

1 Morris Waxler - cross

2 there were -- certainly prior to the IDE, they were
3 in violation of the FDA rules and regulations; and
4 during that period, they violated protocol. So
5 I -- I'm also not a lawyer. This should not -- I'm
6 not a lot of things actually. So I can't speak to
7 the -- whether the level of criminality is
8 approached.

9 Q This letter is dated December 4, 2003, which I
10 will represent to you is two years after the
11 Nevyases ceased their use of the IDE laser.

12 You think this letter is warranted?

13 A Not my judgment.

14 Q Outright criminal activity?

15 MS. FITZGERALD: Objection.

16 BY MR. SILVERMAN:

17 Q Possible outright criminal activity?

18 A I'm familiar with the Office of Criminal
19 Investigation. I have sent my own letters to the
20 Office of Criminal Investigation on other matters.
21 It's available to many citizens who believe that
22 there is an issue.

23 That communication is confidential to the
24 agency, to the Office of Criminal Investigation.
25 And even if it's confidential inside the agency --

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2 because I had occasion when I was branch chief to
3 have to report a clinic that was illegally using
4 off-label, and I reported them to the Office of
5 Criminal Investigation. They did not get back to
6 me, and I was a branch chief.

7 So it is -- it's there as conduit to explore
8 complaints, explore issues that relate to
9 criminality in particular.

10 Q Are you aware that this letter was published
11 on the internet accusing the Nevyases of possible
12 outright criminal activity?

13 MS. FITZGERALD: Objection.

14 BY MR. SILVERMAN:

15 Q And demanding urgent action?

16 THE COURT: I think the Google talks
17 about Dr. Anita -- Dr. Anita Nevyas, target of
18 FDA criminal complaint, December 4, 2003.

19 MR. SILVERMAN: But also, Your
20 Honor, the entire letter was published, not
21 just that --

22 THE COURT: I understand.

23 MS. FITZGERALD: What you just
24 quoted, Your Honor, is a different website,
25 somebody else's website, lasikfraud.com.

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2 THE COURT: I know. What's the end
3 result?

4 THE WITNESS: The question is?

5 BY MR. SILVERMAN:

6 Q Are you aware of the harm that a letter like
7 this, once it's published, can reek?

8 A I mean surely not a -- something you want to
9 have written about yourself. I was not aware, to
10 answer your earlier question, of -- I don't spend
11 my time touring the internet to look for what's on
12 Dom's website or other websites.

13 I try to do my work and keep my clients happy,
14 and so I was not until very recently aware that
15 this was a dispute. So, you know, my feelings
16 about this are irrelevant from a regulatory point
17 of view.

18 Q Isn't it true?

19 A What's that?

20 Q Isn't it true that one of the reasons that
21 confidentiality is given to letters to the Office
22 of Criminal Investigation is because there's such a
23 possibility of harm if they are not treated
24 confidentially?

25 A Correct.

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2 I -- when I sent my letters to the Office of
3 Criminal Investigation, which fortunately are very
4 few and far between, I want the Office of Criminal
5 Investigation to keep it confidential for precisely
6 that reason.

7 Q You don't want it published on the internet;
8 do you --

9 A No.

10 Q -- for the entire world to see?

11 A Correct.

12 - - - - -

13 (Pause.)

14 - - - - -

15 MR. SILVERMAN: Thank you,
16 Dr. Waxler.

17 THE COURT: Mr. Morgan, any
18 questions?

19 MR. MORGAN: None at this time, Your
20 Honor.

21 THE COURT: Well, let me put it this
22 way: Dr. Waxler is going to be leaving. It's
23 not a question like he's a party and you can
24 call him back.

25 MR. MORGAN: Okay.

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2 THE COURT: I don't know if you have
3 any questions or not. If you do, ask them
4 now.

5 MR. MORGAN: Thank you, Your Honor.

6 THE WITNESS: I appreciate that,
7 Judge.

8 BY MR. MORGAN:

9 Q Hi, Dr. Waxler.

10 Those documents that I had sent you regarding
11 the Nevayases' study, can you tell me what you
12 remember saying to me after I spoke to you, you
13 know, after you reviewed them?

14 A Not really. Remind me. I -- you know, this
15 was some time ago. That was --

16 Q Do the words, "Wow, I'm surprised at what they
17 got away with," come to mind?

18 A It could have been. It could have been.

19 Q Remember --

20 A I tend to be expressive sometimes.

21 Q Also you filed a petition -- sorry. You filed
22 a petition in January of this year, correct?

23 A Correct.

24 Q You stated in -- excuse me.

25 You stated in that petition that improper data

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2 was submitted?
3 A Correct.
4 Q Okay.
5 By many doctors, by many, you know --
6 A Correct.
7 Q And that the rates could be skewered?
8 A Correct.
9 Q Does your data also include IDEs?
10 A Correct.
11 Q I'm sorry?
12 A Correct.
13 Q Okay.
14 MR. MORGAN: No further questions,
15 Your Honor.
16 THE COURT: Ms. Fitzgerald, any
17 questions on redirect?
18 MS. FITZGERALD: Yes, Your Honor.
19 Thank you.
20 - - - - -
21 REDIRECT EXAMINATION
22 - - - - -
23 BY MS. FITZGERALD:
24 Q Dr. Waxler, I want to ask you about the
25 advertising issue.

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2 If Dr. Nevyas went on public television to
3 advertise the IDE laser and stated: "I know I'm
4 amazed really every day as I go about my work and I
5 obtain a perfect picture of the cornea showing each
6 elevation greatly magnified, computerized by using
7 a special computerized measuring device which tells
8 us the elevations.

9 "And then we go ahead and we use an Excimer
10 laser, which is a computer-controlled so that each
11 pulse is in precisely the right place. And this is
12 all due to advances in technical aspects which we
13 couldn't have imagined many years ago."

14 Is that a violation to promote the Excimer
15 laser and the device on public television?

16 A Correct. Yes, it is.

17 Let me ask you a question, was the word
18 "investigational device" used in that context?

19 Q No, it was not.

20 A Okay.

21 Q If she discusses on public television, "We'll
22 learn how the Excimer laser works to examine the
23 basics of the Lasik procedure."

24 Is she promoting that Excimer Lasik procedure
25 in violation of federal law?

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2 A Yes. Unless it's stated it's an
3 investigational device.

4 Q And if she states, "It's called the Excimer
5 laser, and today it's used to correct poor vision.
6 Here's how:

7 "The first step in Lasik laser vision
8 correction is to analyze the irregularities of the
9 eye." And then she goes on.

10 Is she violating federal law when she doesn't
11 mention it's an investigational device?

12 A Yes.

13 Q If the Plaintiffs have radio advertisements
14 running stating, "Nevyas Eye Associates, with the
15 tradition of excellent in eye surgery for over 30
16 years performing advanced vision correction,
17 including laser vision correction, in their own
18 fully-accredited Eye Surgery Center," and they
19 advertise for, "Advanced refractive surgery
20 techniques which correct nearsightedness,
21 farsightedness and astigmatism," and the device
22 they are using for the nearsighted procedure is an
23 Excimer laser device, is that a violation of the
24 law?

25 A Yes. If the -- if the term "investigational

1 Morris Waxler - redirect

2 device" is not part of that ad.

3 Q You testified on cross-examination that you
4 were not surprised that the Nevyases stopped using
5 their laser in November of 2001. Why were you not
6 surprised?

7 A Because all of the -- we were successful; that
8 is, the FDA was successful in one way or another
9 getting rid of all of the gray box and black box
10 lasers. That is either they got a PMA, which
11 happened in one case, or they were seized in other
12 cases, or they -- one way or another discontinued.

13 Q Okay.

14 So by directing all these forced inspections,
15 is it your understanding that the FDA put much
16 pressure on the Nevyas to have them stop using that
17 device?

18 A Correct.

19 Q I'm going to show -- you had referenced an
20 email I. Am going to show that document to you?

21 MS. LAPAT: I object to this email.

22 It's absolute, total hearsay. It was
23 generated -- it says in itself that the writer
24 is speaking without personal knowledge.

25 It's -- by the time this witness is going to

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2 look at it, it's triple hearsay.

3 I strenuously object to it being
4 shown to the witness under any circumstances.

5 THE COURT: Let me see it.

6 MS. FITZGERALD: Your Honor, I think
7 the witness has already identified --

8 MS. LAPAT: It is a complete hearsay
9 document.

10 THE COURT: This is a letter or
11 email?

12 MS. FITZGERALD: Regarding the
13 Excimer Laser System and the complaint that
14 had been made.

15 MS. LAPAT: The text is directed to
16 a Mrs. Wills.

17 THE COURT: Yeah. This is -- I will
18 sustain the objection.

19 MS. LAPAT: Thank you, Your Honor.

20 - - - - -

21 (Pause.)

22 - - - - -

23 BY MS. FITZGERALD:

24 Q Should the Plaintiffs have reported Mr. Morgan
25 in 1998 when he had his Lasik surgery under the

1 Morris Waxler - redirect

2 IDE?

3 MR. SILVERMAN: Objection. That's
4 beyond the scope of my cross-examination.

5 THE COURT: Overruled. I think
6 it's --

7 BY MS. FITZGERALD:

8 Q Your answer?

9 A Remind me of when his surgery was.

10 Q Surgery was done in April of 1998.

11 A When were the adverse events? When was the
12 complaint? When did Mr. Morgan have the complaints
13 about the surgery?

14 Q Well, he filed his lawsuit in 2000, in April
15 of 2000. I think he had complaints prior to that
16 point.

17 A No. But when was the first incident -- when
18 was the first report to the Nevyases from him that
19 he had a problem?

20 Q Right away.

21 A Right away. Okay. So then that's the issue.
22 The --

23 THE COURT: See, what happened here,
24 I am allowing this in to show why Dr. Friedman
25 stated what he stated in the letter, but I

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2 realize there's a big controversy between the
3 Nevyases and what was an adverse event here.
4 But it's admissible to show what the basis for
5 Dr. Friedman's complaints in the December 4,
6 '03, letter.

7 THE WITNESS: Adverse events
8 are -- the whole point is to report them at
9 the time they occur and to report them way
10 in -- later is, you know, in violation of the
11 whole point of the IDE.

12 If you want to gather information
13 about the adverse events at the time -- say
14 his eyeball fell out, you know, you want to
15 know it at the time it fell out, not six
16 months later or a year.

17 BY MS. FITZGERALD:

18 Q Does it put other patients out there in the
19 public at risk if the FDA doesn't know about this
20 data and they have surgery with the same device?

21 THE COURT: I know it's public
22 safety. That's been gone over. We understand
23 that aspect of it. That's why -- but, again,
24 I will sustain that -- I won't permit that
25 line of questioning.

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2 BY MS. FITZGERALD:

3 Q Was it up to the Nevyases to decide what was a
4 complication or what was an adverse event, or was
5 that up to the FDA? In other words, can the
6 Plaintiffs figure -- decide which data they are
7 going to submit?

8 A No, I mean --

9 THE COURT: But the doctor decides
10 what's an adverse, event not the FDA. The FDA
11 doesn't practice medicine.

12 THE WITNESS: Is that a question?

13 THE COURT: No.

14 BY MS. FITZGERALD:

15 Q Do you want to respond?

16 A Well, the first responsibility is the
17 principal investigator. The agency is not at the
18 bedside of the patient.

19 So they -- the principal investigator and its
20 coinvestigators are responsible for adhering to the
21 protocol, and adverse events are described in
22 general terms about what they are. But the -- it's
23 certainly true that the principal investigators
24 have that decision making to -- they have to
25 decide. They have criteria for what is adverse

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2 events and what are not adverse events, if there's
3 a loss of best corrected visual acuity, if they
4 have halos.

5 THE COURT: The problem here is
6 while -- the question is: Mr. Morgan is going
7 to say that, but the Nevyases are saying no.
8 His vision didn't change; therefore, we didn't
9 report -- we didn't report it. And
10 that's -- see, I don't want to get involved in
11 the malpractice case again.

12 I think the question is -- one of
13 the issues is was there some reasonable basis
14 for Dr. Friedman to make these claims. I
15 think we are going too far now.

16 BY MS. FITZGERALD:

17 Q One last question on this topic:

18 The FDA wants all of the data for anybody who
19 participates in the study, right?

20 A Correct.

21 Q Did the FDA ever tell the plaintiffs that
22 their advertisements were inappropriate?

23 A Not to my knowledge.

24 Q You didn't --

25 A If I read it, I don't remember.

1 Morris Waxler - redirect

2 Q If you can turn, Doctor, to Friedman 133A,
3 which is that packet of documents.

4 A This here?

5 - - - - -

6 (Pause.)

7 - - - - -

8 BY MS. FITZGERALD:

9 Q I'm directing your attention to Page 49 of
10 that exhibit.

11 A Right.

12 Q What is this document?

13 A I'm sorry?

14 Q Do you recognize this document?

15 A Yes. Yes. I'm sorry. I forgot this.

16 Q Is this a report from by Ms. Silman (ph)?

17 A Yes.

18 Q Do you know her?

19 A Yes.

20 Q If you turn to the last page of the report?

21 A Okay.

22 Q Read that first paragraph if you would, sir.

23 A Start from another deviation?

24 Q One -- Page 3, "During the inspection."

25 A Okay.

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2 During the inspection, Mr. Stokes also
3 discussed the need to have advertisements related
4 to the IDE approved by reviewing IRB. A
5 transcript" -- do you want me to read the entire?
6 "A transcript of the radio advertisement that had
7 aired for several weeks was included with the
8 inspection report.

9 "The advertisement refers to laser vision
10 correction at the Delaware Valley Laser surgery
11 institution. According to Mr. Stokes, the only
12 laser at the Bala Cynwyd Office used for refractive
13 surgery was your IDE laser.

14 "While your Marlton, New Jersey, site had the
15 Summit laser, the advertisement does not specify
16 the location. Future advertisements should specify
17 location of the approved laser as the enclosed
18 advertisement would not be appropriate for
19 soliciting subjects for your IDE study.

20 "All promotional materials designed to solicit
21 participants are to inform subjects about the IDE
22 study need to be approved by the reviewing IRB."

23 Q Okay.

24 So does that paragraph indicate to you that
25 the FDA at least reviewed one of the Nevyases' ads?

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2 A Yes.

3 Q Did they find that ad to be inappropriate?

4 A No.

5 Q Did they not say that the ad does --

6 THE COURT: I think we are going so
7 far afield here.

8 You may disagree, but I get the
9 picture here. But now you are bringing in
10 some document that -- what does the document
11 say? Is it clear that they examined the
12 advertisement of the Nevyses? Is it clear
13 what they did? I think we're getting just so
14 far afield it's going to open up further
15 questions from the other side, and, quite
16 frankly, it's -- I think it's tangential.

17 MS. FITZGERALD: I think it goes to
18 the issue of statements made in Dr. Friedman's
19 letters as to whether there was a basis to
20 make his complaints.

21 THE COURT: I think you covered
22 that.

23 BY MS. FITZGERALD:

24 Q Does the January 7, 1999, letter from
25 Ms. Silman, does that cite a number of violations

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2 and deviations from the FDA's perspective?

3 A Yes.

4 Q This was after --

5 THE COURT: Excuse me.

6 What's the date?

7 THE WITNESS: What's the date?

8 THE COURT: Yeah. Yes.

9 THE WITNESS: It's January 7, 1999.

10 THE COURT: How do I know --

11 THE WITNESS: Yeah. That's correct.

12 THE COURT: Maybe there's been a lot
13 of testimony and I overlooked this: How do we
14 know that Dr. Friedman knew about this?

15 MS. FITZGERALD: He didn't.

16 THE COURT: He did not.

17 MS. FITZGERALD: He did not. He did
18 not have any of this information until 2005.
19 Because -- well, we'll get into that.

20 THE COURT: That's another -- all
21 right. All right. I won't permit anything
22 further on this, nor will I permit any further
23 questioning on redirect -- on recross on it.

24

25

1 Morris Waxler - redirect

2 - - - - -

3 (Pause.)

4 - - - - -

5 BY MS. FITZGERALD:

6 Q If you turn to Page 88 of that exhibit --

7 MS. LAPAT: Objection, Your Honor.

8 I thought you said there wasn't going to be
9 any more questioning about these exhibits.

10 THE COURT: That's what I said.

11 MS. FITZGERALD: I misunderstood,
12 Your Honor. I'm sorry.

13 Then nothing further.

14 THE COURT: Anything further?

15 MR. SILVERMAN: No, Your Honor.

16 THE COURT: Dr. Waxler, thank you.

17 THE WITNESS: Thank you.

18 - - - - -

19 (Witness excused.)

20 - - - - -

21 MS. FITZGERALD: Your Honor, I call

22 Steven Friedman, Dr. Friedman.

23 He would like to take a quick

24 bathroom break.

25 THE COURT: All right. Very well.

1 Morris Waxler - redirect

2 Certainly. He can use this back here, if you
3 want.

4 - - - - -

5 (Recess taken.)

6 - - - - -

7 THE COURT CRIER: State your name
8 for the record.

9 DR. FRIEDMAN: Steven Friedman.

10 THE COURT CRIER: You are previously
11 sworn and still under oath.

12 THE COURT: Doctor, I have a couple
13 questions:

14 The suit against your then client,
15 Mr. Morgan, by the Nevyases was some -- I
16 guess it was in November of '03, or at least
17 that's the court term and number.

18 DR. FRIEDMAN: Early November of --

19 MS. FITZGERALD: Mr. Morgan, I don't
20 believe, is here.

21 THE COURT: Oh.

22 THE COURT CRIER: I didn't see that.

23 THE COURT: Early November of '03.

24 When he comes back I will tell him
25 that's the only question I asked.

1 Nevyas -vs- Morgan & Friedman

2 MS. FITZGERALD: Okay.

3 - - - - -

4 (Pause.)

5 - - - - -

6 THE COURT: Mr. Morgan, I am sorry.
7 I asked Dr. Friedman a question. I didn't
8 realize that you weren't here. No. You have
9 a right to take a break. It's just that I
10 want to repeat that question.

11 MR. MORGAN: Yes, Your Honor.

12 THE COURT: Dr. Friedman, the suit
13 was brought by the Nevyses against your then
14 client, Mr. Morgan, in this case in November
15 of '03?

16 DR. FRIEDMAN: Yes, Your Honor. I
17 think November 7th of '03.

18 THE COURT: Now, when did you get
19 sued in this case, approximately?

20 DR. FRIEDMAN: Well, there's a story
21 that goes with it.

22 THE COURT: All right.

23 DR. FRIEDMAN: The complaint was
24 answered --

25 THE COURT: You answered -- when I

1 Nevyas -vs- Morgan & Friedman
2 say you -- you answered.

3 DR. FRIEDMAN: On behalf of
4 Mr. Morgan.

5 THE COURT: You answered the
6 complaint. Okay.

7 DR. FRIEDMAN: And sometime after
8 the answer, the Plaintiffs withdrew -- they
9 discontinued their lawsuit against Mr. Morgan
10 and filed in federal court a suit against
11 Mr. Morgan and me as codefendants. That --

12 THE COURT: When was that about?

13 DR. FRIEDMAN: Within a couple of
14 months after the answer to the complaint was
15 filed.

16 THE COURT: What happened to that
17 federal suit? It was transferred back here?

18 DR. FRIEDMAN: Judge Joiner
19 dismissed that. He took about 40 days to do
20 that. Dismissed the case, but said they were
21 free to do whatever they wanted to do.
22 Dismissed all pending state court jurisdiction
23 issues and so forth.

24 THE COURT: Then they reinstated
25 this case.

1 Nevyas -vs- Morgan & Friedman

2 DR. FRIEDMAN: The Plaintiffs asked
3 to reinstate the case and to amend the
4 complaint.

5 THE COURT: Okay.

6 DR. FRIEDMAN: They were allowed to
7 reinstate the case. They were denied
8 permission to amend the complaint, but then
9 allowed petition to seek relief to join
10 another defendant, which they did. So their
11 amended complaint was supposed to be just
12 restricted to adding me as a defendant.

13 THE COURT: So they added you as a
14 defendant.

15 DR. FRIEDMAN: Yes.

16 THE COURT: Now two questions:

17 When were you sued in federal court?

18 DR. FRIEDMAN: I'm -- I am not sure.

19 It was within -- it was probably a couple of
20 months after this complaint was answered.

21 THE COURT: When was this complaint
22 answered; do you know?

23 DR. FRIEDMAN: December 8th of
24 200 -- no.

25 THE COURT: Of '03?

1 Nevyas -vs- Morgan & Friedman

2 DR. FRIEDMAN: '03. December 8th of
3 '03.

4 THE COURT: '03.

5 So you get joined in this suit; it
6 was some time in '04, I take it?

7 DR. FRIEDMAN: Yes. I'm -- I don't
8 get served until, I think, early '05.

9 THE COURT: Okay.

10 MR. SILVERMAN: That's an area of
11 dispute, Your Honor.

12 THE COURT: You knew it was as soon
13 as '04.

14 DR. FRIEDMAN: Yes.

15 THE COURT: Because there was the
16 federal suit that was some time in '04, I take
17 it.

18 Now, the question I pose to you is
19 when you wrote this letter of December 4,
20 2003, had you ever been sued yet?

21 DR. FRIEDMAN: No. I mean -- no.
22 By nobody, including the Nevyses.

23 THE COURT: Why don't we break for
24 lunch.

25 MS. FITZGERALD: Fine, Your Honor.

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(Recess taken.)

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CERTIFICATION

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Jamie L. Wiese, RPR
Official Court Reporter

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