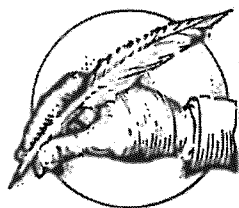


In The Matter Of:
Dean Berg v.
Johnson & Johnson, et al.

John Joseph Godleski, M.D.
September 18, 2012

195 State Street • Boston, MA 02109
Nationwide - Worldwide
888.825.3376 - 617.399.0130
www.court-reporting.com



O'BRIEN & LEVINE
Court Reporting Services
Making Your Case

Original File John J. Godleski_M.D. 9-18-12.txt
Min-U-Script® with Word Index

Page 61

1 We have two case reports where we specifically identified
 2 talc in -- persisting in the body. We have a long series
 3 of epidemiologic studies that show an association between
 4 the use of talc and ovarian cancer. Putting those two
 5 facts together in a case report, you can then say that
 6 there's an association. It's not just the two case
 7 reports.
 8 Q. Do you know --
 9 A. All these case reports establish is the presence
 10 of talc persisting in the genital tract.
 11 Q. Do you know whether Doctors Berkowitz or Welch
 12 share the same opinion as you and Dr. Cramer with regard to
 13 the -- a causative relationship between talc and ovarian
 14 cancer?
 15 A. I'm not sure what they -- what their opinions are.
 16 I believe Dr. Welch has been very impressed with the kinds
 17 of findings that we have and feels that identification of
 18 this is -- is -- is a very important finding. I have no
 19 idea what Dr. Berkowitz believes.
 20 Q. Did Dr. Welch review your expert report in this
 21 case, Exhibit 5?
 22 A. Not that I know of.
 23 Q. Why in Exhibit 3 were you not able to find a
 24 causal relationship between ovarian cancer and talc, or the

Page 62

1 other way around, talc and ovarian cancer?
 2 A. We were not able to say there was a causal
 3 relationship because it was the first case report of this
 4 type of finding.
 5 Q. The epidemiologic research upon which you claim to
 6 rely in finding a causal relationship was available at the
 7 time you and Dr. Cramer prepared Exhibit 3, was -- was it
 8 not?
 9 A. That's correct.
 10 Q. And so what is new specifically in the -- either
 11 the medical literature or in terms of medical developments
 12 that have occurred since 2007 that today allow you to make
 13 a finding of a causal relationship?
 14 A. I think it goes back predominantly to the
 15 epidemiology and also the fact that this wasn't a unique
 16 case, that -- that here's -- here's a second case that
 17 we're talking about today, and we -- we've done additional
 18 cases that -- where we found -- we found talc in the --
 19 Q. You found --
 20 A. -- in the ovary.
 21 Q. Since Exhibit 3 and outside of Exhibit 5 --
 22 A. That's correct.
 23 Q. -- what additional cases?
 24 A. They haven't been published either singly or --

Page 63

1 they're part of a series we've been working on.
 2 Q. Have -- have -- have you -- maybe I'm -- maybe I'm
 3 just not correctly understanding what you're saying, but
 4 are -- are you telling me that you and Dr. Cramer since the
 5 time you published Exhibit 3 have found additional cases
 6 involving talc in the ovaries or lymph nodes of other
 7 women?
 8 A. Yes.
 9 Q. And where and when has this occurred?
 10 A. Where -- where and when.
 11 Q. Well --
 12 A. They -- they -- this is part of the data that we
 13 have -- we have collected. We talk here about wanting to
 14 do additional studies. We haven't developed funding for
 15 those additional studies so that it's been a relatively
 16 slow process. But we've looked at some cases as they've
 17 been seen by Dr. Welch, and since he now polarizes them,
 18 we've -- we've gone on to do some of those cases. In fact,
 19 I think all of them have been seen by Dr. Welch that we've
 20 looked at.
 21 Q. Are any of those cases in litigation, to your
 22 knowledge?
 23 A. Not that I know of.
 24 Q. Is Dr. Welch the treating physician in those

Page 64

1 cases?
 2 A. Dr. Welch is a pathologist who had seen the cases
 3 for whatever reason.
 4 Q. Do you know roughly how many cases he has seen?
 5 A. No.
 6 Q. Roughly how many of those cases has he consulted
 7 with you on?
 8 A. I don't know, maybe a half dozen.
 9 Q. And over what period of time?
 10 A. Since -- since this report.
 11 Q. "This report" being Exhibit 3?
 12 A. Yes.
 13 Q. And are you aware of where those particular women
 14 are being treated?
 15 A. Brigham and Women's Hospital, to the best of my
 16 knowledge.
 17 Q. Are any of them, to your knowledge, clients of Mr.
 18 Smith?
 19 A. Not that I know of.
 20 Q. When do you expect to publish your findings
 21 concerning these particular cases?
 22 A. I'm not sure. When we get -- I mean when we get a
 23 series. We have to do control studies if we're going to
 24 present a series, so that all of that needs to be done.

Page 65

1 Q. Have you made any sort of case notes or other --
 2 prepared any other written materials regarding your
 3 consults on these half dozen or so cases?
 4 A. No. They're in the computer system on my
 5 microscope.
 6 Q. Are these all cases in which you have found talc
 7 in specific tissue slides of patients?
 8 A. There -- they have -- most of them have had talc,
 9 to my knowledge.
 10 Q. And, again, that's roughly half a dozen or so?
 11 A. Thereabouts, yeah.
 12 Q. Okay. Table 1 of your report, Exhibit 5, you
 13 indicate at the bottom in that note that you found three
 14 pure talc particles out of 177 particles analyzed, of which
 15 75 had, quote, "elemental composition indicative of foreign
 16 material components."
 17 A. That's correct.
 18 Q. Okay. Now, if -- if the presence of three talc
 19 particles leads you to conclude that there's a causal link
 20 between talc and ovarian cancer, and specifically Ms.
 21 Berg's ovarian cancer, why don't you reach a similar
 22 conclusion on the basis of the presence of the other 72
 23 particles of non-talc foreign material that you -- that you
 24 found?

Page 66

1 A. Well, there -- there are a lot of silicates found
 2 that include other components, such as the arsenic,
 3 chromium, nickel that had been identified as contaminants
 4 of talc, and I didn't -- I'm talking about those that had
 5 essentially a -- a pure spectrum of talc.
 6 Q. And specifically how many, if you recall, of those
 7 177 particles contained magnesium or silicates?
 8 A. Well, in the third panel of my table, so that
 9 looks like 19.
 10 Q. What were the other -- I'm going to have a tough
 11 time doing the math, but looks like you're saying 177
 12 particles found and analyzed, and we've got three of which
 13 were pure talc and 19 which were magnesium silicates, so
 14 there's 22. So we've got 155 particles that are not
 15 identified.
 16 A. Well, of the -- of the others, as I -- as I say,
 17 they're -- a lot of these particles are iron or calcium,
 18 and the fact that calcification occurs in ovarian cancers,
 19 this is one of the things you see pathologically, that when
 20 you start looking at -- at particles under the
 21 microscope -- under the electron microscope, and as you're
 22 looking in the back scatter mode, where you're going to see
 23 particles and then do an analysis, some of those particles
 24 turn out to be calcium; some of them turn out to be iron.

Page 67

1 And these are then thought to be particles that have
 2 been -- are endogenous, either related to the tumor or
 3 bleeding into the tumor that -- all of which occurs.
 4 And so I could have just not reported those,
 5 realizing and knowing, having analyzed them, that these are
 6 in fact endogenous. Some of these may or may not have even
 7 shown up with polarized light. For example, iron doesn't
 8 necessarily show up very well with polarized light. On the
 9 other hand, calcium does. So the fact that we have these
 10 kinds of particles, that -- that's the -- the difference
 11 between the 177 and the 75.
 12 Q. Are there not other possible sources of iron and
 13 calcium, for example, to show up in the reproductive tract
 14 outside of talc or in addition to talc?
 15 A. I think, given the -- the -- just knowing how the
 16 tumor behaves and knowing that you can have iron collected
 17 in relationship to any kind of bleeding or necrosis, tumor,
 18 calcification is -- is a common event, that identifying
 19 iron and calcium as something other than endogenous, you
 20 know, is possible, certainly, but not -- probably not
 21 likely.
 22 Q. And when you speak of 75 particles having
 23 elemental composition indicative of foreign material
 24 components, that would include the calcium and iron that

Page 68

1 you've mentioned?
 2 A. Generally not.
 3 Q. Not, okay. Tell me what, then, what these 75
 4 particles would contain as far as their elemental
 5 composition.
 6 A. They would have silica; they might have arsenic,
 7 chromium, nickel, or something else, but most of them would
 8 have some form of silica.
 9 Q. Arsenic, chromium, and nickel were the three you
 10 identified?
 11 A. Yes, they -- they were sometimes associated with
 12 magnesium silicates.
 13 Q. What was the composition, then, of the 102 non-
 14 foreign materials? Was that the calcium and iron?
 15 A. That would be carbon -- a lot of them turn out to
 16 be carbon that just shows up with the -- the -- in the --
 17 in the mode that we're using in the microscope. At the
 18 same time, calcium and -- and iron are two others. Sodium.
 19 Q. Sodium?
 20 A. Sodium associated with either iron or -- or
 21 calcium.
 22 Q. Are these types of particles often seen in the
 23 reproductive tract? These types of particles being the
 24 non-foreign materials that you identified.

Page 89

1 Q. Well, let's talk -- I was -- I was referencing
 2 aluminum, titanium, vanadium. And I'm just curious whether
 3 there is any reason why you didn't associate any of those
 4 with a possible cause of Ms. Berg's cancer.
 5 **A. Because there's no -- no basis for that.**
 6 Q. No literature studies, to your knowledge?
 7 **A. No.**
 8 Q. Okay. The silica that you included among the
 9 75 -- the 75 particles determined to be foreign material,
 10 there are other possible sources of silica than talc or
 11 magnesium silicate, are there not?
 12 **A. That magnesia -- yes. So if you -- just because**
 13 **you have magnesium and silica together doesn't make a talc.**
 14 Q. Nor does --
 15 **A. You have to have the right proportions.**
 16 Q. And it's got to be hydrated?
 17 **A. It generally is, but -- but you need the right**
 18 **proportions of -- of silica and magnesium in order to**
 19 **identify it as talc.**
 20 Q. Okay. I don't want to get ahead of myself, but
 21 the right proportions in terms of the peaks that you see
 22 when you do the XRD?
 23 **A. Yeah. And the -- and when you do the quantitative**
 24 **analysis. You need to be in the right ballpark.**

Page 90

1 **MR. MAYWHORT:** Okay. We're going to
 2 have to go off the record for a few
 3 minutes.
 4 **THE VIDEOGRAPHER:** We are going off
 5 the record. The time is 12:01.
 6 (Recess.)
 7 (Mr. Elder left the deposition.)
 8 **THE VIDEOGRAPHER:** We are back on the
 9 record. Time is 12:03.
 10 **BY MR. MAYWHORT:**
 11 Q. Doctor, I take it from your earlier testimony this
 12 morning that in your clinical consulting practice, you
 13 frequently make decisions as to what caused a particular
 14 disease based upon the pathology that you perform?
 15 **A. That's correct.**
 16 Q. And what criteria generally do you use when
 17 expressing an opinion as to the cause of any disease?
 18 **A. Well, I think -- I think more often than not,**
 19 **you're basing your opinion on the body of evidence. If you**
 20 **say smoking causes cancer of the lung, there's a body of**
 21 **evidence that supports that. If you say asbestos causes**
 22 **mesothelioma, there's a body of evidence that supports**
 23 **that. If you say talc causes ovarian cancer, there's a**
 24 **body of evidence that supports that.**

Page 91

1 Q. Okay. So if you were to see an asbestos body
 2 attached to a tumor in the lung that you decided was
 3 metastatic breast cancer, would you think that the asbestos
 4 caused the cancer?
 5 **A. Well, breast cancer is one of the few that**
 6 **asbestos isn't related to. So the body of evidence**
 7 **isn't -- isn't supportive of that.**
 8 Q. Okay.
 9 **A. On the other hand, if -- if it was a lung cancer,**
 10 **and you're seeing an asbestos body, that indicates that**
 11 **there's a substantial asbestos exposure, and so that the**
 12 **body of evidence that's out there that shows a relationship**
 13 **between asbestos exposure and lung cancer, you would**
 14 **certainly make that -- that conclusion.**
 15 Q. And would the same then apply to a talc particle
 16 that was attached to a small cell carcinoma in the lung of
 17 a patient, say with a 60-year history of smoking, would you
 18 conclude that the talc particle had nothing to do with the
 19 small cell carcinoma in the lung of that particular smoker?
 20 **A. You would conclude that smoking was the -- was the**
 21 **major factor. Whether -- whether talc played a role or**
 22 **not, it would depend on how much talc was there, under what**
 23 **circumstance it was there, how long was it there.**
 24 **For example, if -- if talc were used one month**

Page 92

1 **before because the patient had a pleural effusion, you**
 2 **would certainly not conclude that that talc contributed to**
 3 **the cancer in the patient's lung, because he very well**
 4 **could have had the cancer before he ever got the talc.**
 5 Q. And -- and talc has -- to use your term, there's
 6 no body of evidence supporting a relationship between talc
 7 and small cell carcinomas, is there?
 8 **A. That's correct. But if it were an adenocarcinoma,**
 9 **then you could look at the -- the animal studies.**
 10 Q. All right. Just what I -- all I'm trying to -- to
 11 establish here is the mere fact that finding a particle of
 12 foreign material next to or attached to a cancerous tumor
 13 doesn't automatically mean that that particle caused the
 14 tumor?
 15 **A. It depends --**
 16 Q. Right.
 17 **A. -- on -- on a lot -- a lot of things.**
 18 Q. But it doesn't automatically lead you to conclude,
 19 "Aha, I've got a particle and I've got a tumor, therefore
 20 the particle caused the tumor"?
 21 **A. One would -- that wouldn't be your first**
 22 **conclusion.**
 23 Q. But here in this case on page -- let's see -- page
 24 3 of your report, you cite to your 2007 article in the

Page 93

1 next-to-final sentence and say -- then say, "Therefore,
2 based on the findings in this case, it can be stated to a
3 reasonable degree of medical certainty that the talc found
4 in this case is evidence for a causal link between the
5 presence of talc and the development of this patient's
6 ovarian cancer."
7 First, when we're referring to "this case" and
8 "this patient," I presume you're referring to Ms. Berg and
9 not the 68-year-old woman who was the subject of the case
10 report that's Exhibit 3?
11 **A. That's correct.**
12 Q. So based upon your findings, your conclusions in
13 this case, and this case being the Berg case, again, do you
14 have any intention or any present plan to amend your
15 findings and conclusions in the case report that's been
16 marked as Exhibit 3?
17 **A. No.**
18 Q. Why not?
19 **A. Because in -- in 2007 when we -- when we wrote**
20 **this, this was the first case report showing this kind of**
21 **association in a patient.**
22 Q. Should you not now, based upon your findings in
23 the Berg case, go back and amend, though, your conclusion
24 in which you say, "We're not making any findings of

Page 94

1 causality in this case," and say, "Based upon the Berg
2 case, we now conclude that the particles found in the lower
3 lymph nodes of the 68-year-old woman that was the subject
4 of the case report were the cause of her ovarian cancer"?
5 **A. Well, I think we have -- we have two cases now**
6 **that have been -- that are -- one's published, one's under**
7 **discussion here, and -- and we have other cases where we've**
8 **seen this. So based on all of that body of evidence, plus**
9 **the body of epidemiologic evidence, we can -- we can make**
10 **the statement of causality.**
11 Q. Well, shouldn't you amend, then, the statement
12 contained in Exhibit 3 and that was published in Obstetrics
13 & Gynecology at this point in time, 2012, in other words?
14 **A. Well, I don't think I would go back to Obstetrics**
15 **& Gynecology and write a letter that says I -- I now**
16 **believe it's causal. But for the purpose of -- of telling**
17 **the truth here, I believe that, based on what we're seeing**
18 **in the Berg case, this case, and other cases, and the**
19 **epidemiology, that there is a causal relationship.**
20 Q. Don't you think it would be informative to readers
21 of Obstetrics & Gynecology if they understood that one of
22 the senior authors on that case report today believed in
23 fact that the talc particles found in the lower lymph nodes
24 of that patient were causal of her ovarian cancer?

Page 95

1 **A. I think that, based on the evidence that we have**
2 **in the epidemiology as well as these findings in the -- in**
3 **the lymph nodes, and when we write the next paper, I think**
4 **we'll make that statement.**
5 Q. Why not simply write a letter to the editors of
6 Obstetrics & Gynecology expressing that opinion, those
7 findings, so as to be of assistance to the -- to the
8 readers of that article -- that periodical?
9 **A. I think -- I think the point would be stronger if**
10 **we had a case series that showed this. And so when we**
11 **build a case series, we'll do it.**
12 Q. Your report discusses essentially how you reviewed
13 the histopathological slides in Ms. Berg's case. How were
14 those slides provided to you?
15 **A. They were sent from Sioux Valley Hospital.**
16 Q. And do you have any personal knowledge of the
17 protocols and procedures that were used by Sioux Valley
18 Hospital either in obtaining or preparing or maintaining
19 those slides before you received them?
20 **A. No.**
21 Q. Would you agree that histology laboratories in
22 hospitals generally are not designed to keep simple
23 particulate contaminants out of tissue slides?
24 **A. That's true.**

Page 96

1 Q. How did you go -- go about developing the
2 protocols and procedures for reviewing the tissue slides in
3 this case? You've discussed what -- generally what those
4 protocols and procedures were, and I'm just asking you how
5 you went about developing them prior to your receipt of the
6 slides.
7 **A. Okay. The -- the slides came to me. I looked at**
8 **them under the microscope. I looked at them under the**
9 **microscope with polarized light. And those slides, I then**
10 **photographed those slides with a camera through the**
11 **microscope. And then I sent those slides back to -- to the**
12 **hospital. One step before sending them back, I asked for**
13 **the blocks.**
14 Now, when you get the tissue blocks, what's been
15 done with the tissue block is that the tissue has been
16 looked at and sampled by the pathologist. He's made a
17 section of tissue, placed it into a plastic cassette. That
18 then goes through a machine that essentially takes out the
19 water from the specimen and infiltrates the specimen with
20 paraffin. And it's a hot paraffin, so that it's liquid.
21 It goes into the tissue, and then it comes out, and the
22 tissue is embedded into -- into the block. And -- or it's
23 actually embedded into a holder, which then you pour hot
24 paraffin into it. It makes the block, and then you can

Dean Berg v.
Johnson & Johnson, et al.

John Joseph Godleski, M.D.
September 18, 2012

Page 185

1 ERRATA SHEET DISTRIBUTION INFORMATION

2 DEPONENT'S ERRATA & SIGNATURE INSTRUCTIONS

3

4

5 ERRATA SHEET DISTRIBUTION INFORMATION

6

7 The original of the Errata Sheet has been delivered

8 to R. Allen Smith, Jr., Esquire.

9 When the Errata Sheet has been completed by the

10 deponent and signed, a copy thereof should be delivered to

11 each party of record and the ORIGINAL forwarded to William

12 W. Maywhort, Esquire, to whom the original deposition

13 transcript was delivered.

14

15 INSTRUCTIONS TO DEPONENT

16

17 After reading this volume of your deposition, please

18 indicate any corrections or changes to your testimony and

19 the reasons therefor on the Errata Sheet supplied to you

20 and sign it. DO NOT make marks or notations on the

21 transcript volume itself. Add additional sheets if

22 necessary. Please refer to the above instructions for

23 Errata Sheet distribution information.

24

Page 186

1 ATTACH TO THE DEPOSITION OF JOHN JOSEPH GODLESKI, M.D.

2 CASE: DEANE BERG VS. JOHNSON & JOHNSON, ET AL

3 DATE TAKEN: SEPTEMBER 18, 2012

4 ERRATA SHEET

5 Please refer to Page 185 for Errata Sheet instructions and

6 distribution instructions.

7 PAGE LINE CHANGE REASON

8 _____

9 _____

10 _____

11 _____

12 _____

13 _____

14 _____

15 I have read the foregoing transcript of my

16 deposition, and except for any corrections or changes noted

17 above, I hereby subscribe to the transcript as an accurate

18 record of the statements made by me.

19

20 Executed this ____ day of _____, 2012.

21

22 _____

23 JOHN JOSEPH GODLESKI, M.D.

24

Page 187

1 COMMONWEALTH OF MASSACHUSETTS SUFFOLK, SS.

2

3 I, JAMES A. SCALLY, RMR, CRR, a Certified

4 Shorthand Reporter and Notary Public duly commissioned and

5 qualified in and for the Commonwealth of Massachusetts, do

6 hereby certify that there came before me on the 18th day of

7 September, 2012, at 9:15 a.m., the person hereinbefore

8 named, JOHN JOSEPH GODLESKI, M.D., who provided

9 satisfactory evidence of identification as prescribed by

10 Executive Order 455 (03-13) issued by the Governor of the

11 Commonwealth of Massachusetts, was by me duly sworn to

12 testify to the truth and nothing but the truth of his

13 knowledge concerning the matters in controversy in this

14 cause; that he was thereupon examined upon his oath, and

15 his examination reduced to typewriting under my direction;

16 and that this is a true record of the testimony given by

17 the witness to the best of my ability.

18 I further certify that I am neither

19 attorney or counsel for, nor related to or employed by, any

20 of the parties to the action in which this deposition is

21 taken, and further, that I am not a relative or employee of

22 any attorney or counsel employed by the parties hereto or

23 financially interested in the action.

24

15 My Commission Expires: April 23, 2015

16

17

18

19 James A. Scally, RMR, CRR
CSR/Notary Public