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IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA

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HEATHER BROWN, a Disabled :  
Minor, by and through Her :  
Parents and Next Friends, :  
:   
Plaintiffs, :  
: Civil Action No.:  
v. : CV 09-900734  
:   
GEORGE W. DEMUTH, M.D., :  
et al., :  
:   
Defendants. :  
----- x

Tuesday, July 9, 2013

Rockville, Maryland

Videotaped Deposition of

THOMAS LAUGHREN, M.D.

a witness, called for examination by counsel for the  
plaintiffs, pursuant to notice, held at the Hilton  
Washington DC/Rockville Hotel, 1750 Rockville Pike,  
Rockville, Maryland, beginning at 8:09 a.m., before  
Frances M. Freeman, a Notary Public in and for the  
State of Maryland, when were present on behalf of the  
respective parties:

Page 2

1 APPEARANCES:

2 For the Plaintiffs:

3 RIP ANDREWS, ESQUIRE

4 Marsh, Rickard & Bryan, P.C.

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6 Suite 600-D

7 Birmingham, Alabama 35209

8 205/879-1981

9

10 For the Defendants:

11 JOHN R. IPSARO, ESQUIRE

12 Ulmer & Berne

13 600 Vine Street

14 Suite 2800

15 Cincinnati, Ohio 45202

16 513/234-4268

17

18

19 Also Present:

20 STEVEN JONES, Videographer

21

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3 Thomas Laughren, M.D.	Mr. Andrews: 5

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1 PROCEEDINGS

2 THE VIDEOGRAPHER: This marks the beginning

3 of Videotape Number 1 in the Deposition of Dr. Thomas

4 Laughren. We are on the record at 8:09 a.m.,

5 July 9th, 2013, in the matter of Heather Brown, et

6 al., versus George W. Demuth, et al., before the

7 Circuit Court of Montgomery County, Alabama, Civil

8 Action Number CV 09-900734.

9 At this time, would all attorneys please

10 identify themselves for the record.

11 MR. ANDREWS: I'm Rip Andrews for Heather

12 Brown and her family.

13 MR. IPSARO: John Ipsaro on behalf of the

14 Forest defendants.

15 Thereupon,

16 THOMAS LAUGHREN, M.D.

17 a witness, called for examination by counsel for the

18 plaintiffs, and after having been first duly sworn by

19 the Notary Public, was examined and testified as

20 follows:

21 EXAMINATION BY COUNSEL FOR THE PLAINTIFFS

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1 drug. And I can elaborate on that.  
 2 It turns out that even though the  
 3 R-Citalopram is not active at all at the serotonin  
 4 transporter, both the R and the S-Citalopram are  
 5 active on cardiac function.  
 6 And we recently -- FDA recently modified the  
 7 labeling for Citalopram to limit the dose because of  
 8 a concern about a particular cardiac effect that  
 9 occurs at roughly twice the frequency with Citalopram  
 10 because both the R and the S contribute to it.  
 11 And so in that sense, they are different  
 12 drugs. But from the standpoint of activity at the  
 13 serotonin transporter, they are essentially the same  
 14 drug.  
 15 BY MR. ANDREWS:  
 16 Q Do we know the mechanism by which  
 17 antidepressants, SSRIs, can cause suicidality in  
 18 adolescents?  
 19 MR. IPSARO: Objection.  
 20 THE WITNESS: We do not.  
 21 BY MR. ANDREWS:

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1 Q Could it have anything to do with the S  
 2 enantiomer or the R enantiomer?  
 3 MR. IPSARO: Objection.  
 4 THE WITNESS: I don't -- I don't know the  
 5 answer to that. I would have to speculate. I don't  
 6 know.  
 7 However, we have already made the judgment  
 8 that all antidepressants, regardless of mechanism,  
 9 have the risk of inducing suicidality. So the warning  
 10 applies to all antidepressants regardless of the  
 11 mechanism whether it's, you know, through serotonin  
 12 reuptake or norepinephrine reuptake or even recently  
 13 atypical antipsychotics that have been approved for  
 14 antidepressant use have gotten this class warning.  
 15 BY MR. ANDREWS:  
 16 Q Let me ask you to -- well, yes, let me ask  
 17 you to pick up Exhibit 6. We're going way back in  
 18 time here. It's your memo about Celexa.  
 19 A Okay.  
 20 Q All right. And then Exhibit 7 you remember  
 21 was the Hearst -- the first three pages of the Hearst

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1 memo. Would there be documents like this at the FDA  
 2 regarding the FDA's investigation into pediatric  
 3 approval of Lexapro?  
 4 A Oh, yes.  
 5 Q And we can make a FOIA request and say --  
 6 what would you suggest we ask for?  
 7 A The, you know, the relevant reviews and  
 8 memoranda related to the approval of and the approval  
 9 letter for -- you have the supplement number. I  
 10 forget what the supplement number was.  
 11 Q I do, too. It's probably in Exhibit -- well,  
 12 no. It wouldn't be. Anyway. Okay. That helps me.  
 13 Focusing on Exhibit 6, Page 3, about  
 14 two-thirds of the way down on the page, there is a  
 15 note from you. Do you see that?  
 16 A Yes.  
 17 Q And it says, There was a packaging error  
 18 resulting in tablets being distinguishable for drug  
 19 and placebo for nine patients (although still  
 20 blinded).  
 21 That is a representation of the reality that

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1 there was at the beginning of the Study 18 trial a  
 2 potentially unblinding event. Correct?  
 3 A Potentially. Correct.  
 4 Q I mean, that's what we're calling it. There  
 5 was a potentially unblinding event. Correct?  
 6 A Yes. With an emphasis on potential.  
 7 Q Yes, sir. We don't know one way or the other  
 8 whether it would have unblinded the study.  
 9 MR. IPSARO: Objection. Right.  
 10 BY MR. ANDREWS:  
 11 Q Right?  
 12 A Correct.  
 13 Q And then you say, A reanalysis without these  
 14 patients yielded a P value of .52 in favor of  
 15 Citalopram. Correct?  
 16 A Correct.  
 17 Q And .52 would be not statistically  
 18 significant. Correct?  
 19 A That's correct.  
 20 Q So if this potentially unblinding event, if  
 21 these patients were removed, this would no longer be a

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1 positive study?

2 A That's correct.

3 Q So the approval of Lexapro was based on --

4 for pediatric use was based on an Escitalopram

5 positive study and a Citalopram positive study where

6 if you removed nine patients who were potentially

7 unblinded, it was actually a negative?

8 A If you remove nine patients. We considered

9 the issue and made a judgment that they should not be

10 removed.

11 Q Seems like a lot of hoops to jump through to

12 approve this drug for pediatric use.

13 A I didn't consider this a huge hoop. I

14 considered this a nonissue. That there is no reason

15 to believe that -- the fact that tablets have a

16 different color. Any one patient would only get one

17 color tablet.

18 Q I'm saying you're making exception and using

19 a different drug and a different drug study had a

20 potentially unblinding event that would have made the

21 study negative. Is Forest getting some type of

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1 special treatment regarding pediatric depression?

2 A Absolutely not.

3 Q What was your personal involvement in the

4 approval of Lexapro for pediatric use?

5 A Again, I was the -- well, at that point, I

6 was -- I believe I was the division director. I would

7 have to go back and look at the dates of when it was

8 approved.

9 Q Did you have a role in making that decision?

10 A Sure. Ultimately, it was my decision, but

11 there would have been a reviewer and very likely a

12 team leader. I mean, we can get that package. And

13 there probably would have been a review by a primary

14 reviewer, a team leader, and then probably a memo of

15 some sort from me.

16 Q Do you believe that pharmaceutical

17 manufacturers such as Forest have a duty to warn

18 doctors of any potential dangers associated with their

19 drugs?

20 MR. IPSARO: Objection.

21 THE WITNESS: I mean, they have a duty to

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1 provide labeling that includes the information that

2 FDA considers to be important to provide clinicians

3 with the information they need to prescribe the drugs.

4 BY MR. ANDREWS:

5 Q And I'm going to stick on this one. Do you

6 hold the opinion that pharmaceutical manufacturers

7 such as Forest have a duty to warn doctors of any

8 potential dangers associated with their prescription

9 drugs?

10 MR. IPSARO: Objection.

11 BY MR. ANDREWS:

12 Q Yes, no, or you can't answer the question the

13 way it's phrased?

14 MR. IPSARO: Objection.

15 THE WITNESS: I can't answer the question the

16 way it's phrased.

17 BY MR. ANDREWS:

18 Q Let me ask you to look at the label again.

19 It's Exhibit 21. Let me ask you to look at Page 4?

20 A Okay.

21 Q Under warnings, the first one is clinical

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1 worsening and suicide risks. Correct?

2 A Correct.

3 Q And then the middle paragraph begins, The

4 discussion of pooled analysis. Correct?

5 A Correct.

6 Q Let me ask you to look in the middle of that

7 paragraph, a sentence near the right that begins,

8 There was considerable variation. Do you see that?

9 A Yes.

10 Q What it says is, There was considerable

11 variation in risk among drugs, but a tendency toward

12 an increase for almost all drugs studied. Correct?

13 A Correct.

14 Q Does that leave open the interpretation to a

15 physician that some of the drugs studied did not have

16 an increase?

17 A That's not the way I read it. The way I read

18 that initial clause in that sentence is that -- this

19 is what it was intended to convey: That despite the

20 considerable variation and risk among drugs, almost

21 all of them show an increase.