in Bench sheets but claim "no quantifiable amounts of asbestiform minerals"	669
160	11/30/90	J&J Hired Lab (McCrone)	Talc Samples sent to J&J Consumer Products	Using Johnson & Johnson's Test Method 7024 No asbestos minerals were identified in the samples Bench sheet shows Anthophyllite Talc Fiber	670
161	1991	Peer Reviewed Published Paper (Dr. Alice Blount)	Johnson & Johnson's Vermont talc	(PUBLIC - Published Paper): Amphibole fibers are labeled either "needles" or "fibers" depending on how long they are but all are regulatory fibers (3:1 aspect ratio or larger) Sample i - both needles & fibers of amphiboles (KNOWN TO J&J - NOT IN THE PAPER) Sample i is Johnson & Johnson's Vermont talc	675
162	1991	Peer Reviewed Published Paper (Dr. Alice Blount)	Italian consumer-grade talc	(PUBLIC - Published Paper): Amphibole fibers are labeled either "needles" or "fibers" depending on how long they are but all are regulatory fibers (3:1 aspect ratio or larger) Sample h - found asbestos: needles of amphiboles (KNOWN TO J&J - NOT IN THE PAPER) Sample h is Italian Cosmetic-Grade talc	676
163	3/5/91	Microscopic Analysis for Amphiboles & Chrysotile	Vermont	Actinolite fibers 16 times	692
164	3/5/91	Microscopic Analysis for Amphiboles & Chrysotile	Vermont	Tremolite fibers	693

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
165	1/29/92	Johnson & Johnson's Talc Supplier (Cyprus Industrial Minerals)	Vermont	AMPHIBOLES 6 samples <0.1% to 2.3% by weight	699
166	2/10/92	J&J hired consultant (Dr. Alice Blount)	Johnson's Baby Powder	Industrial Hygenist reports all talc contains asbestos "individual deposits, the shape distribution and quantity [of asbestos] remains fairly constant over time"	699
167	3/25/92	Johnson & Johnson's Talc Supplier (Cyprus Industrial Minerals)	Vermont	"The other serious mineralogical contaminant in the talc ores of Vermont is the fibrous variety of the amphibole minerals, tremolite and actinolite... which has been classified as asbestiform minerals by OSHA and EPA." Visible tremolite and actinolite in deposits used for cosmetic talc - Hammondsville and Argonaut	701
168	4/1992	J&J Supplier's Findings	Vermont	Fibrous Tremolite & Actinolite minerals are ubiquitous and are deleterious minerals	703
169	5/21/92	Johnson & Johnson's Talc Supplier (Cyprus Industrial Minerals)	Vermont	Fibrous amphiboles (actinolite) dikes extending in places into the contacting talc ores	704
170	9/92	J&J supplier (Luzenac)	Vermont	Ore characterization for Argonaut Vermont Mine Ore destination includes cosmetics. Associated minerals include actinolite, which is listed as a detrimental mineral	704
171	11/4/92	J&J supplier (Luzenac)	Vermont	Actinolite (needles and blades) are known impurities present in all relevant Vermont deposits and while some locations are known to be avoided "it is impossible to get rid of accidental traces."	704
172	10/13/95	J&J Hired Lab (RJ Lee)	Johnson's Baby Powder	Tremolite	705
173	3/26/96	Johnson & Johnson testing information from its supplier	Composite sample from Vermont	Amphibole	706
174	12/4/97	Johnson & Johnson's Talc Supplier testing w/ an outside lab (Bain Environmental)	Vermont	Chrysotile	707

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
175	3/16/98	Geologist and Mineralogist hired by J&J	Johnson's Baby Powder	Dr. Blount has "written extensively on talc and asbestos contamination in commercial talc preparations." "In her opinion, commercial talcum powder preparations including Johnson & Johnson Baby Powder, contain trace amount of asbestos."	707
176	12/4/00	Johnson & Johnson's Talc Supplier testing w/ an outside lab (Bain Environmental)	Vermont	Asbestos Analysis had a "hit" of asbestos in monthly floated composite talc sample	708
177	11/2001-7/9/2005	Talc Supplier (Rio Tinto lab/Imerys)	Chinese	Chrysotile Estimate of 151 million fibers per gram + Amphibole asbestos near or in Chinese ore bodies	711
178	5/23/02	Johnson & Johnson's Talc Supplier's testing	Vermont	Fibrous Tremolite in waste rock in Argonaut mine	712
179	3/31/03	Johnson & Johnson's Talc Supplier's testing	Vermont	4% Tremolite in the Argonaut mine	713
180	1/5/04	Forensic Analytical (outside lab)	Johnson's Baby Powder	ASBESTOS - anthophyllite 0.20% by weight	714
181	2/26/04	Johnson & Johnson's Talc Supplier's testing	Vermont	Quarterly Composite Testing on Vermont Talc Summary Report for 2003 Found asbestos each quarter reported	717
182	2/26/04	Johnson & Johnson's Talc Supplier's testing	Vermont	Quarterly Composite Testing on Vermont Talc Summary Report for 2001 Found asbestos each quarter reported	720
183	2/27/04	Johnson & Johnson's Talc Supplier's testing	Vermont	Quarterly Composite Testing on Vermont Talc Summary Report for 2002 Found asbestos each quarter reported	724
184	3/11/04	Johnson & Johnson's Talc Supplier's testing	Vermont	Chrysotile 4 samples	728
185	4/10/08	Talc Supplier (Rio Tinto Minerals)	Chinese	"1/3 of Chinese production has some asbestos contamination." "Purchase of finished product from China now carries serious risk of asbestiform contamination."	728
186	4/29/08	Talc Supplier (Rio Tinto Minerals)	Vermont	Asbestiform tremolite-actinolite Argonaut Mine	729

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
187	4/3/09	Talc Supplier reporting findings from the Korean Food and Drug Administration	Chinese	Asbestos found in baby powders using Chinese talc.	739
188	5/14/09	J&J Admission	Chinese	ASBESTOS	740
189	5/15/09	J&J reporting on Chinese Authorities	J&J Talc	ASBESTOS	741
190	2/1/10	J&J supplier (Luzenac/Imerys)	Talc Ore Minerology for Chinese Cosmetic Talc	up to 5% tremolite + trace serpentine Talc is a "main ingredient of baby, body and foot powders (mainly a second and third world business) Sorting and floatation cannot eliminate fibrous minerals from talc	741
191	11/2/11	J&J	Chinese	Decline in high grade talc deposits in China "High-asbestos content in talc deposits/mines of China has also led to quality concerns from clients in cosmetic and pharmaceutical sectors"	741
192	2014	Peer Reviewed Published Paper (Gordon, et. al)	Italian North Carolina Montana	ASBESTOS anthophyllite, tremolite + chrysotile 50 samples 1,840 - 1,104,000 fibers per gram Air monitoring: 1.9 f/cc when using a talc bottle	791
193	5/22/14	Scientific Analytical Institute (Litigation Report)	Italian	Grade 1615 is from Val Chisone Italy in Piedmont. Geologically the talc formed from amphiboles. Labs testing confirmed ASBESTOS Anthophyllite, Tremolite + Chrysotile Asbestos	792
194	8/1/17	MVA Scientific (Litigation Report)	Italian	Lab reviewed 13 Italian samples collected by A. Segrave (expert used by mine owner) Asbestos anthophyllite + tremolite/actinolite 11 samples (85% of the samples) 0.00002% - 0.68% by weight 1.7 - 600 million fibers per gram	803

Decades of Evidence of Asbestos Content in Johnson & Johnson Products

Number	Date	Source of Information	What Was Evaluated	Results	Tally
195	2/2018-9/2021	Material Analytical Services (Litigation Report)	Johnson's Baby Powder + Shower to Shower (Vermont, Italian & Chinese)	ASBESTOS - Tremolite (Richterite), Actinolite + Anthophyllite 7,160-15.1 million fibers per gram 96 Samples	899
196	4/6/18	RJ Lee Litigation Report	Vermont	ASBESTOS - Chrysotile 2 samples	901
197	4/23/18	MVA Scientific (Litigation Report)	Vermont	Reviewed 15 samples collected by Mickey Gunter/RJ Lee from Argonaut mine in Vermont ASBESTOS anthophyllite + tremolite/actinolite 10 samples (67% of the samples) 0.00009% - 4.5% by weight 1.16 - 2,585 million fibers per gram	911
198	7/18/18	J3 Resources (Litigation report)	Johnson's Shower-to-Shower	ASBESTOS - Anthophyllite 11 samples (69% of the samples) 7,419 - 95,321 fibers/bundles per gram concentration + TEM	922
199	1/2019-9/2023	Material Analytical Services (Litigation Report)	Italian (Avon, Chanel, Colgate, Coty, Imerys, and Mennen)	ASBESTOS - Tremolite, Actinolite, Anthophyllite, Chrysotile 77 Samples	999
200	10/11/19	FDA AMA Analytical Services (testing done by an expert J&J recommended and expert)	Johnson's Baby Powder (Chinese)	ASBESTOS - Chrysotile 0.00002%	1000
201	10/29/19	J&J Announcement re lab results from RJ Lee	Johnson's Baby Powder (Chinese)	ASBESTOS 3 samples	1003
202	8/2020-11/2022	Material Analytical Services (Litigation Report)	Chinese (Avon, Chanel, and Imerys)	ASBESTOS - Chrysotile, Tremolite, Actinolite 80 Samples	1083
203	5/6/21	Asbestos TEM Laboratories (Litigation report)	Johnson's Baby Powder	Anthophyllite 52,000,000 fibers/gram	1084
204	5/20/21	Fitzgerald Analytical Consulting & Testing (Litigation report)	Johnson's Baby Powder	Anthophyllite asbestos 58,300,000 structures/gram	1085



Dr. A. J. Goudie
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EXAMINATION
OF
JOHNSON AND JOHNSON'S BABY POWDER

Date: 27 October 1972

MA Number: 2546

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EXAMINATION OF JOHNSON AND JOHNSON'S BABY POWDER

Summary

Two samples of Johnson and Johnson's Baby Powder, batch number 108T and 109T, which correspond to the samples examined by Professor Seymour Z. Lewin of New York University on behalf of the FDA have been examined by x-ray diffraction, light microscopy, transmission electron microscopy and electron diffraction to determine whether they contain any asbestiform minerals.

Both samples contained an insignificant amount of tremolite ($< 0.5\%$). Neither sample contained chrysotile.

Introduction

On behalf of the FDA, Professor Seymour Z. Lewin of New York University is examining a number of commercial talcum powders for the presence of asbestiform minerals. Two of the samples which he has examined are samples of Johnson and Johnson's Baby Powder, batch number 108T and batch number 109T. Johnson and Johnson therefore requested Walter C. McCrone Associates to examine samples from the same batches to determine whether they contained any asbestiform minerals.

Materials and Method of Conducting Tests

Two samples were submitted, identified as Johnson and Johnson's Baby Powder, batch numbers 108T and 109T.

For x-ray diffraction examination, the samples were examined on a Phillips-Norelco verticle diffractometer using $\text{CuK}\alpha$ radiation and a scanning speed of 1° per minute. The dispersion staining technique was used for the light microscopical examination and the electron microscopy-electron diffraction examination was carried out using procedures previously described (MA report 2330-1; dated 10 August 1971).

walter c. mccrone associates, inc.

Results

X-ray Diffraction

The diffractograms were carefully examined in the vicinity of the major peaks of chrysotile and tremolite. Neither mineral was present. The presence of peaks in the vicinity of $12.0-12.5^\circ 2\theta$, the region in which one of the principal lines of chrysotile may be found, was correlated with peaks in the vicinity of $6^\circ 2\theta$ and are thus attributable to chlorites. No significant peaks were observed in the 24° region which would be required were chrysotile present.

Light Microscopy

Using the dispersion staining technique and a liquid of refractive index 1.550, the samples were examined for chrysotile particles and fibers, but none could be found. Using a similar technique with a liquid of refractive index 1.605, the samples were similarly examined for the presence of tremolite and a few individual crystals were found, some rod shaped. The total tremolite content of the two samples would be approximately 0.5% for 108T and about 0.2-0.3% for 109T.

Electron Microscopy and Electron Diffraction

Several electron microscope grids from both samples were examined in their entirety and although some fibers were observed these were shown by electron diffraction to be shards of talc or rolled talc. No chrysotile fibers were found.

Conclusion

A detailed examination of two samples of Johnson and Johnson's Baby Powder, batch numbers 108T and 109T has shown this material to be substantially free of asbestiform minerals. A few tremolite rods were observed in both samples at a level less than 0.5%. No chrysotile has been detected.

Respectfully submitted,

Ian M. Stewart

Ian M. Stewart
Manager, Electron Optics Group

-2- walter c. mccrone associates, inc.

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POWDERS TECHNOLOGIES

BENCHMARK DATA – JOHNSON'S ® Baby Powder

Current Costs (raw material cost only, does not include freight)

- Talc - \$.1185 per pound
- Corn Starch - \$.1785 per pound

Current Formulations

- Johnson's ® Baby Powder – Formula # 777-145-148
 - Windsor 66 Talc – 99.78% (RM08006) Luzenac America, Inc.
 - Fragrance Synfleur J-4270 – 0.22% (RM06032) Bell Flavors and Fragrances
- Johnson's ® Baby Powder Pure Cornstarch with Aloe & Vitamin E – Formula # 8537-5
 - Cornstarch Specially Treated – 99.15% (RM08700) Corn Products Corp
 - Trade Name: Buffalo 348
 - Tribasic Calcium Phosphate, NF – 0.6% (RM07502) Rhone Poulenc
 - Level may be adjusted as needed to achieve desired flow.
 - Fragrance Q-17965 – 0.25% (RM 06105) Quest International
- Johnson's ® Baby Powder Medicated – Formula # 8537-66
 - Cornstarch Specially Treated – 89.75% (RM08700) Corn Products Corp
 - Trade Name: Buffalo 348
 - Zinc Oxide, USP – 10.0 % (RM13017) Zinc Corporation of America
 - Fragrance Q-17965 - 0.25% (RM06105) Quest International

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POWDERS TECHNOLOGIES

Particle Size Requirements

- Body powders pass through a 200 mesh (75 micron) screen.
- Baby powder particle size must be > 5 microns.
- Cornstarch powders generally range from 5 – 26 micron.
- Rice powders generally range from 3-9 micron, so end use as a body powder vs. particle size would need to be assessed.

Key Attributes for Johnson's ® Baby Powder

- Fragrance
 - The most widely recognized fragrance in the world is Johnson's ® Baby Powder.
 - The ideal fragrance character / intensity was the original talc based product packaged in the tin container. This classic fragrance, formulated for the original talc base, remained "fresher" and "of character" longer in the days of the "tin" package.
 - To achieve optimal fragrance character and intensity, perfume oils must be optimized for each substrate, including talc. The exact same perfume oil blended with talcs from different ore bodies will not smell identical.
 - For the North American consumer, the classic Johnson's ® Baby Powder fragrance is synonymous with the Johnson's ® Baby Powder (talc) variant packaged at the Royston production facility.
- Freshness – Dry, Absorbs Wetness
 - Feeling of freshness is end benefit of not only fragrance but:
 - Keeps me dry
 - Keeps me cool
 - Keeps me comfortable
 - Absorbs perspiration
- Softness - Lubricity
 - Feeling of softness is end benefit of not only fragrance but:
 - Skin feels soft
 - Skin is smooth
 - Skin is silky
 - No Friction, No Chafing
 - Clothes go on more easily

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POWDERS TECHNOLOGIES

The Ideal Johnson's ® Baby Powder "Classic" (for North America Consumer)

- Fragrance Character and Intensity to match current Johnson's ® Baby Powder (talc) variant.
- Slip and lubricity minimally to match current Johnson's ® Baby Powder (talc) variant.
- Moisture absorbency minimally to match current Johnson's ® Baby Powder Pure Cornstarch with Aloe & Vitamin E variant.
 - Interest in improving absorbency vs. current.
 - Ideally, particles would not clump or cake after absorbing moisture.
- Maintain current GP's.

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POWDERS TECHNOLOGIES

STRATEGIC THRUST / TECHNICAL APPROACH	POTENTIAL PARTNER(S)	COMMENTS	INTERNAL CONTACT(S)
Improve Feel of Cornstarch Powder			
Modified Starches	National Starch	Confidentiality agreement was in place – need to confirm status.	- Lukenbach (1484) - McCulloch (thru Wiegand)
Enzyme Treated Starches	Corn Products		Lukenbach (1484)
Micronized Wax Additives	Allied		Luizzi (2560)
Encapsulated Starches			
Other	Hercules		
Thermasorb (warming / cooling)			
Improved Absorbency of Cornstarch Powder			
Cornstarch Copolymers	Grain Processing Corporation	Limited Confidentiality-In agreement signed. Sample pending.	Telofski (1821)
Replacement Materials / Combinations – Additives			
Processed Corn Cob			
Tapioca			
Cellulosic Pulps			
- Clays / Synthetic Clays - Laponites - Betonites			- Wiegand (1391) - McCulloch (thru Wiegand)
Diatomaceous Earth			
Acrylic Powders			
Lactose Powders			

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POWDERS TECHNOLOGIES

• Polyethylene Oxide			

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Memorandum

Date June 6, 1985

From QRAC (Quantitative Risk Assessment Committee)

Subject Asbestos in Talc

To W. Gary Flamm, Ph.D.
Director, Office of Toxicological Sciences (HFF-100)

Using Linda Taylor's report [1] and other information on asbestos and talc, we conclude that the added human risk of lung cancer and mesothelioma from possible asbestos in talc is less than 10^{-8} lifetime risk and quite possibly orders of magnitude less. We have used, as our population at risk, infants that may be routinely dusted with talcum powder for an estimated period of 2 years.

Infant Dose and Worker Exposure:

Based upon one experimental 2 yr. exposure scenario for talcum powder dusting, babies would apparently inhale no more than about 6.5×10^3 asbestiform fibers per year (4.95 talc fibers/cc $\times 1000$ cc/l $\times .58$ l/min. breathing rate $\times 43.8$ min/wk powdering $\times 52$ wk/yr. $\times .1\%$ asbestos in talc). The asbestiform fibers are difficult to detect, poorly defined in shape, and of a highly variable subtype. We assume .1% tremolite or anthophyllite asbestos in talc based on 1977 FDA measurements and other recent samples [1, 10, 11]. To be called asbestiform fibers, the fibrous silicates must be greater than 5 μ m. and have length/width ratio greater than 3. These inherent detection and geometrical measurement limitations for asbestos in talc make comparisons with worker exposure to a different type (mainly amosite, crocidolite and chrysotile) and shape of asbestos highly problematical [5]. In fact there is a

general consensus that current talc mines are virtually free of asbestos (offending mines have gradually been abandoned) and that any residual silicates in talc are so finely and smoothly ground as to represent virtually no risk to humans whatsoever even where an occasional fiber just barely satisfies the technical definition for asbestiform fibers. However, this consensus belief would require better geometric measurements than currently exist for both current commercial talc fibers and for workplace asbestos fibers during the past 50 years. Nevertheless, baby exposure in fibers per year is crudely estimated at about 0.3×10^{-6} times that of worker exposure in several well known epidemiological studies (e.g., Selikoff study: 15 f/ml in workplace $\times 12,000 \text{ ml/min}$ breathing rate $\times 60 \text{ min/hr} \times 8 \text{ hr/day} \times 5 \text{ days/wk} \times 50 \text{ wks./yr.} = 2.16 \times 10^{10} \text{ f/yr.}$ vs $6.5 \times 10^3 \text{ f/yr}$ for baby) [1].

A complicating factor, however, is that human cancer risk from these studies seems to follow different time-dose response patterns for the two main cancer endpoints (lung cancer and mesothelioma). Although several human epidemiological studies exist which could be utilized for quantitative risk assessment purposes, it is most illustrative to consider the largest of these occupational studies, namely, that of Selikoff, et. al. [7,8] in which 17,800 insulation workers were exposed to a mixed variety of asbestos fibers (mainly amosite and chrysotile) for about 25 years on average. Through 1976, 2,271 deaths (12.7% of total) had occurred.

Lung Cancer:

Lung cancer rates were about 4.6 times average (486 observed/106 expected). Since this nearly 360% excess lung tumor

rate seems to apply to nonsmokers alone as well as smokers and nonsmokers combined [6], then, assuming hypothetically that one can extend excess relative risks to very low asbestos exposures, one would expect to see an excess lifetime lung tumor rate among asbestos exposed nonsmokers of about 1.8% ($360\% \times$ the normal lifetime nonsmoker lung tumor rate of about .5% - integrating 1979 survival rates against Garfinkel's 1960-1972 nonsmoker age-specific lung tumor rates [12, 13]). Excess lung cancer rates appear to be proportional to dose and duration of exposure, but not to some high power of time-since-first-asbestos exposure [6]. Thus, excess lifetime lung cancer risk for talc exposed babies who will never smoke would appear to be approximately the product of 1) an excess 1.8% lifetime risk for nonsmoking asbestos exposed workers, 2) a baby/worker yearly exposure ratio of 0.3×10^{-6} , and 3) a baby/worker exposure duration ratio of 2 yrs/25 yrs. This product yields a value of $.4 \times 10^{-9}$ added lifetime risk for lung tumors. Similarly, averaging eventual smokers in with the lifelong nonsmokers assumed above, the average added lifetime lung cancer risk for the talc exposed baby will be at worst about 10 times higher or about $.4 \times 10^{-8}$. We note that current (1979) lifetime total respiratory cancer rates are about 5% and have nearly doubled since 1960, possibly reflecting rapidly changing smoking patterns during and after World War II, primarily among women. However, decreased tar levels in cigarettes and decreased per capita use of cigarettes since about 1965 should result in a gradual leveling off or decline in the total respiratory and/or lung cancer rate of the general population [14].

Mesothelioma:

The estimation of lifetime risk of mesothelioma is somewhat more difficult since the mesothelioma response data appears quite nonlinear in time since first exposure. We have investigated four different methods of mathematically modelling the nonlinear mesothelioma data. They all indicate an upper bound on lifetime risk for talc powdered infants of about 10^{-8} risk and quite possibly a much lower upper bound if the conservative assumptions upon which they were based do not hold. These four methods consisted of mathematically treating mesothelioma as 1) a nonincidental tumor with no time lag between tumor initiation and death, 2) a nonincidental tumor with a 10 year time lag between tumor initiation and clinical observation, 3) an incidental tumor, and 4) treating asbestos as a first stage intervener in an Armitage-Doll multistage carcinogenic process [9].

In fact methods 1-3 yielded virtually identical risks ($.5-.75 \times 10^{-8}$ risk). While method 4 yielded a risk 2-3 times higher (1.5×10^{-8} risk), it could easily have yielded a risk up to several orders of magnitude lower than 10^{-6} if we had simply assumed asbestos intervenes at a later stage of the carcinogenic process in this hypothetical Armitage-Doll multistage model. There was general concurrence among these four methods, and it suffices to briefly summarize Method 1. Method 1: based upon fitting $bt^{3.1}$ (nonincidental analysis) to a

1922-1946 cohort of the Selikoff, et. al. data.

A reasonably simple way to estimate the median life (ML) risk to median survival age 77 (in 1979) for humans exposed 2 yrs. to talcum

powder during infancy is given by the product of the following terms:

- (a) (77 yrs. since first exposure for infants/37 yrs. since first exposure for 1922-46 cohort as of 1978⁺)^{3.1} = 9.70.
- (b) (2 yr. infant exposure duration/34 yrs. approx. worker exposure duration for 1922-1946 worker cohort) = .059.
- (c) (infant/worker) yearly exposure ratio = 0.3×10^{-6} .
- (d) 1922-1946 cohort cumulative mesothelioma response of 3.75% (180 mesotheliomas/4,800 cohort members).

This product yields a median life risk of $R_{ML} = 0.64 \times 10^{-8}$.

Tumors other than Lung and Mesothelioma: (Selikoff study)

Although significant tumor increases were observed at other sites in the workers (e.g., esophagus, stomach and colon), their risk is dominated by that of the lung (less than 10^{-9} or 10^{-8} risk, depending upon whether or not the baby becomes a smoker) and by mesothelioma risk (less than 10^{-8} risk).

Other Comments on Total Cancer Risk:

These estimates of added lifetime human cancer risk are 2 orders of magnitude below those implied in Linda Taylor's memo 1) due to the fact that the more recent detection studies suggest .1% or less asbestos in talc on average rather than the 1% assumed by Dr. Taylor; and 2) due to a 10 fold conversion error going from fibers/cc in the air to fibers inhaled/yr by the infant.

Although mothers may receive an exposure for each infant powdered, their added lifetime risk from talc should be relatively smaller than the infant's since their mouths and noses are considerably further from the densest portion of the talc cloud than is the case for the captive infant during the daily powdering period (the inverse square law for exposure may apply).

Finally, the risks implied by the Selikoff study are generally on the high side of those implied by the other smaller epidemiological studies and we see little value in repeating calculations here for those studies (see reference 6 for details).

Ovarian Talc Study:

For completeness, a discussion is presented on a human epidemiological study purporting to show an association between talc use (talcum powder used for genital dusting on the perineum or on sanitary napkins) and ovarian cancer.

The Cramer et.al. study [2], which purported to show a significantly increased relative risk for ovarian cancer associated with talc use, 1) appears to have been misinterpreted statistically, 2) was uncorrected for several likely biasing factors and 3) appears to have been strongly contradicted by another study showing a reduced relative risk as significant in the negative direction as the Cramer study was in the positive direction.

The Cramer study's most prominent analysis (Mantel-Haenszel) was adjusted for only 2 factors and gave a relative risk (RR) of around 1.92 (p less than .003) and 95% confidence limits of 1.27 to 2.89 for 215 cases (talc users for genital or sanitary napkin dusting) vs 215 controls. Cramer's more comprehensively adjusted but seemingly de-emphasized multivariate regression analysis for 9 possible simultaneously confounding variables yielded a smaller and much less significant relative risk of 1.61 (p=.03), with 95% confidence limits of 1.04-2.49. It should be noted that the crude relative risk with no adjustments whatsoever was 1.89. In any case, if the authors had limited their logistic regression analysis as they subsequently did for their Mantel-Haenszel analysis, to those 121 cases where the first chosen control did not refuse to participate

(refusal bias), then the resulting p-value can be predicted through extrapolation of the other reported analyses to be greater than .05 and perhaps greater than .1. Unfortunately, the authors did not report this analysis. Instead they selectively chose to point out only that the relative risk of those exposed to talc both as a genital dusting powder and through sanitary napkins declined from a relative risk of 3.28 (p less than .001) to 2.44 (p less than .05) when the potentially biasing control refusals were eliminated from analysis. Apparently the authors felt it unnecessary to report those p-values that were greater than .05.

Since there were twice as many singles among the cases (21%) as among the controls (11%), the life style of singles might easily have biased the original overall relative risk of 1.92 [3]. However, the multivariate logistic analysis (RR=1.61) using all of the original 215 cases and 215 controls clearly adjusted for marital status along with such variables as religion, educational level, ponderal index, age at menarche, exact parity, oral contraceptive or menopausal hormone use, and smoking. The partially adjusted Mantel-Haenszel analysis (RR=1.92) only adjusted for menopausal status and crude parity.

Furthermore, it is generally assumed that any real positive cancer effect will show an increased risk with increased dose. Cramer only reported one subanalysis where he crudely considered dose response. He divided the small group of talc-dusted diaphragm users into those using diaphragms less than 5 years and into those using diaphragms more than five years. However, rather than showing an increased relative risk with increased dose (increased length of usage), the relative risk actually decreased noticeably

though not in a "statistically significant" fashion from 1.82 to 1.23 as diaphragm use increased from less than 5 years to more than 5 years.

In addition to the above interpretations of Cramer's own results, several potentially biasing factors could not be adjusted for by the logistic analysis. First, a possible positive correlation between talc use and ovarian disease etiology due to patient-perceived hygienic or cosmetic reasons would bias the relative risk upwards [4]. Second, a recall bias among hospital cases relative to community controls is quite plausible since cases may have greater incentive as well as opportunity to recall whether they should classify themselves as talc users [3]. Talc users from the community may well be modest in either participating as controls (the refusal bias already discussed) or in subsequently admitting talc use as a control subject. The recall bias might be expected to be even greater - as was possibly observed - for estimation of the relative risk for those using talc both on sanitary napkins and as a dusting powder ($RR=3.28$, p less than .001; or $RR=2.44$, p less than 0.05, after the refusal bias is eliminated) than for those engaged in only a single type of use.

Finally a talc and ovarian cancer study by Hartge, et. al. [4], appears to strongly contradict the reportedly positive Cramer study. Overall 135 cases and 171 control women matched by age, race and hospital were questioned on talc use. The estimated relative risk of ovarian cancer by talc users was reported to be 0.7 (95% confidence interval of 0.4 to 1.1). Adjustments for race, age, and gravidity (pregnancy) had no effect upon the estimate. No subanalyses

resulted in relative risks significantly greater than 1. It would appear that no refusal bias was operative in the Hartge study since none was reported. Also it would appear that recall bias was non-existent since there appeared to be no recall bias on the use or nonuse of douching.

SUMMARY

In summary, any hypothetical systemic added lifetime cancer risk (e.g., mesothelioma and lung cancer) to humans due to asbestos fibers in talc (principally for babies subject to 2 years of talc dusting) appears to be less than 10^{-8} added lifetime risk and possibly several orders of magnitude lower risk still, depending upon assumptions and uncertainties alluded to above, especially those regarding geometrical shape of any possible asbestos fibers in talc, and limits of detection for asbestos in talc. In addition, there appears to be no association between customary human talc use per se and ovarian cancer.

Robert Brown
Robert Brown

ATTACHMENT:

Signature Page

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SIGNATURE PAGE

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