

1 NO. 90-CI-06033

JEFFERSON CIRCUIT COURT
DIVISION ONE

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4 JOYCE FENTRESS, et al

PLAINTIFFS

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VS TRANSCRIPT OF THE PROCEEDINGS

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9 SHEA COMMUNICATIONS, et al

DEFENDANTS

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WEDNESDAY,
NOVEMBER 16, 1994
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1 other placebo-controlled double-blind studies that were part
2 of the NDA.

3 Q. So other studies could have been done but they
4 just weren't part of the NDA?

5 A. That's possible.

6 Q. Okay. Let me show you what's been marked as
7 Plaintiffs' Exhibit 227.

8 I believe it's already been entered, Judge.

9 Doctor, to back up a little bit, earlier you
10 said when Mr. McGoldrick was asking you questions, that the
11 first time the issue of using Prozac and the incidence of
12 suicide was raised in 1990 by Doctor Teicher's article;
13 correct?

14 A. It was the first time that I was aware of the
15 issue having arisen at that time.

16 Q. Okay. So let's make sure we're clear on this.
17 That issue was raised by the German government back in 1984;
18 correct?

19 A. I have heard that indication, yes.

20 Q. Have you ever seen any information about the
21 BGA?

22 A. No, I had not; I have not.

23 Q. You have not still, even in your position at
24 Lilly now?

25 A. Correct.

1 A. Yes, ma'am.

2 Q. Okay. Were you personally aware that in 1984,
3 the German government raised the issue of an increased risk of
4 suicide and the use of Prozac?

5 A. No. I was not aware of that specific question
6 back in 1984.

7 Q. Okay. Did you inform the PDAC that the German
8 government had raised that issue back in 1984?

9 A. I did not.

10 Q. Were you aware in 1991, when you testified
11 before the PDAC, that Lilly had in fact hired experts back in
12 1985 and 1986 to look at this issue with regards to the German
13 government?

14 A. I had heard that there were some individuals
15 that have consulted previously with Lilly on those issues but
16 did not know specifically whether it was related to the BGA or
17 the issue in general.

18 Q. Okay. Did you tell the PDAC in 1991, that Lilly
19 had previously -- and I'm talking about prior to Doctor
20 Teicher raising the issue, that Lilly had previously hired
21 experts to look at the issue of increased suicide and the use
22 of Prozac?

23 A. I think as part of the presentation it was made
24 clear that a very thorough and comprehensive analysis of the
25 worldwide data on suicide and Prozac had been made. In fact,

1 I was personally aware of the analyses of the depression
2 studies both from the U. S. and those conducted overseas and,
3 in fact, when those data are combined in analysis, the numbers
4 are even more in the favor of Prozac than what I shared with
5 Mr. McGoldrick that was published in the British medical
6 journal.

7 Q. Let's try it one more time. Specifically, did
8 you tell the PDAC that prior to 1990, when the German
9 government raised this issue, that Lilly hired experts to
10 investigate the issue of increased suicide and the use of
11 Prozac, yes or no?

12 A. That was not a question I was asked by the PDAC,
13 so I did not answer that question.

14 Q. Did you volunteer it?

15 A. No.

16 Q. You talked about a lot of stuff and they didn't
17 ask you questions, didn't you?

18 A. No. I think everything I talked about was
19 relative to the question that the PDAC was addressing; that
20 is, is there any credible evidence. So we shared U. S.,
21 O.U.S. data, depression, nondepressed patients, 10,000
22 patients; that's what they saw, that's what they deliberated
23 upon.

24 Q. You didn't think the fact that the BGA had
25 raised this issue back in 1984 and Lilly had investigated it

1 although I don't see any purpose in it.

2 Q. Did you inform the committee that there was a
3 package insert in use in Germany, on the day of the advisory
4 committee, that recommended the use of sedatives in people who
5 were suicidal or agitated on Prozac?

6 A. My recollection of that package insert was not a
7 recommendation to use a sedative, merely outlining that as a
8 possible addition to the therapeutic regimen of patients being
9 treated with fluoxetine. To me, that's quite different from a
10 recommendation to do.

11 Q. This, I think, says you may want to use a
12 sedative; correct?

13 A. You may. They were leaving it to the
14 clinician's discretion to determine if it was indicated or not
15 indicated.

16 Q. Did you tell the PDAC that in 1991, when you
17 were there for 45 minutes to an hour talking about how
18 wonderful this drug was and how it didn't cause anybody to
19 commit suicide or violent-aggressive behavior?

20 A. That was not one of the points of discussion.

21 Q. The answer is you didn't; right?

22 A. Again, I did not feel there would be any reason.

23 Q. How about concomitant medication use in the
24 clinical trials? Did you tell the PDAC members about that
25 when you were there?