IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK
NO. 1:12-md-02331-BMC-PK

\- - -

IN RE: PROPECIA (finasteride) PRODUCTS LIABILITY LITIGATION	:	MDL No.2331
vs.	:	Honorable Brian M. Cogan
	:	Magistrate Judge Peggy Kuo
This Document Relates to ALL CASES	:	

\- - -

JULY 12, 2016

\- - -

VIDEOTAPE deposition of KEITH D. KAUFMAN, M.D., taken pursuant to notice, held at MORGAN LEWIS, 1701 Market Street, Philadelphia, Pennsylvania, beginning at 9:00 a.m., on the above date, before LISA MARIE CAPALDO, RPR, Registered Professional Reporter and Notary Public in and for the Commonwealth of Pennsylvania.

\- - -

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

reflection of adverse event reports. Adverse events do not derive from the questionnaire.

Q. Okay. So did you use -- we can agree you used a sexual function questionnaire in '87 and '89, right?

A. Yes.

Q. You didn't use one in '92, right?

A. Correct.

Q. But you combined the data for all three to report sexual adverse events in the label?

A. That's correct.

None of the adverse event data comes from the questionnaire. And patients were always queried about adverse events at every visit in all three studies in a similar manner.

Q. Let me direct your attention to the patient package insert, Page -- and specifically I want to direct your attention to Page 13.

Do you have that there,

Doctor?

A. Yes.

Q. Okay. Under the heading, what are the possible side effects of Propecia, it says, starting with these men, these men reported one or more of the following: less desire for sex, difficulty in achieving an erection, and a decrease in the amount of semen. Each of these side effects occurred in less than two percent of men. These side effects went away in men who stopped taking Propecia.

Did I read that correctly?

A. That's correct.

Q. Okay. Now, the patient package insert is actually written for the user of the drug, correct?

A. Yes.

Q. Okay. So it's written in a way that's not nearly as technical as the actual label itself?

A. Yes.

Q. And there's an expectation

or a hope that men who take this drug will actually get this patient's package insert and read it, correct?

A. Yes.

Q. All right. And what Merck was telling these men was:

If you get a side effect from this drug related to a sexual adverse event, when you stop taking the drug, it will go away?

A. It actually says that it may go away whether you continue the drug or if you stop it and that it went away in all men -- or in men who stopped taking the drug.

Q. All right. That's my only question.

It says specifically, the side effects went away in men who stopped taking Propecia, correct?

A. Because that's a true statement.

Q. Okay. You can't get any clearer than that, can you?

on drug in terms of what happened afterwards.

BY MR. BECKER:

Q. All right. So let's look at some of the clinical data you had.

I'm showing you what's been marked as Exhibit-52.

Do you have that there in front of you?

A. Uh-huh.

Q. This is an e-mail that we went over with Dr. Round. And I'll represent to you, sir, that it's dated November 3rd, 2000. I know that because in what's called MedData, the date appears, but the date does not appear on this particular e-mail.

A. Uh-huh.

Q. You know who Patrick Ruane is, correct?

A. Yes.

Q. He is somebody that worked with you and Dr. Round, correct?

A. Yes.

Q. And you asked him to inquire into rates of sexual adverse events stemming from the clinical trials at or about this time period, correct?

A. Yes.

Q. All right. And he wrote back to you, during years three through five in the Phase III pivotal studies, six patients who were taking finasteride, one milligram, discontinued due to drug-related sexual experiences, the AEs for five patients resolved. For one patient, AN 1125 from Dr. Rittmaster's cite, the AE erectile dysfunction was still continuing when he discontinued the study. At the time of his discontinuation visit, he was off therapy for 66 days. It does not look like the patient was contacted for resolution of the AE.

Did I read that correctly?

A. Yep.

Q. Okay. So you had reports of six men who discontinued the drug due to

sexual adverse experiences, outlined in paragraph one here, correct?

A. Yes.

Q. Five resolved. One did not, right?

A. At the point of last contact.

Q. Okay. And nobody at Merck made any effort to actually contact him and see if that resolution occurred, correct?

MR. MORROW: Object to the form.

THE WITNESS: I don't believe that's true.

BY MR. BECKER:

Q. Well, it says here in the last sentence, it does not look like the patient was contacted for resolution of the AE.

Did I read that correctly?

THE WITNESS: You did, but it doesn't say that the patient wasn't contacted. And, in fact,

in other documentation about this patient, I believe the reference is that the patient was contacted and had the adverse event present at the later point of last contact.

BY MR. BECKER:

Q. And when was that?

A. I believe that was roughly six months from discontinuation of medication. So it would have been a few months later than the discontinuation visit.

Q. So six months following discontinuation, this patient still was suffering from the adverse event, correct?

A. The patient was still reporting the adverse event.

Q. Okay. The second paragraph goes on to note, during years three through five in the Phase III pivotal studies, 23 patients who were taking finasteride, one milligram, experienced

drug-related sexual adverse experiences. Of these 23 patients, the AEs for seven patients were still present when they discontinued/completed the study. Of the 16 who had AEs resolved, the AEs for seven patients resolved on therapy, and the AEs for nine patients resolved while off therapy.

Did I read that correctly?

A. Uh-huh.

Q. So yet a second group of patients totaling 23 people, correct, that you were evaluating in this e-mail. True?

A. Yes.

Q. Okay. Of those, seven patients were still experiencing the adverse event when they discontinued the study, correct?

A. On drug.

Q. Well, it says, the AEs for seven patients were still present when they discontinued/completed the study, correct?

A. Right. But when they discontinue or complete the study, they are generally on drug.

Q. Well, but when they discontinue, they are no longer on the drug anymore, right?

A. Well, the next day.

Q. Okay. So when did their AEs go away?

A. I can't answer that from this e-mail.

Q. All right. But they still had them on the last day of contact, right?

MR. MORROW: Object to the form.

THE WITNESS: On drug, presumably.

BY MR. BECKER:

Q. Okay. But the next day, they are off the drug, right?

A. Yes.

Q. And you have no idea how long those adverse events continued for,

correct?

MR. MORROW: Object.

THE WITNESS: If we don't have the data, then we don't know.

BY MR. BECKER:

Q. Okay. But for the next 16 men, you do appear to have the data, correct?

A. Right. But what that means is that the patients achieved resolution either on or off therapy while they were still participating in the trial. Once the trial is over, we usually lose contact with the patient.

Q. Okay. For the second group of 16, seven of the men resolved while on the drug, correct?

A. Yes.

Q. And nine of the patients resolved while off therapy, correct?

A. Correct.

Q. How long did it take for them to resolve?

A. I don't know the answer.

I'd have to look at the spreadsheet.

Q. Okay. Now, it's fair to say that Merck never defined the temporal nexus between discontinuation and resolution, correct?

MR. MORROW: Object to the form.

THE WITNESS: Again, the way you're asking that question, the temporal nexus?

BY MR. BECKER:

Q. Well, you knew that for some men, it was going to take a little bit of time for the symptom to resolve, correct?

A. Either in the finasteride or the placebo group.

Q. And you never defined that in the label, correct?

A. I'm sorry. Never defined what?

Q. You never defined, in the label, whether or not -- or how long it would take for these symptoms to resolve upon discontinuation, true?

MR. MORROW: Object to form.
THE WITNESS: That's not in the label. That's correct.
BY MR. BECKER:
Q. Okay. And is there anything in this e-mail that we're looking at that suggested these men were in the placebo wing of the study?
A. The placebo wing, at this time of the extension, was only five -- the continuous group that was on placebo the whole time, that was only five percent of the entire trial.
Q. Right. And so --
A. So we don't have a balanced placebo group after we get through the second year.
Q. Okay. All I'm asking is this:
These men that are being reported here, these 29 men --
A. Yes.
Q. -- they were on finasteride, right?