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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

- - -

IN RE: PROPECIA : Master File
(FINASTERIDE) PRODUCTS : No.
LIABILITY LITIGATION : 1:12-md-02331
 : -BMC-PK

_____ :
 : MDL No. 2331

This Document Relates : Honorable
to: : Brian M.
 : Cogan

ALL CASES :
 : Magistrate
 : Judge Peggy
 : Kuo

- - -

April 19, 2016

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Confidential videotape
deposition of CYNTHIA GROSSEL SILBER,
M.D., taken pursuant to notice, was held
at the law offices of Morgan, Lewis &
Bockius LLP, 1701 Market Street, 18th
Floor, Philadelphia, Pennsylvania,
beginning at 8:14 a.m., on the above
date, before Kimberly A. Cahill, a
Federally Approved Registered Merit
Reporter and Notary Public.

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1 that -- how did you learn how to
2 interpret this data? Where did you learn
3 that skill?

4 A. I learned how to look at
5 data from my medical training; and
6 specifically postmarketing data, I
7 learned when I joined Merck. I was
8 trained by my colleagues in management.

9 Q. So to the extent that you
10 were evaluating data from an
11 epidemiological perspective, that was all
12 on-the-job training; correct?

13 A. I would not say that I was
14 evaluating data from an epidemiologic
15 perspective.

16 Q. What is a safety signal?

17 A. A safety signal is the
18 combination of a product and an adverse
19 event that may represent an association
20 between the two or may not.

21 Q. In a given patient
22 population; correct?

23 A. Not necessarily.

24 Q. Well, you have users of a

1 particular drug. Right?

2 A. Well, if that's your sense.
3 You can't have a combination of an
4 adverse event with a drug without having
5 the population defined as those people
6 who take the drug.

7 Q. So you are in effect
8 studying the outcome of a particular drug
9 on a patient population; correct?

10 (Pause.)

11 THE WITNESS: But that was
12 -- yes, but that was not the --
13 the extent of that work.

14 BY MR. BECKER:

15 Q. And that study of the
16 outcome of a drug on a patient population
17 is the hallmark of epidemiology, is it
18 not?

19 MR. HARRELL: Object to
20 form.

21 THE WITNESS: I don't know
22 what the hallmark of epidemiology
23 is.

24 BY MR. BECKER:

1 Q. It's a form of epidemiology;
2 correct?

3 A. I don't know.

4 Q. Do you know what
5 epidemiology is?

6 A. I can't give you a
7 definition.

8 Q. As a medical doctor, have
9 you ever heard the term epidemiology?

10 A. Yes, I have.

11 Q. What's your understanding of
12 that term?

13 A. My understanding of that
14 term is that it is the science of the
15 study of populations.

16 Q. So let's go back to where we
17 started. If you didn't have any formal
18 training in epidemiology, to the extent
19 you were studying a patient population at
20 Merck related to the use of Propecia, all
21 that knowledge came from on-the-job
22 training; correct?

23 A. No, not all that knowledge
24 came from on-the-job training.

1 Q. Where did you get it then
2 beyond --

3 A. I --

4 Q. -- at Merck?

5 A. No, a lot of the knowledge
6 that we use comes from our past medical
7 training.

8 Q. Like what?

9 A. Like knowledge about disease
10 states, knowledge about drug use,
11 knowledge about medical conditions.

12 Q. But it's fair to say you
13 have no formal education in epidemiology
14 or the study of patient populations;
15 correct?

16 MR. HARRELL: Object to
17 form.

18 THE WITNESS: I do not have
19 a degree in epidemiology.

20 BY MR. BECKER:

21 Q. Did you ever take any
22 courses in epidemiology?

23 A. Yes, I did.

24 Q. How many?

1 A. One.

2 Q. How many credits?

3 A. It was in medical school.

4 There are no credits in medical school.

5 Q. So like a semester or a year

6 --

7 A. Uh-hum.

8 Q. -- or a quarter?

9 A. Yes.

10 Q. Which one?

11 A. I believe it was a semester.

12 Q. So your formal education
13 regarding the study of epidemiology is
14 one semester of study for one class in
15 medical school; correct?

16 A. That is my formal education.

17 Q. Go back to your resume, if
18 you would.

19 A. Yes.

20 Q. Well, let me ask you a
21 question about that: Because you have
22 relatively little formal education in
23 epidemiology, you understand that signals
24 can be calculated to a numerical value;

1 correct?

2 MR. HARRELL: Object to
3 form.

4 THE WITNESS: Signals can be
5 calculated in different ways. It
6 depends upon the source of the
7 data.

8 BY MR. BECKER:

9 Q. One of those is a numerical
10 value; correct?

11 A. I -- I don't know to what
12 you're referring. I can't answer a
13 general question like that.

14 Q. Okay. If -- you have an
15 understanding, though, that signals can
16 be calculated; correct?

17 A. Again, I don't know to what
18 type of data you're referring.

19 Q. Well, when you're looking
20 for a particular safety signal, what are
21 you looking for?

22 A. We're looking for evidence
23 that the particular adverse event either
24 is related to the drug or is not.

1 Q. And how do you calculate
2 that or how do you quantify it?

3 A. We do not necessarily
4 quantify it. It depends on the data
5 source.

6 Q. Let's take Propecia, for
7 example.

8 A. Uh-hum.

9 Q. Okay? One of the adverse
10 events that's been alleged in this case
11 is that sexual dysfunction can continue
12 after discontinuation of the drug.

13 You have an understanding of
14 that; correct?

15 A. Yes.

16 Q. So how would you quantify
17 whether or not the data that Merck has in
18 its possession does or does not
19 demonstrate a safety signal?

20 MR. HARRELL: Object to
21 form.

22 Go ahead.

23 THE WITNESS: If you are
24 asking for quantification, the

1 place I would go would be the
2 clinical trial data.

3 BY MR. BECKER:

4 Q. What if you wanted to -- but
5 you can evaluate safety signals not just
6 based on clinical trial data. Right?

7 A. Yes, but it's much more
8 difficult to quantify and I thought
9 that's what we were discussing.

10 Q. I am. So I'm asking you, if
11 you were going to look at a drug safety
12 profile over time, from launch to today,
13 how would you quantify that?

14 A. I would go to the clinical
15 trial data.

16 Q. And that's all you would
17 look at. You wouldn't look at any --

18 A. For quantification, that's
19 the best data.

20 Q. Would you defer -- you're
21 not claiming to be an epidemiologist;
22 correct?

23 A. I am not.

24 Q. As a person -- you don't

1 claim your expertise is in epidemiology;
2 correct?

3 A. Correct.

4 Q. Would you defer to the
5 testimony of -- or to the findings of
6 epidemiologists regarding safety signals
7 over your own?

8 A. I would work with an
9 epidemiologist on my team.

10 Q. Okay. But would you
11 ultimately defer to their calculations
12 and computations, quantifications over
13 your own?

14 A. I would need to see a
15 specific example.

16 Q. Let's go back to your
17 resume. Directing you to bullet point
18 number 1 on page 7 under "Major
19 Responsibilities at Merck Research
20 Laboratories," it says, "Signal detection
21 and safety surveillance for multiple
22 marketed products and for products
23 currently in development."

24 Do you see that?

1 A. Yes, I do.

2 Q. My questions, by the way,
3 throughout the deposition, unless I
4 direct you otherwise, are going to be
5 solely related to Propecia and Proscar.
6 Okay?

7 A. Yes.

8 Q. Can we have that
9 understanding?

10 A. Yes.

11 Q. Okay.

12 What -- in terms of your
13 work on Propecia, what does bullet point
14 -- or number 1 reference or refer to?

15 A. Can you be a bit more
16 specific?

17 Q. Yeah, what did you do to,
18 quote, unquote, engage in signal
19 detection and safety surveillance for
20 Propecia?

21 A. I participated in the
22 processes that we have at Merck that were
23 extant at the time for postmarketing
24 signal detection and postmarketing data

1 oversight.

2 Q. And what does that mean?

3 A. That means that I was
4 responsible for the oversight of the
5 interpretation -- but not by myself. I
6 was part of a team that oversaw the
7 interpretation of the postmarketing data
8 that Merck received from Propecia.

9 Q. So let's see if we have some
10 areas of agreement here. A safety signal
11 can identify an association between a
12 drug and a particular outcome. Do you
13 agree with that?

14 A. It can.

15 Q. So, for example, you could
16 have a safety signal based on the
17 clinical trial data and the postmarketing
18 reports that Merck received establishing
19 an association between Propecia and
20 persistent sexual dysfunction; correct?

21 I'm not saying that one
22 exists, but you could -- you could reach
23 that conclusion.

24 MR. HARRELL: Object to

1 form.

2 Go ahead.

3 THE WITNESS: It would be
4 very difficult to reach the
5 conclusion from postmarketing
6 data.

7 BY MR. BECKER:

8 Q. All I'm asking you is this:
9 You can evaluate -- when looking at to
10 determine whether or not a safety signal
11 exists, you're evaluating data to see if
12 an association exists between a drug and
13 a particular outcome; correct?

14 A. Yes.

15 Q. So you could evaluate data
16 to look at whether or not Propecia is
17 associated with persistent sexual
18 dysfunction; correct?

19 A. We can evaluate reports of
20 patients on Propecia who have persistent
21 erectile dysfunction. Whether or not we
22 can come to any firm conclusions is
23 highly dependent on the type of data that
24 we have.

1 Q. So that is a, yes, you could
2 evaluate that question based on the data
3 you have; correct?

4 MR. HARRELL: Object to
5 form.

6 THE WITNESS: No, that is
7 that I could evaluate the data.

8 MR. BECKER: I'm ask --
9 that's all I'm asking.

10 THE WITNESS: Okay.

11 BY MR. BECKER:

12 Q. You could look at a given
13 data set --

14 A. Uh-hum.

15 Q. -- and evaluate whether that
16 data set has enough information in it to
17 establish an association between Propecia
18 and a negative outcome; correct?

19 A. I'm sorry. Could you repeat
20 the question?

21 Q. Sure.

22 Merck has certain adverse
23 events that it receives once a drug is
24 launched in the community; correct?

1 A. Correct.

2 Q. And it chronicles those
3 adverse events as they come in in
4 realtime. True?

5 A. Yes.

6 Q. And part of your job is to
7 evaluate those adverse events as they
8 come in over time; correct?

9 A. Yes.

10 Q. And part of the reason
11 you're evaluating those adverse events is
12 to determine whether or not there is an
13 association between an alleged adverse
14 event and the particular drug that you're
15 looking at; correct?

16 A. Yes.

17 Q. And you use that
18 postmarketing data to reach the
19 conclusion of yes, maybe, or no. Right?

20 A. We use that postmarketing
21 data as part of a larger package of data.
22 We don't often use the postmarketing data
23 in a vacuum.

24 Q. Now, when you refer to in

1 bullet point 1 here on your resume of
2 signal detection and safety surveillance
3 -- do you see that?

4 A. Uh-hum.

5 Q. -- what did you specifically
6 do to determine whether or not there was
7 a safety signal related to an association
8 between Propecia and persistent sexual
9 dysfunction following discontinuation of
10 use?

11 A. Whether there was a signal?

12 Q. Yes.

13 A. Is that the question?

14 Q. No. The question is, what
15 did you do to determine whether or not a
16 signal existed?

17 A. When I picked up the
18 product, the issue was already one that
19 was under ongoing analysis in the
20 program, so I did not do signal detection
21 for this particular adverse event.

22 Q. So let me make sure I
23 totally have that clear. So from
24 whatever the date was, whether it was

1 2006 or '7 or '8 or whenever you joined
2 the Propecia team, is it your testimony
3 you never engaged in signal detection
4 related to Propecia and persistent
5 ongoing sexual dysfunction?

6 A. I engaged in signal
7 evaluation. The signal had been
8 identified by the time I joined the
9 program. It had already been reviewed.

10 Q. So let me go back and get a
11 sense what that means. Are you saying
12 that there was a signal that was
13 identified between Propecia and
14 persistent sexual dysfunction prior to
15 your joining the team?

16 A. Prior to my joining the
17 team, there was investigation of that
18 product-event combination, yes.

19 Q. And what was the outcome?

20 A. The outcome when I joined
21 the team was that persistent erectile
22 dysfunction was not causally associated
23 with Propecia.

24 Q. So there was no signal by

1 the time you -- when you joined the team,
2 the view of Merck was that there was no
3 signal establishing an association
4 between Propecia and persistent ongoing
5 sexual dysfunction following
6 discontinuation of use?

7 A. I don't think I would say
8 there was -- there had been a signal and
9 we were following it on an ongoing basis.

10 Q. Okay. So that --

11 A. It's a product-event
12 combination. That's all it is.

13 Q. I get that. A signal, just
14 so -- let's make it clear for the jury --

15 A. Uh-hum.

16 Q. -- a signal does not equate
17 to causation. Right?

18 A. Correct.

19 Q. But a signal is, like, if
20 you were to -- if you're building a
21 puzzle, okay, you got lots of pieces in
22 the puzzle. Right?

23 A. Uh-hum.

24 Q. Yes?

1 A. Yes.

2 Q. You got the border and then
3 you got the inner parts. Right?

4 A. Yes.

5 Q. And the puzzle has a
6 picture. Right?

7 A. Yes.

8 Q. And you're trying to figure
9 out what that picture is by putting those
10 pieces together. Right?

11 A. Yes.

12 Q. And a signal is a piece of
13 the puzzle that might lead to a
14 conclusion that a particular outcome is
15 causative; correct?

16 MR. HARRELL: Object to
17 form.

18 THE WITNESS: I'm sorry. I
19 don't follow your analogy.

20 BY MR. BECKER:

21 Q. A signal might establish an
22 association between a drug and a negative
23 outcome; correct?

24 MR. HARRELL: Object to

1 form.

2 THE WITNESS: A signal is
3 the beginning of the process of
4 evaluation.

5 BY MR. BECKER:

6 Q. Right. It's one piece in
7 the puzzle. Right? As you try and build
8 this picture to get to whether or not the
9 drug causes a particular outcome. True?

10 MR. HARRELL: Object to
11 form.

12 Go ahead.

13 THE WITNESS: I'm sorry.
14 I'm just not -- I'm not following
15 the analogy.

16 BY MR. BECKER:

17 Q. Okay. Well, let me make
18 sure I understand what you're saying
19 clearly. Had Merck identified a signal
20 -- I'm not asking if they agreed that it
21 was causative or not, but prior to your
22 arrival, when you joined the Propecia
23 team, had Merck identified a signal
24 existed between Propecia and ongoing

1 sexual dysfunction following
2 discontinuation of use?

3 A. Yes.

4 Q. And you joined the team
5 sometime in the 2007-2008 timeframe to
6 the best of your recollection?

7 MR. HARRELL: Object to
8 form; asked and answered.

9 BY MR. BECKER:

10 Q. Let me put it this way: You
11 joined the team well before 2012;
12 correct?

13 A. Yes.

14 Q. And Merck did not amend its
15 label in the United States to tell men
16 about the association, this signal you
17 had identified, between Propecia and
18 persistent ongoing sexual dysfunction
19 following discontinuation of use until
20 April of 2012; correct?

21 A. I --

22 MR. HARRELL: Object to
23 form.

24 THE WITNESS: -- object to

1 the -- I object to the word
2 association.

3 BY MR. BECKER:

4 Q. Okay. Well, you don't get
5 the right to object. You get to answer
6 my questions and your lawyer gets to
7 object --

8 A. Well --

9 Q. -- so I'll ask you again:
10 You testified earlier that somebody had
11 established a signal between Propecia and
12 persistent ongoing sexual dysfunction
13 prior to you joining the team in the mid
14 2000s; correct?

15 A. Yes.

16 Q. And it would take another
17 four, five, six years till that signal
18 was indicated in the warning label here
19 in the United States; correct?

20 MR. HARRELL: Object to
21 form.

22 Go ahead.

23 THE WITNESS: I was not
24 objecting in a legal sense to the

1 use of the word association.

2 So I would say a couple of
3 things. I would say --

4 MR. BECKER: Stop. I'm --
5 no, no, no --

6 MR. HARRELL: She gets to
7 answer her question.

8 MR. BECKER: No, she gets to
9 answer the question that I asked.

10 MR. HARRELL: You can't cut
11 her off while she's answering.

12 MR. BECKER: But then she
13 gets to answer -- I don't have a
14 judge here so I can't stop her as
15 nonresponsive.

16 MR. HARRELL: I'm sorry, but
17 you asked a question and she's
18 answering.

19 MR. BECKER: I asked a
20 yes/no question.

21 MR. HARRELL: You let her
22 answer the question.

23 MR. BECKER: I'm going to
24 withdraw the question.

1 BY MR. BECKER:

2 Q. When was the first time that
3 the United States warning label discussed
4 a potential signal between -- a potential
5 association between persistent ongoing
6 sexual dysfunction following
7 discontinuation of use and Propecia?

8 A. I believe it was between the
9 end of 2010 and the beginning of 2011.

10 Q. There was a warning label --
11 you have an understanding that Merck put
12 in a CBE regarding erectile dysfunction
13 in 2011; correct?

14 A. Yes.

15 Q. And you have an
16 understanding that the FDA amended the
17 language from Merck's CBE and expanded it
18 to sexual dysfunction in 2012. True?

19 A. Yes.

20 Q. And that was the first time
21 that this potential association was
22 discussed in the United States warning
23 label; correct?

24 A. Yes.

1 MR. HARRELL: Object to
2 form.

3 THE WITNESS: Yes.

4 BY MR. BECKER:

5 Q. Let me go back to your
6 resume for just one other quick second.
7 Bullet point number 2 indicates,
8 "Analysis of safety signals and
9 development of strategic response to
10 safety issues for both marketed products
11 and products in development."

12 Do you see that?

13 A. Yes, I do.

14 Q. As it related to Propecia,
15 what did you do to analyze the safety
16 signal?

17 A. We followed the Merck
18 procedures that were in place at the time
19 that consisted of review of individual
20 reports, review of aggregate data, and
21 review of literature on the subject.

22 Q. And what, if anything, was
23 the outcome of that analysis?

24 A. With regard to --