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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.**