

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  
VOLUME XXXVII

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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?