

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

3                       - - -

4   IN RE:                                 : Master File No.:  
   PROPECIA (FINASTERIDE)             : 1:12-md-02331-JG-  
5   PRODUCTS LIABILITY                 : VVP  
   LITIGATION                            : MDL No. 2331

6           \_\_\_\_\_

   This Document Relates To: Honorable John Gleeson  
7   : Magistrate Judge  
   ALL CASES                             : Viktor Pohorelsky

8     
9   - - -

  DECEMBER 17, 2015

10                                        - - -

11                                        Videotape deposition of  
12   ELIZABETH ROUND, M.D., taken pursuant to  
13   notice, was held at the law offices of  
14   Venable LLP, 1270 Avenue of the Americas,  
15   24th Floor, New York, New York 10020,  
16   beginning at 9:06 a.m., on the above  
17   date, before Amanda Dee Maslynsky-Miller,  
18   a Certified Realtime Reporter and Notary  
19   Public in and for the State of New York.

20     
21   - - -

  GOLKOW TECHNOLOGIES, INC.  
22                 877.370.3377 ph | 917.591.5672 fax  
  deps@golkow.com

1 A. Uh-huh.

2 Q. Yes?

3 A. Yes.

4 Q. This document appeared in  
5 your custodial production, okay.

6 A. Okay.

7 Q. Referring to Exhibit-55,  
8 this is a peer-reviewed article from  
9 Traish, et al., entitled, "Adverse Side  
10 Effects of Five Alpha Reductase Inhibitor  
11 Therapy, Persistent Diminished Libido and  
12 Erectile Dysfunction and Depression in a  
13 Subset of Patients."

14 Do you see that there?

15 A. Yes.

16 Q. And it's got a date code of  
17 2010 under -- right before the abstract.

18 Do you see that?

19 A. Yes.

20 Q. Why did you have this in  
21 your file?

22 A. Finasteride is a five alpha  
23 reductase inhibitor. PROPECIA® is a five  
24 alpha reductase inhibitor.

1 Q. So what?

2 A. The title says, Adverse Side  
3 Effects of Alpha Reductase Inhibitors.

4 Q. So were you evaluating --  
5 were you reviewing this article to get an  
6 understanding of what the authors'  
7 conclusions were with respect to the  
8 impact of finasteride on persistent  
9 dysfunction of diminished libido and  
10 erectile dysfunction?

11 MR. MORROW: Objection.

12 THE WITNESS: It was a  
13 published paper about drugs that  
14 act as finasteride does, as a five  
15 alpha reductase inhibitor.

16 BY MR. BECKER:

17 Q. But it's a paper  
18 specifically on PROPECIA®, right?

19 MR. MORROW: Objection.

20 THE WITNESS: Five alpha  
21 reductase inhibitors. I believe  
22 it also includes dutasteride.

23 BY MR. BECKER:

24 Q. It included PROPECIA®,

1 right?

2 A. Correct.

3 Q. You read the paper?

4 A. Yes.

5 Q. What, if anything, did you  
6 do -- what did you do after you read it?

7 MR. MORROW: Objection.

8 BY MR. BECKER:

9 Q. What did you do with the  
10 information?

11 MR. MORROW: Same objection.

12 BY MR. BECKER:

13 Q. Did you do anything with the  
14 information after you read it?

15 MR. MORROW: Same.

16 THE WITNESS: We assimilated  
17 the information. We acknowledged  
18 that we had this information.

19 BY MR. BECKER:

20 Q. Do you know who Dr. Traish  
21 is?

22 A. Not personally. I know -- I  
23 mean, I just see him as the author here.

24 Q. I want to go through part of

1 this document with you.

2 Directing your attention to  
3 the results section. For the --

4 A. What page?

5 Q. The results on the abstract.

6 But before we do that, let  
7 me -- let me go back.

8 So you had a copy of this  
9 document in your file, correct?

10 A. Yes.

11 Q. And you read it, right?

12 A. Yes.

13 Q. And it's fair to say that  
14 the conclusion of this document is that  
15 Dr. Traish expressed some concern about  
16 persistent diminished libido and erectile  
17 dysfunction following discontinuation of  
18 use, correct?

19 A. Yes.

20 MR. MORROW: Objection.

21 Document speaks for itself.

22 BY MR. BECKER:

23 Q. And after reviewing this  
24 document, is it fair to say that Merck

1 took no action?

2 MR. MORROW: Objection.

3 BY MR. BECKER:

4 Q. To change the label?

5 MR. MORROW: Same.

6 THE WITNESS: There was no  
7 change to the label.

8 BY MR. BECKER:

9 Q. Okay. Let's go through the  
10 document. In the results section of the  
11 abstract, it says, Prolonged adverse  
12 effects on sexual dysfunction such as  
13 erectile dysfunction and diminished  
14 libido are reported by a subset of men,  
15 raising the possibility of a causal  
16 relationship.

17 Did I read that correctly?

18 A. Yes.

19 Q. What's your opinion on that?

20 MR. MORROW: Objection.

21 BY MR. BECKER:

22 Q. Well, you were -- or are a  
23 clinician, clinical researcher at Merck  
24 for the better part of the last quarter

1 century, right?

2 A. Right.

3 Q. Your job, part in part, is  
4 to identify causal risks associated with  
5 known drugs, right?

6 MR. MORROW: Objection.

7 BY MR. BECKER:

8 Q. Right?

9 A. Yes.

10 Q. Okay. So what I'm asking  
11 you is, did this give you any concern,  
12 Dr. Traish's report, that there may, in  
13 fact, be a causal relationship between  
14 finasteride and persistent ongoing sexual  
15 dysfunction?

16 MR. MORROW: Objection.

17 THE WITNESS: He raised the  
18 possibility, the possibility of a  
19 causal relationship.

20 BY MR. BECKER:

21 Q. I'm sorry, I didn't mean to  
22 interrupt you.

23 A. No. I mean, he didn't  
24 really have a lot of objective evidence

1 in this paper.

2 Q. So he raised the possibility  
3 of a causal relationship, right?

4 A. Yes.

5 Q. And armed with that  
6 knowledge, Merck did nothing to change  
7 the label, true?

8 MR. MORROW: Object to the  
9 form.

10 THE WITNESS: We did not  
11 change the label based on this  
12 paper.

13 BY MR. BECKER:

14 Q. Turn to the next page of the  
15 document, if you would.

16 Do you see in the second  
17 column?

18 A. Yes.

19 Q. The paragraph that starts  
20 with, The potential widespread.

21 A. Uh-huh.

22 Q. Okay. About six sentences  
23 down, Dr. Traish writes, To date.

24 Do you see that?



1 A. Yes.

2 Q. To date the adverse side  
3 effects of five alpha reductase  
4 inhibitors on sexual function,  
5 gynecomastia and the impact on the  
6 overall health have received minimal  
7 attention. However, in some patients,  
8 these side effects are persistent with  
9 regard to sexual function and with  
10 emotional toll, including decreased  
11 quality of life.

12 Did I read that correctly?

13 A. Yes.

14 Q. Do you agree or disagree  
15 with that statement?

16 MR. MORROW: Objection.

17 THE WITNESS: I don't have a  
18 basis to agree or disagree with  
19 that statement.

20 BY MR. BECKER:

21 Q. Well, didn't you testify  
22 earlier that your job was to figure out  
23 causal relationships of identified risks  
24 associated with the pharmaceutical?

1 MR. MORROW: Object to the  
2 form.

3 THE WITNESS: Yes.

4 BY MR. BECKER:

5 Q. And one of the risks  
6 associated with the use of PROPECIA® that  
7 Dr. Traish is raising is persistence with  
8 regard to sexual -- decreased sexual  
9 function and emotional issues, right?

10 MR. MORROW: Object to the  
11 form.

12 BY MR. BECKER:

13 Q. That's one of the things  
14 he's talking about; isn't that true?

15 MR. MORROW: Same objection.

16 THE WITNESS: That's one of  
17 the things he's talking about.

18 BY MR. BECKER:

19 Q. So I'm asking, as a  
20 clinician who has worked at Merck for the  
21 better part of 25 years, do you agree or  
22 disagree with that statement?

23 MR. MORROW: Same objection.

24 Asked and answered.

1 THE WITNESS: He's making an  
2 introductory statement here.

3 BY MR. BECKER:

4 Q. That doesn't answer my  
5 question, ma'am.

6 A. He's not --

7 MR. MORROW: Let her finish  
8 her answer.

9 BY MR. BECKER:

10 Q. My question is a yes-or-no  
11 question. It's you either agree or  
12 disagree with the statement, Doctor?

13 MR. MORROW: That's not  
14 necessarily true. Objection.

15 THE WITNESS: He makes the  
16 statement: However, in some  
17 patients these side effects are  
18 persistent.

19 BY MR. BECKER:

20 Q. That's right. And I'm  
21 asking whether or not you agree with  
22 that.

23 MR. MORROW: Objection.

24 THE WITNESS: I don't know

1           that he's proved to me they're  
2           persistent.

3       BY MR. BECKER:

4           Q.       So you do not agree to with,  
5       then?

6                   MR. MORROW:   Object to the  
7       form.

8                   THE WITNESS:   I said he has  
9       not proved to me these are  
10      persistent.

11      BY MR. BECKER:

12           Q.       Let me see if I can do it  
13      this way.

14                   If he hasn't proved it to  
15      you, are you taking the position that you  
16      don't believe him?

17                   MR. MORROW:   Objection.

18                   THE WITNESS:   I believe that  
19      some of this data is very flawed.

20      BY MR. BECKER:

21           Q.       That's not my question,  
22      Doctor.   My question is simply, do you  
23      believe the statement that these effects,  
24      sexual dysfunction, are persistent with

1 regard to some patients? Do you believe  
2 that?

3 MR. MORROW: Object to the  
4 form. Asked and answered.

5 BY MR. BECKER:

6 Q. Do you believe that some men  
7 who take finasteride will, in fact, have  
8 ongoing sexual dysfunction following  
9 discontinuation of use?

10 MR. MORROW: Object to the  
11 form.

12 THE WITNESS: I do not know  
13 that that has been definitively  
14 proved.

15 BY MR. BECKER:

16 Q. That wasn't my question.  
17 My question was, do you  
18 believe it's possible?

19 MR. MORROW: Objection.  
20 Speculation. She answered your  
21 question. You just don't like the  
22 answer.

23 THE WITNESS: I believe men  
24 can get persistent sexual

1 dysfunction, whether it's related  
2 to finasteride therapy or not, I  
3 don't know.

4 BY MR. BECKER:

5 Q. Now, we looked at an e-mail  
6 earlier, right, where you had evidence of  
7 a man who had persistent sexual  
8 dysfunction following discontinuation of  
9 use, right?

10 MR. MORROW: Objection.

11 THE WITNESS: I had evidence  
12 of a man whose sexual AE was still  
13 present 66 days after he finished  
14 therapy.

15 BY MR. BECKER:

16 Q. Does 66 days fit into your  
17 definition of --

18 A. I don't have a definition.

19 Q. Turn to Page 4 of document.

20 Do you see this highlighted  
21 section here, Doctor? Dr. Traish writes,  
22 Additional evidence is found in clinical  
23 studies and in the Merck database, which  
24 strongly suggest that in some patients

1 these sexual adverse effects are  
2 persistent.

3 Did I read that correctly?

4 A. Yes.

5 Q. Do you agree with that  
6 statement?

7 MR. MORROW: Objection.

8 THE WITNESS: I have no idea  
9 what he's referring to there.

10 BY MR. BECKER:

11 Q. We looked at a document that  
12 had -- we looked at the document  
13 regarding the Phase 3 clinical trials  
14 that reported, from the trials --

15 A. Yes.

16 Q. -- persistent ongoing sexual  
17 dysfunction, correct?

18 MR. MORROW: Objection.

19 THE WITNESS: I'm not sure  
20 how -- where he's making this  
21 statement from. Additional  
22 evidence is found in the clinical  
23 studies and in the Merck database.

24 MR. BECKER: I'm going to --

1 I have to object to that.

2 THE WITNESS: All right.

3 BY MR. BECKER:

4 Q. Doctor, I need you to listen  
5 to the question that I'm answering -- I'm  
6 asking and answer those.

7 A. Okay.

8 Q. Okay. If your lawyer wants  
9 to ask you questions at the end, he's  
10 free to do that.

11 A. Okay.

12 Q. But I need you to answer my  
13 questions.

14 A. Okay.

15 Q. And my question is this: We  
16 looked at a document that was an e-mail  
17 to you and Dr. Kaufman that said, or  
18 evidenced, persistent ongoing sexual  
19 dysfunction from the Phase 3 clinical  
20 trials, right?

21 MR. MORROW: Objection.

22 THE WITNESS: From years  
23 three to five, yes.

24 BY MR. BECKER:



1 Q. And you testified earlier  
2 that Sweden amended the label in 2009 to  
3 reflect persistent ongoing sexual  
4 dysfunction, correct?

5 MR. MORROW: Objection.

6 THE WITNESS: Yes.

7 BY MR. BECKER:

8 Q. And that information was  
9 corroborated by Merck's adverse event  
10 database and reports of ongoing sexual  
11 dysfunction in that database, right?

12 MR. MORROW: Objection.

13 THE WITNESS: Yes.

14 BY MR. BECKER:

15 Q. And that information was  
16 reported publicly, correct?

17 A. Yes.

18 Q. Isn't that what he's talking  
19 about here, that there was evidence from  
20 the Merck database, that's the adverse  
21 event database, suggesting persistent  
22 ongoing sexual dysfunction?

23 MR. MORROW: Object to the  
24 form.

1 THE WITNESS: That's why I  
2 asked the question, I didn't know  
3 what he was referring to.

4 BY MR. BECKER:

5 Q. Well, you have an  
6 understanding, Doctor, as a 25-year  
7 employee of Merck, that there is an  
8 adverse event database, right?

9 A. Correct.

10 MR. MORROW: Objection.

11 BY MR. BECKER:

12 Q. And that adverse event  
13 database is put in place so that Merck  
14 and regulatory agencies can identify  
15 signals of potential causative risks  
16 associated with the use of a drug, right?

17 MR. MORROW: Objection.

18 THE WITNESS: It's put in  
19 place to collect adverse events in  
20 postmarketing.

21 BY MR. BECKER:

22 Q. So as to identify potential  
23 causative risks of the use of a drug,  
24 right?

Elizabeth Round, M.D.

1 MR. MORROW: Objection.

2 THE WITNESS: Yes.

3 BY MR. BECKER:

4 Q. That was a yes, right?

5 MR. MORROW: Objection.

6 THE WITNESS: Yes.

7 BY MR. BECKER:

8 Q. And upon reviewing that  
9 information, Sweden required you to  
10 change the label to reflect persistent  
11 erectile dysfunction following  
12 discontinuation of use?

13 A. Yes.

14 Q. Okay. So my question is, do  
15 you agree or disagree that additional  
16 evidence is found in the clinical studies  
17 and in the Merck database which strongly  
18 suggests that in some patients the sexual  
19 adverse effects are persistent?

20 MR. MORROW: Objection.

21 THE WITNESS: I'm not -- I'm  
22 not clear what studies he's  
23 referring to when he says "in  
24 clinical studies;" what studies he

1           has access to, what he's talking  
2           about.

3       BY MR. BECKER:

4           Q.     I'm simply asking, Doctor,  
5       whether you agree or disagree with this  
6       statement? You either do or you don't.

7           MR. MORROW: Object to the  
8       form.

9           THE WITNESS: I'm not sure  
10       that it's strong evidence.

11       BY MR. BECKER:

12       Q.     How about some evidence?

13       MR. MORROW: Objection.

14       BY MR. BECKER:

15       Q.     The fact of the matter is,  
16       Doctor, there is evidence in your  
17       database, in Merck's database and in the  
18       Phase 3 year three through five clinical  
19       trials that suggests that some -- that in  
20       some patients, the sexual adverse effects  
21       are persistent; isn't that true?

22       MR. MORROW: Objection.

23       THE WITNESS: There are  
24       reports of persistent sexual

1           adverse events in the Merck  
2           database.

3       BY MR. BECKER:

4           Q.       So is that a yes, that is  
5       true?

6                   MR. MORROW:  Objection.

7                   THE WITNESS:  That -- that  
8           is true.  I would not put it in  
9           this context.  You're asking me to  
10          agree with the whole sentence.

11       BY MR. BECKER:

12           Q.       He goes on to say, Clearly  
13          the sexual adverse events do not  
14          necessarily resolve completely in all  
15          patients who discontinue use of  
16          finasteride, again supporting the  
17          premises that in some patients, these  
18          sexual side effects remain persistent.

19                   Did I read that correctly?

20           A.       Yes.

21           Q.       Do you agree or disagree  
22          with that statement, Doctor?

23                   MR. MORROW:  Objection.

24                   THE WITNESS:  He's talking

1 about in the postmarketing  
2 reports, yes.

3 BY MR. BECKER:

4 Q. So you agree --

5 A. In the postmarketing  
6 reports.

7 Q. Let me finish my question,  
8 Doctor.

9 You agree that -- that  
10 sexual adverse events do not necessarily  
11 resolve completely in all patients who  
12 discontinue use of finasteride?

13 MR. MORROW: Object to the  
14 form.

15 THE WITNESS: Based on the  
16 postmarketing reports. He  
17 introduces that section by talking  
18 about postmarketing.

19 BY MR. BECKER:

20 Q. You agree with that  
21 statement? That's all I'm asking.

22 MR. MORROW: Objection.

23 THE WITNESS: That's the AEs  
24 that are in the label now.

1 BY MR. BECKER:

2 Q. Well, but, Doctor, in  
3 fairness, the AEs that are in the label  
4 are buffered by the sentence that they  
5 discontinue upon -- that they go away --  
6 they resolve upon discontinuation, right?

7 MR. MORROW: Object to the  
8 form.

9 THE WITNESS: I was  
10 referring to the postmarketing  
11 section.

12 BY MR. BECKER:

13 Q. Well, but this is prior to  
14 the amendment to the U.S. label, right?

15 A. What is? This paper?

16 Q. This article is written in  
17 2010, is it not?

18 A. Yes.

19 Q. Okay. And you had yet to --  
20 Merck had yet to amend the United States  
21 label to reflect the fact that  
22 postmarketing surveillance reported  
23 persistent ongoing sexual dysfunction  
24 following discontinuation of use, right?

1 A. Correct.

2 Q. And armed with this article,  
3 you did nothing?

4 MR. MORROW: Objection.

5 THE WITNESS: Correct.

6 BY MR. BECKER:

7 Q. Let me show you --

8 - - -

9 (Whereupon, Exhibit-56,  
10 Irwig Article, "Persistent Sexual  
11 Side Effects of Finasteride for  
12 Male Pattern Hair Loss," Bates  
13 MRKP0002137734-40, was marked for  
14 identification.)

15 - - -

16 MR. BECKER: Sorry, guys, I  
17 only have two of these. No, I  
18 have three.

19 56.

20 MR. MORROW: Give me a  
21 minute.

22 MR. BECKER: Take your time.

23 So I've got two or three  
24 more documents before a natural



1 stopping point. Do you want to  
2 press forward to, like, 12:30-ish?  
3 It's up to all you. You're the  
4 witness and you guys --

5 MR. MORROW: I'm sorry, say  
6 it again.

7 MR. BECKER: I have, like,  
8 two or three more documents until  
9 a natural break. We'll go to  
10 about 12:30? But you have a  
11 witness and you guys are the court  
12 reporter. So whatever you want to  
13 do.

14 MR. MORROW: How do you  
15 feel? Do you want to keep going  
16 or do you want to take a break?

17 MR. BECKER: The faster we  
18 go, the faster we end.

19 THE WITNESS: Let's see what  
20 it looks like.

21 - - -

22 (Whereupon, a discussion off  
23 the record occurred.)

24 - - -

1 BY MR. BECKER:

2 Q. So I have in front of you  
3 there, Doctor, Exhibit-56.

4 Do you see that there?

5 A. Yes.

6 Q. Okay. This also appeared in  
7 your custodial file.

8 Do you recall reviewing this  
9 document or reading this article?

10 A. I recall the article.

11 Q. Okay. It's an article from  
12 Dr. Irwig, of the George Washington  
13 University, entitled, "Persistent Sexual  
14 Side Effects for Finasteride For Male  
15 Pattern Hair Loss."

16 Did I read that correctly?

17 A. Yes.

18 Q. And it appears in the  
19 Journal of Sexual -- Sex Medicine,  
20 correct?

21 MR. MORROW: Objection.

22 THE WITNESS: Yes.

23 BY MR. BECKER:

24 Q. The article is dated 2011.

1 Do you see that there?

2 A. Yes.

3 Q. I want to go through just  
4 some of his results.

5 All right. You recall  
6 reading this article at the time you  
7 received it?

8 A. I read it at the time I  
9 received it, yes.

10 Q. And in connection with that,  
11 you had an understanding that Dr. Irwig  
12 had evaluated a cohort of men who  
13 believed that they had persistent ongoing  
14 sexual dysfunction following  
15 discontinuation of use, correct?

16 A. Yes.

17 Q. And he reported, after that  
18 review, that 94 percent of the subjects  
19 developed low libido, correct?

20 MR. MORROW: Objection.

21 THE WITNESS: That's what  
22 the statement says here.

23 BY MR. BECKER:

24 Q. And 92 percent developed

1       erectile dysfunction.

2                       Do you see that?

3               A.       Yes.

4                       MR. MORROW:    Form.

5       BY MR. BECKER:

6               Q.       92 developed decreased

7       arousal?

8                       MR. MORROW:    Object to the

9       form.

10                      THE WITNESS:   Yes.

11       BY MR. BECKER:

12              Q.       And 69 percent developed

13       problems with orgasms.

14                      Do you see that there?

15                      MR. MORROW:    Object to the

16       form.

17                      THE WITNESS:   Yes.

18       BY MR. BECKER:

19              Q.       Do you have any evidence, as

20       you sit here today, that that data was,

21       in fact, inaccurate?

22                      MR. MORROW:    Objection.

23                      This is.

24                      THE WITNESS:   This is a

1           selected group of patients with  
2           sexual AEs following finasteride.

3       BY MR. BECKER:

4           Q.     Right. I mean, it's men who  
5           are saying, I continue to have adverse  
6           events -- I continue to have sexual  
7           dysfunction following the time I stopped  
8           taking PROPECIA®, right?

9           A.     Yes.

10          MR. MORROW:  Objection.

11       BY MR. BECKER:

12          Q.     And they're reporting these  
13          are their symptoms, true?

14          A.     Yes.

15          Q.     What, if anything, did Merck  
16          do with this data?

17          MR. MORROW:  Object to the  
18          form.

19          THE WITNESS:  We reviewed  
20          the paper.

21       BY MR. BECKER:

22          Q.     And based upon your review,  
23          what did you do?

24          A.     I don't recall that we took

1 any action, if that's what you're asking.

2 Q. He reports that, The mean  
3 duration of finasteride use was 28 months  
4 and the mean duration of persistent  
5 sexual side effects was 40 months from  
6 the time of finasteride cessation to the  
7 interview date.

8 Do you see that?

9 A. I do.

10 Q. Would 40 months constitute  
11 persistent ongoing sexual dysfunction?

12 MR. MORROW: Objection.

13 THE WITNESS: I don't have a  
14 definition for persistent.

15 BY MR. BECKER:

16 Q. So if a label talks about  
17 symptoms being resolved upon  
18 discontinuation of use, don't you think  
19 it would be fair to tell doctors and  
20 patients what the temporal nexus was  
21 between the time the person discontinued  
22 the use and the date when the symptoms  
23 actually went away?

24 MR. MORROW: Objection.

1 THE WITNESS: Well, we  
2 didn't. We stated they were  
3 resolved upon discontinuation.

4 BY MR. BECKER:

5 Q. But let's assume for  
6 argument's sake that these men's symptoms  
7 resolved at 40 months. Isn't there a  
8 difference between a label that says your  
9 symptoms will resolve 40 months after you  
10 discontinue use versus your symptoms will  
11 ultimately resolve?

12 Isn't there a fundamental  
13 difference between those two statements?

14 MR. MORROW: Object to the  
15 form.

16 THE WITNESS: There is a  
17 difference.

18 BY MR. BECKER:

19 Q. Is Merck putting patient  
20 safety first when it refuses to identify  
21 the temporal connection between  
22 discontinuation of drugs and how long it  
23 takes for those symptoms to actually  
24 resolve?

1 MR. MORROW: Object to the  
2 form.

3 THE WITNESS: No. The  
4 persistence of sexual AEs has been  
5 added to the label based on  
6 postmarketing. We've also  
7 established that postmarketing  
8 data is limited. And this author  
9 himself cites the limitations of  
10 this study; the post hoc approach,  
11 selection bias, record bias, no  
12 serum hormone level.

13 MR. BECKER: Objection,  
14 nonresponsive. Move to strike  
15 everything after "no."

16 MR. MORROW: Objection.

17 BY MR. BECKER:

18 Q. My question is, Doctor, if  
19 we can agree that time from  
20 discontinuation to resolution is  
21 important, shouldn't you tell patients  
22 what that time is?

23 MR. MORROW: Object to the  
24 form. That's a different



1 question.

2 THE WITNESS: It would  
3 appear to be very variable for  
4 each of these patients.

5 BY MR. BECKER:

6 Q. That didn't answer my  
7 question.

8 You either should or  
9 shouldn't have to tell them what the time  
10 is.

11 What's your view?

12 MR. MORROW: Objection.

13 THE WITNESS: I don't think  
14 there's a need to tell them the  
15 time.

16 BY MR. BECKER:

17 Q. So in Merck's view, if the  
18 time to resolution was three and-a-half  
19 years, it would be okay to withhold that  
20 information from patients?

21 MR. MORROW: Object to the  
22 form. Mischaracterizes the  
23 testimony.

24 You may answer.

1 THE WITNESS: No, that  
2 shouldn't be withheld from the  
3 patient.

4 BY MR. BECKER:

5 Q. So at what point in time  
6 does persistence become -- at what point  
7 in time do you believe Merck should alert  
8 patients that it takes to resolve these  
9 symptoms after discontinuation?

10 MR. MORROW: Object to the  
11 form.

12 MR. BECKER: Let me start  
13 over because I agree with his  
14 objection on that one.

15 BY MR. BECKER:

16 Q. It's fair there's no --  
17 there's no indication in the label that  
18 symptoms will resolve after a given  
19 amount of time has passed, right?

20 A. Right.

21 Q. All the label says is that  
22 stop taking the drug and the symptoms go  
23 away?

24 A. Uh-huh.

1 Q. Yes?

2 A. Yes. In the clinical  
3 trials --

4 MR. MORROW: Objection.

5 THE WITNESS: -- yes.

6 BY MR. BECKER:

7 Q. Isn't it a fair inference  
8 from that, that the symptoms resolve  
9 quickly after you discontinue use?

10 MR. MORROW: Objection.

11 Speculation.

12 THE WITNESS: Based on the  
13 clinical trials, I don't believe  
14 it was a long time.

15 BY MR. BECKER:

16 Q. That wasn't my question.

17 My question was, wasn't the  
18 inference that Merck was making was that  
19 symptoms would quickly resolve upon  
20 discontinuation of use?

21 MR. MORROW: Object to the  
22 form.

23 THE WITNESS: I don't know  
24 that the argument was quickly

1 resolve. We just said that they  
2 would -- they resolved on  
3 discontinuation, what we saw in  
4 the clinical trials.

5 BY MR. BECKER:

6 Q. Can we -- would you agree  
7 with me that the longer it takes to have  
8 these symptoms resolve after  
9 discontinuation of use, the more  
10 obligation Merck has to alert patients of  
11 that -- of that issue?

12 MR. MORROW: Object to the  
13 form.

14 THE WITNESS: We now have  
15 reports in the adverse experiences  
16 section that talk about  
17 persistence. We don't put a  
18 qualifying -- a qualifying time  
19 period on that.

20 MR. BECKER: Objection.  
21 Hold on. Nonresponsive. Move to  
22 strike.

23 BY MR. BECKER:

24 Q. Let me see if I can do it

1 this way, Doctor.

2 Would you agree that if in  
3 some men these symptoms occurred six  
4 months after discontinuation of use, that  
5 Merck would have an obligation to report  
6 that in the label?

7 MR. MORROW: Objection.

8 THE WITNESS: Do you mean  
9 that these events had a new onset  
10 six months after?

11 BY MR. BECKER:

12 Q. No, no. I'm asking you,  
13 Merck does not dispute the fact that  
14 sexual -- adverse sexual events can occur  
15 while on a drug; you don't dispute that,  
16 do you?

17 A. No.

18 Q. Merck takes the position  
19 that at some point following  
20 discontinuation of use, those symptoms go  
21 away, right?

22 A. As observed in the trials,  
23 yes.

24 Q. What I'm trying to get at

1 is, how long after discontinuation of use  
2 should Merck tell patients and doctors  
3 those symptoms take to resolve?

4 Do you understand my  
5 question?

6 A. I do understand the  
7 question.

8 MR. MORROW: Objection.

9 You can answer.

10 BY MR. BECKER:

11 Q. And my question is, would  
12 you agree that if the symptoms did not  
13 resolve for a month, that Merck should  
14 alert patients who take the drug that it  
15 may take up to a month for their sexual  
16 dysfunction -- for their sexual function  
17 to return?

18 MR. MORROW: Objection.

19 BY MR. BECKER:

20 Q. Should you tell patients  
21 that?

22 MR. MORROW: Objection.

23 BY MR. BECKER:

24 Q. Should you tell patients

1 that?

2 MR. MORROW: Objection.

3 THE WITNESS: If we had that  
4 information, yes.

5 BY MR. BECKER:

6 Q. Okay. Now, you have a  
7 worldwide adverse event database, right?

8 A. Yes.

9 Q. And you had clinical trials,  
10 right?

11 A. Yes.

12 Q. And in those clinical  
13 trials, the data reported resolution  
14 after discontinuation of use for some  
15 patients, right?

16 A. Yes, yes.

17 Q. And sometimes that  
18 resolution took several hundred days or  
19 up to a year, right?

20 MR. MORROW: Objection.

21 THE WITNESS: I don't know  
22 that.

23 BY MR. BECKER:

24 Q. If the data demonstrates

1 that resolution took a long time  
2 following discontinuation of use,  
3 shouldn't you have told patients and  
4 doctors that?

5 MR. MORROW: Object to the  
6 form.

7 THE WITNESS: I don't  
8 remember the data on how long it  
9 took to -- for resolution.

10 BY MR. BECKER:

11 Q. That wasn't my question,  
12 though.

13 A. I understand.

14 Q. So I'd like an answer to my  
15 question.

16 MR. MORROW: Same objection.

17 THE WITNESS: If -- it may  
18 have been useful to put that in.

19 - - -

20 (Whereupon, Exhibit-57,  
21 4/6/11 E-mail to Cynthia Silber  
22 from Christine Alberts,  
23 Bates MRKP0001390080-81, was  
24 marked for identification.)



1 was drawing a distinction between Europe  
2 and the U.S., so I was trying to talk to  
3 you about that.

4 So let me see if I can do it  
5 this way.

6 MR. MORROW: Objection.

7 BY MR. BECKER:

8 Q. Why did you conduct this  
9 review in April of 2011?

10 A. I don't recall.

11 Q. Do you think it might have  
12 been in response to the mounting evidence  
13 from the Traish article, the Irwig  
14 article and Merck's own experience with  
15 sale and distribution of the drug?

16 MR. MORROW: Object to the  
17 form.

18 THE WITNESS: I don't  
19 recall.

20 BY MR. BECKER:

21 Q. Okay. Now, if you look at  
22 Exhibit 58 --

23 A. Yes.

24 Q. -- it says, in Paragraph 2,

1 To identify cases that may represent  
2 persistent sexual dysfunction, the MAH  
3 reviewed the reports with an outcome of  
4 not recovered in whom finasteride therapy  
5 was discontinued.

6 Do you see that there?

7 A. Yes.

8 Q. And it found a total of 446  
9 reports, right?

10 A. Yes.

11 Q. You then went back and  
12 looked at the Worldwide Adverse  
13 Experience System, right?

14 MR. MORROW: Objection.

15 BY MR. BECKER:

16 Q. Or that was in context with  
17 the Worldwide Adverse Experience System,  
18 true?

19 A. Yes.

20 MR. MORROW: Objection.

21 THE WITNESS: Yes.

22 BY MR. BECKER:

23 Q. And this memo indicates, The  
24 Worldwide Adverse Experience System, WAES

1 database, was searched for spontaneous  
2 reports of sexual dysfunction received  
3 from healthcare providers, including  
4 regulatory agencies and consumers and  
5 patients on therapy with finasteride, 1  
6 milligram, and .2 milligram tablet  
7 PROPECIA®, from market introduction, 11  
8 September 1998, to 31 December 2010.

9 Do you see that?

10 A. Yes.

11 Q. Did I read that correctly?

12 A. Yes.

13 Q. And then it goes on to  
14 identify the search terms, right?

15 A. Yes.

16 Q. Persistence is not included  
17 in this search term, is it?

18 A. There is no term for  
19 persistence.

20 Q. That was my next question.

21 The reason why it's not  
22 included is because you didn't have a  
23 field in the MedDRA database to chronicle  
24 persistence, right?

1 MR. MORROW: Object to the  
2 form.

3 THE WITNESS: It's not that  
4 we don't have a field, MedDRA  
5 doesn't have the field.

6 BY MR. BECKER:

7 Q. You could have created one,  
8 right?

9 MR. MORROW: Objection.

10 THE WITNESS: I'm not sure  
11 of the process for creating terms.

12 BY MR. BECKER:

13 Q. Are you saying that you were  
14 absolutely precluded from looking or --  
15 at a term that existed within the  
16 narrative reports of the adverse event  
17 database?

18 MR. MORROW: Objection.

19 THE WITNESS: I'm not saying  
20 we were precluded. I think the  
21 next paragraph explains what --  
22 what the CREMS group did to  
23 uncover adverse experiences that  
24 were continuing after the

1           discontinued -- not recovered  
2           after they discontinued the drug.  
3           That's how they did it.

4   BY MR. BECKER:

5           Q.     Doctor, I really need you to  
6   answer the questions I'm asking.

7           MR. MORROW:   She is  
8   answering the questions.

9           MR. BECKER:   She is not  
10   answering.   She is not.

11          MR. MORROW:   You just don't  
12   like it.

13          MR. BECKER:   Believe me,  
14   there's plenty in this depo I  
15   like.

16          MR. MORROW:   Move to strike.

17   BY MR. BECKER:

18          Q.     There -- there was no term  
19   for persistence in the MedDRA database,  
20   right?

21          MR. MORROW:   Objection.

22          THE WITNESS:   There was no  
23   term.

24   BY MR. BECKER:

1 Q. There was no term for  
2 withdrawal syndrome in the MedDRA  
3 database, right?

4 A. I don't know that.

5 Q. There was no term for not  
6 recovered in the MedDRA database, right?

7 A. I don't know that.

8 MR. MORROW: Objection.

9 BY MR. BECKER:

10 Q. The term you searched was  
11 not recovered, right?

12 MR. MORROW: Objection.

13 THE WITNESS: We searched  
14 for an outcome of not recovered on  
15 the adverse experience reports.

16 BY MR. BECKER:

17 Q. So the only way that you  
18 could do that was if you actually found  
19 all of the reports and read all of the  
20 narratives, right?

21 MR. MORROW: Object to the  
22 form.

23 THE WITNESS: I'm not sure  
24 about that.

1 BY MR. BECKER:

2 Q. You don't have any -- with  
3 these other terms, you can run a query  
4 within MedDRA to actually pull up these  
5 various adverse events, right?

6 A. All these adverse experience  
7 terms, yes.

8 Q. Wouldn't it have been  
9 easier, from a postmarketing surveillance  
10 standpoint, to actually include a term  
11 for persistence?

12 MR. MORROW: Object to the  
13 form.

14 THE WITNESS: I don't know  
15 whether it would have been easier.

16 BY MR. BECKER:

17 Q. But you knew that  
18 persistence might be a problem as early  
19 as 1998, right?

20 MR. MORROW: Objection.

21 THE WITNESS: We knew --  
22 1998?

23 BY MR. BECKER:

24 Q. Dr. Kaufman wrote about

1 ejaculate disorders in 1998, that  
2 reversibility was impossible --  
3 reversibility upon discontinuation was  
4 impossible, due to postmarketing reports,  
5 right? You remember that document?

6 MR. MORROW: Objection.

7 THE WITNESS: It was  
8 impossible to establish based on  
9 postmarketing reports.

10 BY MR. BECKER:

11 Q. So you knew as early as 1998  
12 that some men were continuing to  
13 experience sexual dysfunction following  
14 discontinuation of use, right?

15 MR. MORROW: Object to the  
16 form. Mischaracterizes prior  
17 testimony.

18 You may answer.

19 THE WITNESS: Could you  
20 repeat that question?

21 BY MR. BECKER:

22 Q. Based on Dr. Kaufman's  
23 e-mail, Merck was aware of the fact, as  
24 early as 1998, that there were reports of



1 persistent ongoing sexual dysfunction  
2 following discontinuation of use, true?

3 MR. MORROW: Same objection.

4 THE WITNESS: I understood  
5 Dr. Kaufman's e-mail to mean that  
6 you couldn't prove reversibility  
7 from postmarketing reports, not --

8 BY MR. BECKER:

9 Q. Let's go to something you do  
10 understand.

11 MR. MORROW: Are you  
12 finished with your answer?

13 BY MR. BECKER:

14 Q. Were you finished with your  
15 answer?

16 A. Yes.

17 Q. You received an e-mail in  
18 2000 that provided evidence of persistent  
19 ongoing sexual dysfunction from the  
20 clinical trial itself, right?

21 MR. MORROW: Objection.

22 THE WITNESS: We reviewed  
23 that e-mail. We had an e-mail,  
24 with no data on it, that said that

1 A. No.

2 MR. MORROW: Objection.

3 BY MR. BECKER:

4 Q. The drug is on the market  
5 with a label that talks about  
6 persistence?

7 A. It has a label, adverse  
8 events in the postmarketing --

9 Q. So a doctor reading that --

10 A. -- section. It does not  
11 contain that in the warning section of  
12 the label.

13 Q. A doctor reading that would  
14 be able to counsel his or her patient on  
15 reports of ongoing persistent erectile  
16 dysfunction so as the patient could make  
17 an informed choice, right?

18 MR. MORROW: Object to the  
19 form.

20 THE WITNESS: Yes.

21 BY MR. BECKER:

22 Q. That wasn't in the label  
23 prior to 2012 in the United States,  
24 right?

1 A. No.

2 MR. MORROW: Objection.

3 BY MR. BECKER:

4 Q. So prior to 2012, when that  
5 finally made it into the label, does the  
6 benefit of hair growth outweigh the risk  
7 of persistent to permanent erectile  
8 dysfunction?

9 MR. MORROW: Object to the  
10 form.

11 THE WITNESS: That has to be  
12 a choice for the patient seeking  
13 treatment.

14 BY MR. BECKER:

15 Q. How does a patient make an  
16 informed choice if they don't know the  
17 risk is present?

18 A. They can't.

19 MR. MORROW: Object to the  
20 form.

21 BY MR. BECKER:

22 Q. Exactly. And so prior to  
23 2012 when the FDA approved the label, the  
24 only person or people that could make

1 that assessment was Merck, right?

2 MR. MORROW: Objection.

3 THE WITNESS: Based on the  
4 label in the U.S., the physician  
5 did not have that information.

6 BY MR. BECKER:

7 Q. Right. So the only people  
8 that had that information at their  
9 disposal were, in fact, Merck, right?

10 MR. MORROW: Objection.

11 THE WITNESS: It was in the  
12 EU label.

13 BY MR. BECKER:

14 Q. Right. But you testified  
15 earlier, you have no idea if you gave  
16 this document to the FDA, right?

17 MR. MORROW: Objection.

18 THE WITNESS: I did.

19 BY MR. BECKER:

20 Q. And so if the FDA didn't  
21 have this data, there would be no way  
22 they could evaluate it, right?

23 MR. MORROW: Objection.

24 THE WITNESS: The FDA -- I'm