UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

– – –

IN RE: PROPECIA (FINASTERIDE) PRODUCTS LIABILITY LITIGATION	:	Master File No. 1:12-md-02331-BMC-PK
	:	MDL No. 2331
This Document Relates to: ALL CASES	:	Honorable Brian M. Cogan
	:	Magistrate Judge Judge Peggy Kuo

– – –

May 19, 2016

Confidential - Subject to Protective Order

Oral sworn videotape deposition of CHARLOTTE B. MERRITT, taken at the Short Hills Hilton, John F. Kennedy Parkway, Short Hills, New Jersey, 08078, before Patricia R. Frank, Certified Court Reporter and Notary Public of the State of New Jersey, commencing at 9:31 a.m., on the above date.

– – –

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

let's look to the next label.

(Letter from Dr. Wilkin to Dr. Rozycki and attached 2002 Propecia label marked Exhibit No. 210 for identification.)

BY MR. FISHER:

Q. This is a label from 2002, Exhibit 210. When you're ready, if you turn to the adverse event section -- adverse reaction section in this exhibit, please? It's on page 11.

A. Okay.

Q. You're there on page 11, adverse reactions?

A. Yes.

Q. And you see that here it's still just limited to the 12-month data, right?

MR. HUDSON: Objection.

Q. It begins, "In controlled clinical trials for Propecia of 12-month duration" -- and goes on, right?

MR. HUDSON: Objection.

THE WITNESS: It mentions the fifth year of treatment at the end of that paragraph.

Q. I'm going to come to that. That's right. I'm going to come to that in a moment.

At the beginning it says, "In controlled

clinical trials for Propecia of 12 months" -- and it reports the findings, right?

A. It reports the 12-month incidences, yes.

Q. And if you drop down to the second to last paragraph -- second to last sentence in that paragraph, it states, "Resolution occurred in men who discontinued therapy."

Do you see that?

A. Yes.

Q. So the word "all" has been removed in this label.

A. Yes, it has.

Q. Why was that?

A. Well, as you saw, there were some men in whom after some period of time the AEs did not resolve so this is -- so the word "all" was no longer factual as relates to the longer term data beyond the initial period of the trial.

Q. The sentence has also been changed to take out "58 percent" and replace it with the word "most." Do you see that?

A. Yes.

Q. And you would agree with me that the only change that reflects the fact that there were in fact men who had -- who did not have resolution upon

discontinuation, the only thing that reflects that here is the taking out of the word "all," right?

MR. HUDSON: Objection. Go ahead.

Q. It doesn't also say there were men who did not experience resolution upon discontinuation, right?

A. No, it doesn't say that.

MR. HUDSON: Objection.

Q. And then as you point out, in the last sentence that's been -- the new sentence there, it says, "The incidence of each of the above side effects decreased to less than or equal to 0.3 percent by the fifth year of treatment with Propecia," right?

A. Yes.

Q. Okay. So that's a reference to the fifth year, but there's no reference anywhere else to years two, three or four, right?

A. No, there's not.

Q. Well, isn't this precisely what Dr. Kaufman said in his 2000 e-mail was deceptive, to simply report on the results in the fifth year of the study and not --

A. It's not --

MR. HUDSON: Objection.

Q. I'm going to show you Exhibit 218. Do you recognize this document, 218, a standby statement, Q & A Merck statement in response to the EMEA's recommended label update of Propecia?

A. Not specifically, no.

Q. Okay. Well, I can show you a document that you are on that shows that you were involved in editing of this. Do you need to see that to --

A. No, no, no. It was part of my responsibility to review these types of things. I just meant that I don't have any -- I don't have a specific recollection of this one in particular.

Q. So you don't have any doubt that you were involved in the editing --

A. No.

Q. -- and preparation of this document, right?

A. I was involved in the review of it and perhaps in drafting some of the responses.

Q. So this is a -- as I stated, it's a Merck statement in response to the EMEA's recommended label update, March 17, 2009. And it says, "Communication Issue. We may receive questions from media about the post-marketing reports of persistence of erectile dysfunction following

discontinuation of Propecia and its severity and frequency."

Do you see that?

A. Um-hum.

Q. And the standby statement includes in the middle paragraph there the following statement: "In the Phase 3 clinical trials for Propecia, resolution of erectile dysfunction occurred in men who discontinued therapy because of this side effect."

Do you see that?

A. Yes.

Q. And we talked about that before lunch, about the fact that between the 2001 and 2002 label -- labels the word "all" was removed before the word "men" there, right?

A. Correct.

Q. Because there were cases in the clinical trials of men who discontinued therapy and did not have resolution of the adverse event, right?

A. Yes, that's been established.

Q. On the next page, Ms. Merritt, there is the Q and A. Do you see that?

A. Yes.

Q. And it notes that the -- in the second question, that the labeling change is currently