118

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1 objectionable when we asked your client that 2 question? 3 DR. FRIEDMAN: How come it's objectionable when what? 5 MS. NEWMAN: When we asked your client that question, "Did you report it to the FDA," and 6 7 you wouldn't let him answer the question. 8 DR. FRIEDMAN: I'll have to review what 9 he said in his deposition. I'm not going to accept 10 that as your representation. 11 MS. NEWMAN: Go ahead. We can go on. 12 Q. I'm sorry. I forget the answer. Was the 13 outcome of his surgery reported to the Food and Drug 14 Administration? 15 A. Yes. Where is there an indication that Mr. Morgan's 16 17 outcome was reported to the Food and Drug 18 Administration? 19 MS. NEWMAN: Well, I'm going to object 20 only because, again, we're talking about potentially 21 somewhere around 2,000 pages of documents which 22 aren't here, and if you happen to have them, I'm not 23 going to allow her to look through them now anyway. 24 If you want to ask her if it's in the medical 1 records that she brought, which is what you asked 2 her to bring with her, then that she can answer. 3 Q. In the medical record is there any indication 4 of a report to the Food and Drug Administration? 5 A. Not in the office chart. 6 Is there any other record that would indicate 7 there was a report to the Food and Drug 8 Administration?

A. There are records of reports to the Food and

Q. Now, do I understand from what you've told me

that you reported the outcome of the LASIK surgery

to the Food and Drug Administration, but that such

report did not call it either a complication or an

MS. NEWMAN: One second.

between the witness and Ms. Newman.)

Q. Did you want to add to your answer

question. I had a question for her. Go ahead.

(A discussion took place off the record

MS. NEWMAN: Go ahead. I'm sorry.

MS. NEWMAN: No. She answered your

Drug Administration.

adverse event?

A. Correct.

1 Q. Doctor, at the the bottom of page 1133 and top 2 of 1134 it says under Complications and Adverse 3 Events, "Complications or adverse events that are 4 observed by the investigator or reported by the 5 subject should be recorded on the data collection 6 sheets or in the computerized database for all 7 adverse events, a description of the event, day 8 first observed, any action taken and ultimate 9 outcome will be recorded." Did I read that 10 correctly? 11 A. (Examines document.) Yes, you read it 12 13 Now, I realize that you're saying that you 14 didn't record this as a complication, what happened 15 to Mr. Morgan; is that correct? 16 MS. NEWMAN: Or an adverse event. 17 That was my next question. I understand, 18 Doctor, from what you've said, you don't regard what 19 happened to Mr. Morgan in the two years after his 20 LASIK surgery as either a complication or an adverse 21 event? 22 MS. NEWMAN: Related to the surgery. 23 That's what she said. You can't leave out that 24 part. 121 1 Q. Related to the surgery. All right. Let's add 2 that. 3 A. Correct. 4 0. Doctor, do you consider this a complication or 5 adverse event, in the two years following his LASIK 6 surgery, as unrelated to his surgery? 7 MR. LAPAT: Objection. 8 MS. NEWMAN: No. It's the same 9 objection that I made before in terms of taking 10 words which are defined under FDA protocol and now 11 using them in a confusing and, frankly, not fair 12 manner to the witness. But if you want to ask her 13 about the outcome, go ahead, but not using it in 14 those terms. 15 Q. Well, what I'm trying to do, it says for all adverse events here, "a description of the event, 17 day first observed, any action taken and ultimate 18 outcome will be recorded." It doesn't say adverse events related to the surgery or not related to the 19 20 surgery. It just says, "all adverse events." 21 MS. NEWMAN: You're reading from the 22 protocol; correct?

DR. FRIEDMAN: I am.

MS. NEWMAN: And before you read into

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after . . .

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