

1 IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY  
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA

2 - - -  
3 DOMINIC MORGAN : SEPTEMBER TERM, 2000  
4 :  
5 vs. :  
6 :  
7 HERBERT J. NEVYAS, M.D.. :  
8 and :  
9 JOANN Y. NEVYAS, M.D. :  
10 and :  
11 ANITA NEVYAS-WALLACE, M.D. : NO. 002621  
12 and :  
13 IRA B. WALLACE, M.D. :  
14 and :  
15 EDWARD A. DEGLIN, M.D. :  
16 and :  
17 MITCHELL STEIN, M.D. :  
18 and :  
19 NEVYAS EYE ASSOCIATES, P.C.:  
20 and :  
21 NEVYAS EYE ASSOCIATES OF :  
22 NEW JERSEY, P.C. :

23 - - -  
24 Friday, December 14, 2001  
Philadelphia Pennsylvania  
- - -

1 Oral deposition of ANITA NEVYAS-WALLACE, M.D.,  
2 taken pursuant to notice at The Widener Building,  
3 Mezzanine Conference Room, One South Penn Square,  
4 Philadelphia, Pennsylvania, at 10:10 o'clock a.m.,  
5 on the above date, before Suzanne M. Feezle-  
6 Gigliotti, Court Reporter and Commissioner.

7 - - -  
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1 THE COURT REPORTER: Will there be the  
2 usual stipulations?

3 MS. NEWMAN: Reading and signing.

4 (It is hereby stipulated and agreed by  
5 and among counsel that sealing and filing are  
6 waived; all objections, except as to the form of the  
7 question, are reserved until the time of trial.)

8 ---

9 ANITA NEVYAS-WALLACE, M.D., having been  
10 duly sworn, was examined and testified as  
11 follows . . .

12 DR. FRIEDMAN: Okay. The usual  
13 stipulations and reading and signing you said, and  
14 will that be within 30 days of when the deposition  
15 transcript has been produced?

16 MS. NEWMAN: Whatever the rules say,  
17 sure.

18 DR. FRIEDMAN: Can we agree to 30  
19 days?

20 MS. NEWMAN: We agree to try our best.

21 DR. FRIEDMAN: Fine.

22 BY DR. FRIEDMAN:

23 Q. Doctor, I'm Steven Friedman, sitting next to  
24 me is Michael Friedman and we represent Dominic

1 INDEX

2 EXHIBIT NO. DESCRIPTION PAGE

3 Nevyas-Wallace 1 Two-page Curriculum  
4 Vitae of Anita Nevyas-  
5 Wallace, M.D. 56

6 Nevyas-Wallace 2 Larger Brochure Entitled  
7 Refractive Surgery  
8 Services of the Delaware  
9 Valley Refractive Surgery  
10 Partnership 220

11 Nevyas-Wallace 3 Smaller Brochure Entitled  
12 Refractive Surgery  
13 Services of the Delaware  
14 Valley Refractive Surgery  
15 Partnership 220

16 INSTRUCTIONS NOT TO ANSWER

17 BY MS. NEWMAN:

- 18 Page 8, Line 22 Page 121, Line 4
- 19 Page 10, Line 22 Page 131, Line 17
- 20 Page 11, Line 4 Page 143, Line 8
- 21 Page 11, Line 9 Page 169, Line 1
- 22 Page 11, Line 14 Page 170, Line 14
- 23 Page 11, Line 19 Page 170, Line 22
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- Page 107, Line 4 Page 209, Line 6
- Page 116, Line 7

25 ---

1 Morgan who is a plaintiff in a lawsuit in which you  
2 are one of the defendants.

3 I'm going to be asking you a number of  
4 questions today. If you don't understand a  
5 question, I would like you not to guess at any  
6 answers. I would like you to tell me you don't  
7 understand and we'll see what we can figure out.  
8 I'm sure your counsel also doesn't want you to do  
9 any guessing.

10 MS. SANDS: Mr. Friedman, you'll have  
11 to keep your voice up because I can't hear.  
12 Whatever is blowing back there, it's preventing me  
13 from hearing you.

14 Q. Can you hear me adequately, Doctor?

15 A. Yes.

16 Q. I could barely hear your yes . . .

17 MS. NEWMAN: I'm sorry. For the  
18 record, there are very large fans that are blowing  
19 in back of us. It's a difficult room for a  
20 deposition. I think everybody is going to have to  
21 try to do their best. But unless there is a way to  
22 turn these fans off, it is going to be very  
23 difficult for everybody.

24 DR. FRIEDMAN: Well, Susie, you'll be

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1 law firm, and if there was, it would seem to me that  
2 those documents would be subject to attorney-client  
3 privilege anyway.

4 DR. FRIEDMAN: They may be subject to  
5 that, but I'm only asking what the name of the law  
6 firm was.

7 MR. LAPAT: I don't see how that in any  
8 way bears on the allegations in the Complaint.

9 MS. NEWMAN: Well, why don't we try  
10 getting a yes or no question. Was there a law firm  
11 involved?

12 THE WITNESS: No.

13 MS. NEWMAN: Okay.

14 MR. LAPAT: Would this be an  
15 appropriate time to take a quick break?

16 DR. FRIEDMAN: No, it's not, unless you  
17 want to take a very short break.

18 MR. LAPAT: I was just hoping to run to  
19 the men's room.

20 DR. FRIEDMAN: Okay. Then it's an  
21 appropriate time.

22 (A break was taken from 1:15 p.m. to  
23 1:22 p.m.)

24 BY DR. FRIEDMAN:

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1 A. No.

2 Q. I'm going to show you what was given to me  
3 before by counsel for Dr. Herbert Nevyas, and this  
4 is page 1102, and is this the protocol that you're  
5 talking about?

6 A. **(Examines document.) Yes.**

7 MS. NEWMAN: At least one page of the  
8 protocol.

9 Q. Well, does that page reflect the title of the  
10 protocol?

11 A. **It looks like it, yes.**

12 MS. NEWMAN: Can we have that attached  
13 as an exhibit so we know later what page you're  
14 talking about?

15 DR. FRIEDMAN: It's page 1102.

16 MS. NEWMAN: Okay.

17 Q. Does that protocol have what are called  
18 inclusion criteria and exclusion criteria?

19 A. Yes.

20 Q. I'm going to show you . . .

21 MS. NEWMAN: Hold on one second.

22 DR. FRIEDMAN: You can take time to  
23 talk with your counsel, if you wish.)

24 (A discussion took place off the record

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1 Q. Doctor, for the operation of the LASIK device  
2 in April 1998 was there a protocol that you were  
3 following?

4 A. **What was the question?**

5 DR. FRIEDMAN: Read the question.

6 (The pending question was read by the  
7 court reporter.)

8 A. Yes.

9 Q. And what was that protocol?

10 A. **It was a protocol with the FDA in which data  
11 was reported.**

12 Q. Did the protocol specify who was to have LASIK  
13 surgery performed?

14 A. Yes.

15 Q. And did the protocol specify who was not to  
16 have LASIK surgery performed?

17 A. Yes.

18 Q. Did you use that protocol when you operated on  
19 Mr. Morgan?

20 A. Yes.

21 Q. Did you adhere to that protocol when you  
22 operated on Mr. Morgan?

23 A. Yes.

24 Q. Do you know the name of that protocol?

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1 between the witness and Ms. Newman.)

2 MS. NEWMAN: I'm sorry. Please ask  
3 your question.

4 Q. I'm going to show you what is marked page 1118  
5 of what was given to me by counsel for Dr. Herbert  
6 Nevyas, and ask you is this the inclusion criteria  
7 and the beginning of the exclusion criteria?

8 A. **(Examines document.) Yes.**

9 Q. Is this page, which is 1119, the rest of the  
10 exclusion criteria?

11 A. **(Examines document.) Yes.**

12 Q. Now, under inclusion criteria number 6 it  
13 says, "Best corrected visual acuity of 20/40 or  
14 better in both eyes"; is that correct?

15 A. Yes.

16 Q. Was Mr. Morgan's visual acuity 20/40 or better  
17 in both eyes?

18 A. Yes.

19 Q. And where in the record does it say his visual  
20 acuity was 20/40 or better in both eyes?

21 A. **3/24/97, subjective refraction to 20/40  
22 minus.**

23 Q. Is 20/40 minus the same as 20/40?

24 A. **It is considered 20/40.**

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- 1 Q. Doctor, if it's considered 20/40, why do they  
2 write it as 20/40 with a minus?
- 3 A. **To indicate that there was some equivocation  
4 on one character.**
- 5 Q. What do you mean by "equivocation"?
- 6 A. **That the patient had some unsureness about a  
7 single character on the line. That's still  
8 considered achieving that line.**
- 9 Q. Doctor, were you aware that Mr. Morgan also  
10 had the measurements of 20/40 minus 2 and 20/50?
- 11 A. **The 20/40 -- the 20/50 was not a refraction.**
- 12 Q. And what about the 20/40 minus 2?
- 13 A. **Yes.**
- 14 Q. And is 20/40 minus 2 also considered the same  
15 as 20/40?
- 16 A. **It doesn't matter.**
- 17 Q. Why doesn't it matter?
- 18 A. **Because he was on repeat refraction refracted  
19 to 20/40 minus and that's 20/40.**
- 20 Q. Doctor, do you see in this inclusion criteria  
21 Number 9, and does that say, "Stable manifest  
22 refraction defined as less than one-half diopter  
23 change in cylinder during year prior to the  
24 screening examination"?

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- 1 A. **Yes.**
- 2 Q. Did Mr. Morgan meet that criteria?
- 3 A. **Yes.**
- 4 Q. Doctor, you've told me when he came to see you  
5 he had the best vision that he had ever reported in  
6 his life. Is that stable?
- 7 MS. NEWMAN: I don't think that she  
8 said that, so she can't answer as phrased. The  
9 record will speak for itself, what she said. You  
10 have taken her words out of context. Ask the  
11 information that you want in a different question.  
12 She's not answering that one.
- 13 Q. Doctor, how did you determine that his vision  
14 had been stable for one year prior to the screening  
15 examination?
- 16 A. **By history.**
- 17 Q. Doctor, I want to call your attention to  
18 exclusion criteria number 6, which says, "History or  
19 current evidence of any other physical condition or  
20 illness which would contraindicate outpatient  
21 refractive surgery or preclude the patient's  
22 participation in this study." Do you see that?
- 23 A. **Yes.**
- 24 Q. Did I read that correctly?

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- 1 A. **Yes.**
- 2 Q. Did Mr. Morgan meet that exclusion criteria?
- 3 A. **Yes.**
- 4 Q. Doctor, are you aware that Mr. Morgan had a  
5 prior history of retinopathy of prematurity?
- 6 A. **Yes.**
- 7 Q. And that he had prior strabismus surgery?
- 8 A. **Yes.**
- 9 Q. Are you saying that a history of retinopathy  
10 of prematurity is not a contraindication to LASIK  
11 surgery?
- 12 A. **That is correct.**
- 13 Q. Are you saying that prior strabismus surgery  
14 is not a contraindication to LASIK surgery?
- 15 A. **That is correct.**
- 16 Q. Doctor, I want you to look at pages 1108 and  
17 1109. I'll read this and ask you if I've read it  
18 correctly. "Informed consent was obtained from all  
19 patients prior to the surgical procedure. Patients  
20 were considered eligible for LASIK treatment if they  
21 were at least 18 years of age and not more than 64  
22 years of age, generally had a preoperative best  
23 spectacle corrected visual acuity, parenthesis,  
24 BSCVA, end parenthesis, of 20/40 in the operated

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- 1 eye, had a stable refraction with the refracted area  
2 consisting of myopia between minus 0.0 and minus  
3 25.00 diopters with or without astigmatism."
- 4 MS. NEWMAN: What are you reading  
5 from? Is that part of the protocol?
- 6 DR. FRIEDMAN: That's the bottom.
- 7 Q. Did I read that correctly?
- 8 MS. NEWMAN: No, no, no. Is that part  
9 of the protocol that you're reading or is it from a  
10 different document?
- 11 DR. FRIEDMAN: That's part of the  
12 protocol.
- 13 MS. NEWMAN: Thank you.
- 14 Q. Doctor, is that part of the protocol?
- 15 A. **(Examines document.) You read that  
16 correctly.**
- 17 Q. And continuing on it says, "Patients had no  
18 current or significant previous history of ocular  
19 diseases or conditions or other systemic disease  
20 that prohibited the patients from having refractive  
21 surgery and were taking no medications that would  
22 interfere with postoperative wound healing." Did I  
23 read the next sentence correctly?
- 24 A. **(Examines document.) Yes.**

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1 Q. Following that it says, "Patients who had a  
2 visually impaired fellow eye, parenthesis, 20/50 or  
3 worse BSCVA, closed parenthesis, were also  
4 uneligible for LASIK surgery," period. Did I read  
5 that correctly?

6 MS. NEWMAN: The "period" being at the  
7 end of the sentence as part of the grammar and not  
8 as a word; correct?

9 DR. FRIEDMAN: Yes, grammar.

10 A. (Examines document.) Yes.

11 Q. And the last sentence of that paragraph says,  
12 "The current postoperative visit schedule is one  
13 day, four days, two weeks, one month, three months,  
14 six months and 12 months after LASIK surgery." Did  
15 I read that correctly?

16 A. (Examines document.) Yes.

17 Q. Now, did Mr. Morgan have a preoperative best  
18 spectacle corrected visual acuity of 20/40 in the  
19 operated eye?

20 A. Yes.

21 Q. Where is that reflected in the record?

22 A. 3/24/97, the subjective refraction.

23 Q. You're talking about the 20/40 minus in both  
24 eyes?

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1 went through this -- four days after his left eye  
2 was done did he not complain about the vision?

3 A. He did.

4 Q. Did Mr. Morgan have a complication of LASIK  
5 surgery in either eye?

6 A. No.

7 Q. Did Mr. Morgan have an adverse event of LASIK  
8 surgery in either eye?

9 MS. NEWMAN: As of when?

10 DR. FRIEDMAN: Anytime after the LASIK  
11 surgery was performed.

12 MS. NEWMAN: Up until the last time she  
13 saw him?

14 DR. FRIEDMAN: Yes.

15 A. No.

16 Q. And why do you say he did not have any adverse  
17 event?

18 MS. SANDS: I'm sorry?

19 MS. NEWMAN: Can you answer that as  
20 phrased?

21 THE WITNESS: No. I can't answer that,  
22 no.

23 MS. NEWMAN: I object to the form.  
24 It's a badly worded question.

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1 A. Yes, I am.

2 Q. Doctor, I want to show you pages 1133 and 1134  
3 of what were previously given to me by attorney for  
4 Dr. Herbert Nevyas, and I want to call your  
5 attention to where it says, "complications and  
6 adverse events," and what it lists under those  
7 complications and adverse events.

8 A. (Examines document.)

9 MS. NEWMAN: Do you have a question,  
10 Counsel?

11 DR. FRIEDMAN: I want her just to look  
12 at that.

13 Q. Now, Doctor, are you aware of what  
14 Mr. Morgan's present visual acuity is?

15 A. No.

16 Q. But, Doctor, were you aware that he was not  
17 pleased with his vision after he had the LASIK  
18 surgery performed?

19 MS. NEWMAN: When?

20 DR. FRIEDMAN: Starting with the very  
21 first visit back after his left eye he complained.

22 MS. NEWMAN: Are you asking if he  
23 wasn't pleased after the first visit?

24 Q. Were you aware that he had complained -- we

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1 Q. Doctor, I'm going to read what it defines  
2 adverse events as: "Postoperative complications  
3 that are serious in nature of vision or life  
4 threatening and all unanticipated adverse device  
5 effects should be recorded as adverse events. LASIK  
6 adverse events should include, but are not limited  
7 to," and it gives a list.

8 Was Mr. Morgan's visual acuity  
9 postoperative an anticipated or unanticipated  
10 event?

11 MS. NEWMAN: Can you pick a date?

12 Because she said already that early after the  
13 surgery that she would expect the vision -- at one  
14 time she was talking about where it was recorded as  
15 20/70 postoperatively, and there were a lot of  
16 visits afterwards and in between.

17 Q. Doctor, when was the last time Mr. Morgan was  
18 seen at Nevyas Eye Associates?

19 A. 3/27/2000.

20 Q. And 3/27/2000 was almost two years after the  
21 surgery was performed, just about a month shy of  
22 being two years after surgery.

23 A. Is that a question?

24 Q. Is that correct? Is that a correct statement?

1 A. Yes.

2 Q. As of that time, almost two years after the  
3 LASIK surgery was performed, did you consider  
4 Mr. Morgan to have had an adverse event during that  
5 time?

6 A. No.

7 Q. How do you define an adverse event?

8 MS. NEWMAN: No. That's not a proper  
9 question. You asked it in terms of the protocol,  
10 and in terms of the protocol, she answered your  
11 question.

12 Q. In terms of the protocol, Doctor, looking at  
13 complications or adverse events, how do you define  
14 what happened to Mr. Morgan?

15 MS. NEWMAN: I'm going to object to the  
16 form, because you're assuming in the question that  
17 what happened to Mr. Morgan is either an adverse  
18 event or a complication, which she has already said  
19 it's not.

20 Q. Doctor, let's look at that last visit of  
21 3/27/2000. What was Mr. Morgan's visual acuity at  
22 that time?

23 A. 20/80 minus.

24 Q. How many lines of vision drop is that from his

1 A. Not an event of the surgery.

2 Q. Not . . .

3 A. Not a consequence of the surgery.

4 Q. And how did you determine it was not a  
5 consequence of the surgery?

6 A. By examining the patient.

7 Q. Doctor, let's make a category, adverse events  
8 as a consequence of the surgery and adverse events  
9 not related to the surgery. Was this an adverse  
10 event not related to the surgery?

11 MR. LAPAT: I object to this question.  
12 Adverse event is a defined term with a specific  
13 meaning, and I think the problem here is you're  
14 conflating Mr. Morgan not getting the result he  
15 desired with an adverse event. Those are not  
16 necessarily the same thing, and certainly your  
17 question is improper and confusing and designed to  
18 mislead the witness.

19 MS. NEWMAN: I'm going to object and  
20 instruct her not to answer on the same reason. She  
21 has already told you that it is not an adverse event  
22 as a consequence of the surgery. Now you're taking  
23 "adverse event" and you're using it in a totally  
24 different matter, which is very confusing.

1 preoperative visual acuity?

2 A. Four.

3 Q. Are you saying that four lines is not  
4 considered an adverse event?

5 MS. NEWMAN: For Mr. Morgan?

6 DR. FRIEDMAN: For Mr. Morgan.

7 MS. NEWMAN: I object to the form. You  
8 can answer it as per Mr. Morgan.

9 A. I can't answer it as phrased.

10 Q. You can't answer it as what?

11 A. As phrased.

12 Q. What's your problem with the question?

13 A. Whether a drop in vision is necessarily  
14 referable to the surgery.

15 Q. Well, for whatever reason, was Mr. Morgan's  
16 vision worse in the two year period after surgery  
17 than it was before surgery?

18 A. Yes.

19 Q. And your answer is yes?

20 A. Yes.

21 Q. For whatever reason, was this drop in visual  
22 acuity considered by you as an adverse event?

23 MS. NEWMAN: Asked and answered.  
24 Answer it again.

1 I don't think you're trying to ask her  
2 is it not a good thing that his vision dropped four  
3 lines. I think that anybody will say it's not a  
4 good thing under any circumstances if a person's  
5 vision has dropped four lines, but you can't use the  
6 word "adverse event" after it has already been  
7 defined in the protocol for the same meaning.

8 Q. Doctor, was the outcome of Mr. Morgan's  
9 surgery reported to either the Institutional Review  
10 Board or the Food and Drug Administration?

11 A. Yes.

12 Q. And how was it reported?

13 MS. NEWMAN: You asked a compound  
14 question. If you want to start with which one it  
15 was reported to?

16 DR. FRIEDMAN: Sure.

17 Q. Was the outcome of Mr. Morgan's surgery  
18 reported to the Institutional Review Board?

19 A. I believe so.

20 Q. Was the outcome of Mr. Morgan's surgery  
21 reported to the Food and Drug Administration?

22 A. Yes.

23 MS. NEWMAN: How come it's not  
24 objectionable to ask her that question, but it was

1 objectionable when we asked your client that  
2 question?

3 DR. FRIEDMAN: How come it's  
4 objectionable when what?

5 MS. NEWMAN: When we asked your client  
6 that question, "Did you report it to the FDA," and  
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.

16 Q. Where is there an indication that Mr. Morgan's  
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 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 correctly.

13 Q. 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 Q. 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.

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 Q. Is there any other record that would indicate  
7 there was a report to the Food and Drug  
8 Administration?

9 A. There are records of reports to the Food and  
10 Drug Administration.

11 Q. Now, do I understand from what you've told me  
12 that you reported the outcome of the LASIK surgery  
13 to the Food and Drug Administration, but that such  
14 report did not call it either a complication or an  
15 adverse event?

16 A. Correct.

17 MS. NEWMAN: One second.  
18 (A discussion took place off the record  
19 between the witness and Ms. Newman.)

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

21 Q. Did you want to add to your answer  
22 after . . .

23 MS. NEWMAN: No. She answered your  
24 question. I had a question for her. Go ahead.

1 Q. Related to the surgery. All right. Let's add  
2 that.

3 A. Correct.

4 Q. 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  
16 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  
19 events related to the surgery or not related to the  
20 surgery. It just says, "all adverse events."

21 MS. NEWMAN: You're reading from the  
22 protocol; correct?

23 DR. FRIEDMAN: I am.

24 MS. NEWMAN: And before you read into

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1 the record the protocol's definition of adverse  
2 events and complications. Did I hear that? Because  
3 if that's true, it would seem to me that what that  
4 is referring to is adverse events as defined in  
5 there related to the surgery.

6 MR. LAPAT: What are you suggesting?  
7 That if he's walking down the street and had a heart  
8 attack that that's an adverse event that she needs  
9 to report?

10 DR. FRIEDMAN: No.

11 MR. LAPAT: Because we would all agree  
12 that that's an adverse event, wouldn't we?

13 MS. NEWMAN: And that's the point. Is  
14 that that cannot in any way reasonably be read to  
15 read that way. If you want to clarify for her that  
16 she didn't read it that way, that's fine. But  
17 that's exactly taken to the extreme. None of us  
18 would think -- he was in a car accident after this  
19 surgery, that certainly is an adverse event, and I  
20 don't think that you're saying that Dr. Wallace  
21 should have reported that to the FDA.

22 DR. FRIEDMAN: It says here, "Events  
23 that are observed by the investigator or reported by  
24 the subject."

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1 reported to the FDA. Did she do that?

2 MS. NEWMAN: Did she report something  
3 that she did not believe to be an adverse event of  
4 the surgery to the FDA under the FDA protocol?

5 DR. FRIEDMAN: That's been answered.  
6 It's because what he believed . . .

7 MS. NEWMAN: I think that you're making  
8 an argument to the jury. She's not answering the  
9 question the way you have phrased it. If you want  
10 to argue that to the jury, go ahead. That is an  
11 unfair and improper question to this ask witness.

12 MR. LAPAT: Again, you're conflating  
13 adverse event with Mr. Morgan not getting the result  
14 that he desired, and it's not the same.

15 BY DR. FRIEDMAN:

16 Q. For the report that you did make to the Food  
17 and Drug Administration where you reported what the  
18 outcome of the surgery was, in what report would  
19 that have been?

20 A. **That would have been in a data compilation  
21 sent to the FDA.**

22 Q. What date would the compilation be?

23 A. **I don't know.**

24 MS. NEWMAN: No, data compilation.

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1 MS. NEWMAN: So are you saying then  
2 that if he told her about that car accident that she  
3 would be liable for not reporting it to the FDA?  
4 That doesn't make sense.

5 DR. FRIEDMAN: The reason we're here is  
6 because of a lawsuit which he's claiming that he had  
7 either a complication or adverse event . . .

8 MS. NEWMAN: I understand that, and  
9 she's told you she doesn't believe that it's related  
10 to the surgery.

11 DR. FRIEDMAN: It doesn't say that. It  
12 says here, "Complications or adverse events that are  
13 observed by the investigator or reported by the  
14 subject."

15 MR. LAPAT: By definition, with what  
16 you just said, of course it relates to the surgery.

17 DR. FRIEDMAN: He reported it to her,  
18 "We have a lawsuit here." He's claiming it is  
19 either a complication or adverse event.

20 MS. NEWMAN: And we're claiming it's  
21 not; right?

22 DR. FRIEDMAN: But it says right here,  
23 anything that's observed by the investigator or  
24 reported by the subject should be recorded and then

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1 Q. Data compilation, but what date would that  
2 data compilation have been?

3 A. **I don't know.**

4 Q. How were the data compilations kept? Are they  
5 a running, that is to say, are they done on a yearly  
6 basis, a quarterly basis? How are they kept?  
7 Monthly?

8 A. **I don't know the exact frequency.**

9 Q. I'm going to show you what is page 1112 and  
10 this has a Table 3 and a Table 4. Table 3 is called  
11 Postoperative Best Uncorrected Visual Acuity,  
12 parenthesis BUCVA, closed parenthesis, and Table 4  
13 is called Postoperative Best Spectacle Corrected  
14 Visual Acuity, parenthesis, BSCVA, closed  
15 parenthesis. Did I read that correctly?

16 A. **(Examines document.) Yes.**

17 Q. And for "A. Nevvas" at "One Month" under "For  
18 All Patients Listed at 20/50 to 20/100" in Table 3  
19 there are two patients and "For 20/200 or Worse"  
20 there are also two patients; is that correct?

21 A. **(Examines document.) Which table are you  
22 referring to?**

23 Q. Table 3.

24 A. **Yes.**

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1 A. To let people know that there is a possibility  
2 that they might be candidates to be more independent  
3 from their glasses and contact lenses.

4 Q. And in that KYW advertisement what were the  
5 patients instructed to do to find out that  
6 information?

7 MS. NEWMAN: Do you remember?

8 MS. SANDS: Objection.

9 MR. LAPAT: Objection.

10 MS. NEWMAN: Do you remember, Doctor?

11 THE WITNESS: I think I remember.

12 MS. NEWMAN: Tell him to the best of  
13 your recollection.

14 A. I think they were instructed to call a phone  
15 number for more information.

16 Q. What phone number was that? I mean, who owned  
17 that phone number?

18 MS. NEWMAN: I object to the form of  
19 "who owned it," but go ahead, you can answer.

20 A. I don't know what number ran in the ad.

21 Q. Doctor, who were they supposed to call? I  
22 know there was a number, but who was being called at  
23 the other end of that number?

24 A. Nevyas Eye Associates.

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1 Q. What is the requirement for daytime driving in  
2 Pennsylvania?

3 A. I'm not sure.

4 Q. What is the requirement for nighttime driving  
5 in New Jersey?

6 A. I don't know.

7 Q. What is the requirement for daytime driving in  
8 New Jersey?

9 A. I don't know.

10 Q. In April of 1998 were you aware of the  
11 requirements but have since forgot, for example, in  
12 either Pennsylvania or New Jersey?

13 MS. NEWMAN: Do you know what you have  
14 forgotten is the question.

15 A. I don't know what I've forgotten.

16 Q. When you first saw Mr. Morgan in 1998 was he  
17 working or not, do you have any recollection or can  
18 you tell from your . . .

19 A. He was a computer worker is what I have  
20 written here.

21 Q. Was he working full time, part time? Do you  
22 have any indication of that?

23 A. No.

24 Q. Was he working daytime or nighttime?

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1 Q. Did the Food and Drug Administration ever give  
2 you or Nevyas Eye Associates any parameters as to  
3 what you could advertise?

4 MS. NEWMAN: I'm going to object. I  
5 don't believe there is anything legally by the Food  
6 and Drug Administration having anything to do with  
7 monitoring a physician's advertising.

8 Q. Doctor, what are the visual requirements for  
9 driving in Pennsylvania?

10 A. 20/50 or better in one eye. I'm not sure.

11 MS. NEWMAN: Is that an amendment to  
12 your answer?

13 THE WITNESS: It's an amendment to my  
14 answer.

15 Q. Are you saying you don't know what the  
16 requirements are for driving?

17 A. I'm saying that I think I just quoted the  
18 requirements for night driving.

19 Q. Let me get this straight. 20/50 vision in one  
20 eye?

21 A. In one eye.

22 Q. 20/50 vision or better in one eye is the  
23 requirement for night driving in Pennsylvania?

24 A. Yes.

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1 A. No. I don't have any indication.

2 Q. Doctor, is LASIK surgery considered elective  
3 surgery?

4 A. Yes.

5 Q. Are there any situations where LASIK surgery  
6 is not elective surgery?

7 A. What do you mean by "elective"?

8 Q. Well, in your consent form that you use, do  
9 you describe LASIK surgery as being elective or not?

10 A. (Examines documents.) Yes.

11 Q. Yes, you describe LASIK surgery as being what?

12 A. Elective.

13 Q. Are there any circumstances where LASIK  
14 surgery is not elective?

15 A. No.

16 Q. Can LASIK surgery improve a patient's visual  
17 acuity over his best corrected visual acuity before  
18 the LASIK surgery?

19 A. Can it ever? Has it ever?

20 Q. Yes.

21 A. It's been reported.

22 Q. Did you tell that to Mr. Morgan?

23 A. I told him the opposite.

24 Q. What did you tell Mr. Morgan?

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- 1 **A. I told him that his vision would not be any**  
 2 **better than the best correction and that it might**  
 3 **drop.**  
 4 Q. When you told him that his vision might drop,  
 5 did you indicate to him how much it might drop?  
 6 **A. Yes. I told him he could lose one or both**  
 7 **eyes or he could die.**  
 8 Q. Where does it indicate that?  
 9 **A. I didn't write that here, but that is what I**  
 10 **told him. Here I wrote, "Discussed in detail that**  
 11 **visual acuity will not improve and that damage to**  
 12 **retina from ROP is not going to improve. Also**  
 13 **discussed that best corrected visual acuity could**  
 14 **decrease."**  
 15 Q. Did you discuss how much the visual acuity  
 16 could decrease?  
 17 MR. LAPAT: She just said she told him  
 18 he could lose both eyes or die.  
 19 DR. FRIEDMAN: Counsel, let me have it  
 20 from the witness.  
 21 **A. I told him he can go completely blind.**  
 22 Q. In April 1998, what was the visual acuity  
 23 defect beyond which you would not perform LASIK?  
 24 **A. What do you mean by "visual acuity defect"?**

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- 1 Q. Well, how bad would a visual acuity have to  
 2 be, how abnormal would a visual acuity have to be in  
 3 1998 beyond which you would not perform LASIK?  
 4 **A. How many diopters of myopia?**  
 5 Q. Let's do diopters and let's do Snellen's.  
 6 MS. NEWMAN: I'm going to object only  
 7 to the form of the question that it excludes all  
 8 other indications or exclusions, et cetera, for  
 9 LASIK, and with that she can answer your question.  
 10 **A. How many diopters of myopia would I have**  
 11 **operated?**  
 12 Q. That's the first part of the question.  
 13 **A. Okay. About 11.**  
 14 Q. And the second part of the question, visual  
 15 acuity in terms of Snellen's Eye Chart?  
 16 **A. Best corrected acuity needed to be the 20/40**  
 17 **level.**  
 18 Q. The 20/40 level?  
 19 **A. (Witness nods head.)**  
 20 Q. Is the 20/40 level different than the 20/50  
 21 level?  
 22 **A. The 20/40 level is different from the 20/50**  
 23 **level.**  
 24 Q. Are you answering yes, it is, or are you

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- 1 repeating my question?  
 2 **A. I was answering.**  
 3 Q. I'm sorry. My question was is the 20/40 level  
 4 different from the 20/50 level, and do I understand  
 5 your answer is yes, it is different?  
 6 **A. Yes.**  
 7 Q. And, Doctor, why would the 20/40 level have  
 8 been your cutoff for performing LASIK in April of  
 9 1998?  
 10 **A. It was stipulated in our protocol.**  
 11 Q. Was there any other reason?  
 12 **A. It seemed appropriate to me.**  
 13 Q. It seemed appropriate?  
 14 **A. It seemed appropriate.**  
 15 Q. And why did it seem appropriate?  
 16 **A. Because that was my judgment.**  
 17 Q. Doctor, why was it your judgment that it was  
 18 appropriate to have a cutoff in the 20/40 level for  
 19 doing LASIK surgery in April 1998?  
 20 MS. NEWMAN: Is there something that  
 21 you're getting at here? Because I'm not hearing  
 22 it. She is answering your questions and I'm not  
 23 really understanding where you're going. Doctor, do  
 24 you understand?

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- 1 DR. FRIEDMAN: She hasn't answered  
 2 anything.  
 3 MS. NEWMAN: She has answered.  
 4 DR. FRIEDMAN: No. She said, first of  
 5 all, that it was a protocol and then I said, "Well,  
 6 are there other reasons," and she said, "Well, it  
 7 seemed appropriate," and I'm trying to find out why  
 8 she feels it's appropriate.  
 9 MS. SANDS: She told you.  
 10 DR. FRIEDMAN: Because it's in her  
 11 judgment.  
 12 MS. NEWMAN: Right.  
 13 DR. FRIEDMAN: I'm trying to find out  
 14 why in her judgment it's appropriate.  
 15 MS. NEWMAN: I don't understand that  
 16 question. If the doctor can understand it, she can  
 17 answer it. Go ahead.  
 18 **A. I don't understand the question.**  
 19 Q. Doctor, did you have any thoughts, opinions or  
 20 feelings as to a cutoff point of the 20/40 level for  
 21 LASIK surgery in April 1998 that were separate from  
 22 what the FDA had put in the protocol?  
 23 MS. NEWMAN: Other than what she had  
 24 already said, that it seemed appropriate and was her

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1 judgment? She said that. You're looking at me like  
2 how can I say that? Because she just said that,  
3 Steve.

4 DR. FRIEDMAN: I would like to hear her  
5 answer, not yours.

6 MS. NEWMAN: No, no, other than what  
7 she's already said?

8 DR. FRIEDMAN: She hasn't answered.

9 MR. LAPAT: She just said those words.

10 MS. NEWMAN: She said what I just said,  
11 Steve. Those are not my words, those are her words.  
12 You just asked her the question.

13 DR. FRIEDMAN: And then I asked her why  
14 is it appropriate and she said in her judgment.

15 MS. NEWMAN: Right.

16 DR. FRIEDMAN: I'm trying to find out  
17 is she just repeating what is in the protocol or is  
18 she using her own judgment as a physician as to why  
19 she is agreeing with the FDA on that 20/40 level.

20 MS. NEWMAN: She just said it seemed  
21 appropriate in her judgment.

22 BY DR. FRIEDMAN:

23 Q. Why was it appropriate in your judgment,  
24 Doctor?

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1 **acuity without an improvement in his best corrected**  
2 **acuity.**

3 Q. Doctor, how much of the cornea is used for  
4 focusing in a patient like Mr. Morgan?

5 **A. How much of the cornea?**

6 Q. How much of focusing of the eye is due to the  
7 cornea in a patient such as Mr. Morgan?

8 MR. LAPAT: Objection; vague.

9 MS. NEWMAN: Can you answer that? I  
10 don't know what you mean in terms of "a patient such  
11 as Mr. Morgan."

12 Q. Specifically in Mr. Morgan in April 1998, was  
13 his focusing for visual acuity more dependent upon  
14 his lens or his cornea?

15 **A. Both were essential.**

16 Q. I understand. Which would have the greater  
17 effect on his visual acuity?

18 MR. LAPAT: Objection.

19 MS. NEWMAN: If you can answer, go  
20 ahead.

21 **A. Effect compared to what?**

22 Q. Effect in focusing, Doctor.

23 **A. If which were suddenly absent, what would have**  
24 **the more profound impact on his refraction?**

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1 MS. NEWMAN: If you can answer it any  
2 further than you did, you can go ahead.

3 **A. I believe that's a complete answer.**

4 Q. Do you have any foundation for why that would  
5 be appropriate in your judgment?

6 MS. NEWMAN: Other than the hour that  
7 we spent at the beginning of the deposition on her  
8 training and experience in this area?

9 Q. Doctor, what concerns would you have about  
10 doing LASIK on a patient whose best corrected visual  
11 acuity was worse than the 20/40 level?

12 MS. NEWMAN: I object to the point that  
13 it's put in a vacuum, but to the degree that she  
14 can, she can answer.

15 **A. That even an excellent refractive result might**  
16 **not be pleasing to the patient.**

17 Q. Why would that be any different for vision  
18 worse than the 20/40 level as compared to vision  
19 better than the 20/40 level?

20 MS. NEWMAN: I don't understand that.  
21 If the doctor does, she can answer it.

22 **A. A patient whose vision is diminished is likely**  
23 **to be unhappy with his best corrected acuity and may**  
24 **not be happy with an improvement in his unaided**

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1 Q. Okay. You can answer that question. Go  
2 ahead.

3 MR. LAPAT: That's an absurd question.

4 DR. FRIEDMAN: She is asking her own  
5 questions.

6 MS. NEWMAN: No. She's asking you what  
7 you just asked.

8 MR. LAPAT: She's asking you to clarify  
9 the question because she said basically . . .

10 Q. Doctor, if there is such a thing as focusing  
11 and Mr. Morgan focused and when he focused he did  
12 100 percent of his focusing, you said that both the  
13 cornea and the lens were important for focusing.  
14 And I'm just asking you was the cornea responsible  
15 for 50 percent of his focusing, 75 percent, 99  
16 percent?

17 MS. NEWMAN: As compared only to the  
18 lens?

19 DR. FRIEDMAN: As compared to the  
20 lens.

21 MS. NEWMAN: If you can answer that  
22 question, you can do it. If you can't, tell him.

23 MR. LAPAT: Objection.

24 **A. I can't.**

1 MS. NEWMAN: It sounds to me which toe  
2 is more effective for your balancing, the middle one  
3 or the one next to it. Go on.

4 Q. When you saw Mr. Morgan in March and April of  
5 1998 preoperatively, did he have any indication of  
6 cataracts in his eyes?

7 A. No.

8 Q. Is it your understanding that Mr. Morgan has  
9 developed cataracts in his eyes since his LASIK  
10 surgery has occurred? Your understanding and I'm  
11 talking to the period up to the last time you saw  
12 Mr. Morgan in the Nevyas Eye Associates group, which  
13 was about almost two years after the surgery.

14 MR. LAPAT: Objection.

15 MS. NEWMAN: I believe it was March of  
16 2000. You can answer.

17 A. Yes.

18 Q. And would you tell me what you found in terms  
19 of his cataracts?

20 A. "Oil drop nuclear sclerosis, worse o.d. than  
21 o.s., even with hard contact lenses in both eyes to  
22 neutralize the potential, open quote, oil drop,  
23 closed quote, effect of corneal ablation." What was  
24 the question?

1 A. **Seeing a second image as a ghost next to the  
2 first, an outline of a second image.**

3 Q. Was Mr. Morgan complaining of a ghost image?

4 A. Yes.

5 Q. When was this nuclear sclerosis first detected  
6 by you or anybody else in your group?

7 A. 3/9/2000.

8 Q. And who detected that?

9 A. **Dr. Herbert Nevyas.**

10 Q. Can you read what he says about that, just his  
11 handwriting?

12 A. **Just his handwriting. "Dilated, some nuclear  
13 sclerosis both eyes," then I'm going to have to turn  
14 to the narrative.**

15 Q. What narrative is that?

16 A. **Dictated off the chart notes.**

17 Q. Is this something that's part of the patient's  
18 chart?

19 MS. NEWMAN: No, it's not.

20 A. **No. "Difficult to evaluate in read reflex  
21 because of LASIK ablation. Ophthalmoscopic  
22 Examination: ROP," retinopathy of prematurity.  
23 "Number two, dragged disc both eyes, question of  
24 nuclear sclerosis, write to Hopkins, return six**

1 Q. Where are you reading from?

2 A. **My Impression on March 27th.**

3 Q. March 27th, 2000?

4 A. Yes.

5 Q. And where is that at, under Impression?

6 A. **The bottom of the page.**

7 Q. Okay. Finish reading it then.

8 A. **"However, laser interferometry and potential  
9 acuity meter do not show improved retinal acuity.  
10 Cataract surgery o.d. could possibly help visual  
11 acuity, but probably no real change. No change in  
12 ghost image with hard contact lenses."**

13 MS. NEWMAN: Wait one second. Let's  
14 take a break.

15 (A break was taken from 3:25 p.m. to  
16 3:30 p.m.)

17 Q. Doctor, you were reading under the Impression  
18 about the oil drop nuclear sclerosis. Does that  
19 mean a cataract?

20 A. Yes.

21 Q. And had you finished reading what you wrote  
22 there?

23 A. **I think I finished.**

24 Q. What are ghost images?

1 months."

2 Q. Question of nuclear sclerosis.

3 A. **No, it doesn't say that. It says, "some  
4 nuclear sclerosis."**

5 DR. FRIEDMAN: Are you saying that I'm  
6 not entitled to have the typed things in my  
7 production requests?

8 MS. NEWMAN: I'm not sure. They're not  
9 part of the chart.

10 DR. FRIEDMAN: Have you indicated to me  
11 that you have such things but that you are not going  
12 to be producing them and why?

13 MS. NEWMAN: I don't know. There have  
14 been a lot of discovery requests.

15 DR. FRIEDMAN: Aren't you supposed to  
16 tell me what you are going to produce and why?

17 MS. NEWMAN: I don't know. There have  
18 been numerous discovery requests in this case, the  
19 hundreds of interrogatories and requests for  
20 production of documents, what you have asked for in  
21 this case and what my answers have been and whether  
22 or not you are entitled to them.

23 DR. FRIEDMAN: Don't you think it would  
24 be nice if you did note what I had asked for?

1 MS. NEWMAN: Go on.  
 2 DR. FRIEDMAN: It doesn't have anything  
 3 to do with what the time was.  
 4 MS. NEWMAN: Question, please.  
 5 BY DR. FRIEDMAN:  
 6 Q. Doctor, what were you charging in April 1998  
 7 for performing LASIK eye surgery? What did you  
 8 charge Mr. Morgan?  
 9 MS. NEWMAN: That you may answer. Go  
 10 ahead.  
 11 A. \$2,500.00 per eye.  
 12 Q. Was that your usual and customary fee?  
 13 A. Yes.  
 14 Q. Was that fee larger than what was necessary to  
 15 recover the costs of manufacture, research,  
 16 development and handling of the device?  
 17 MS. NEWMAN: Don't answer the  
 18 question.  
 19 MR. LAPAT: Objection.  
 20 MS. NEWMAN: Just don't answer the  
 21 question, next question.  
 22 Q. Doctor, do you know what it costs to  
 23 manufacture, research, develop and handle the  
 24 device?

1 MS. NEWMAN: Don't answer the  
 2 question. Next question, please.  
 3 MR. LAPAT: Objection.  
 4 Q. In performing LASIK surgery, I believe you  
 5 said that the results could not make a person's  
 6 visual acuity any better than what his best  
 7 corrected acuity preoperatively. Did you say that?  
 8 MR. LAPAT: Objection. Who knows what  
 9 you just said. That was a badly mangled question  
 10 and I don't think she understands it.  
 11 MS. NEWMAN: Did you understand the  
 12 question, Doctor?  
 13 THE WITNESS: No.  
 14 Q. Doctor, I want to just turn your attention to  
 15 when LASIK surgery is performed, in what number of  
 16 patients or percentage of patients are the results  
 17 to the patient not satisfactory?  
 18 MS. NEWMAN: Don't answer the question.  
 19 MR. LAPAT: Objection; vague.  
 20 MS. NEWMAN: She can't answer what  
 21 someone else thinks and what someone else feels.  
 22 Q. Doctor, what percentage of patients that you  
 23 or your group have performed LASIK surgery on have  
 24 expressed dissatisfaction with the procedure?

1 MS. NEWMAN: Don't answer the  
 2 question.  
 3 MR. LAPAT: Objection.  
 4 MS. NEWMAN: Next question, Counsel.  
 5 Q. Doctor, at the time that you operated on  
 6 Mr. Morgan in 1998 had you had experience doing  
 7 LASIK surgery on other patients with retinopathy of  
 8 prematurity?  
 9 MS. NEWMAN: You may answer.  
 10 A. I don't recall.  
 11 Q. At the time you operated on Mr. Morgan in  
 12 April 1998 had you had any experience operating on  
 13 patients whose visual acuity was in the 20/50 level?  
 14 MS. NEWMAN: Don't answer the question.  
 15 Q. Had you had any experience at the time you  
 16 operated on Mr. Morgan in April 1998 performing  
 17 LASIK on patients who had visual acuity in the 20/40  
 18 level?  
 19 MS. NEWMAN: Can you answer that?  
 20 A. Yes.  
 21 Q. And had you had experience with patients who  
 22 had visual acuity in the 20/40 minus radius?  
 23 A. I don't recall.  
 24 Q. Pardon me?

1 A. I don't recall.  
 2 Q. How about 20/40 minus 2?  
 3 MS. NEWMAN: Do you recall?  
 4 A. I don't recall.  
 5 Q. I'll ask it in case I didn't cover it, how  
 6 about 20/50?  
 7 MS. NEWMAN: I said, "Don't answer the  
 8 question."  
 9 Q. Doctor, how do you explain Mr. Morgan's  
 10 decreased visual acuity postoperatively?  
 11 MS. NEWMAN: As of March 27, 2000?  
 12 DR. FRIEDMAN: Yes.  
 13 A. He's developed cataracts.  
 14 Q. Is that the only reason for his decreased  
 15 visual acuity? Is there any other . . .  
 16 A. I can't say.  
 17 Q. During the time that you were seeing  
 18 Mr. Morgan did you consider that there would be any  
 19 other explanation other than cataracts?  
 20 A. Yes.  
 21 Q. And what did you consider?  
 22 A. Considered retinal disease, considered optic  
 23 nerve disease, considered corneal problems.  
 24 Q. And did you eliminate these?