IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA

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

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:

APPEARANCES:

For the Plaintiffs:

RIP ANDREWS, ESQUIRE
Marsh, Rickard & Bryan, P.C.
800 Shades Creek Parkway
Suite 600-D
Birmingham, Alabama 35209
205/879-1981

For the Defendants:

JOHN R. IPSARO, ESQUIRE
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Suite 2800
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513/234-4268

Also Present:

STEVEN JONES, Videographer

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PROCEEDINGS

THE VIDEOGRAPHER: This marks the beginning of Videotape Number 1 in the Deposition of Dr. Thomas Laughren. We are on the record at 8:09 a.m., July 9th, 2013, in the matter of Heather Brown, et al., versus George W. Demuth, et al., before the Circuit Court of Montgomery County, Alabama, Civil Action Number CV 09-900734.

At this time, would all attorneys please identify themselves for the record.

MR. ANDREWS: I'm Rip Andrews for Heather Brown and her family.

MR. IPSARO: John Ipsaro on behalf of the Forest defendants.

Thereupon,

THOMAS LAUGHREN, M.D.

a witness, called for examination by counsel for the plaintiffs, and after having been first duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR THE PLAINTIFFS

drug. And I can elaborate on that.

It turns out that even though the R-Citalopram is not active at all at the serotonin transporter, both the R and the S-Citalopram are active on cardiac function.

And we recently -- FDA recently modified the labeling for Citalopram to limit the dose because of a concern about a particular cardiac effect that occurs at roughly twice the frequency with Citalopram because both the R and the S contribute to it.

And so in that sense, they are different drugs. But from the standpoint of activity at the serotonin transporter, they are essentially the same drug.

BY MR. ANDREWS:

Q Do we know the mechanism by which antidepressants, SSRIs, can cause suicidality in adolescents?

MR. IPSARO: Objection.

THE WITNESS: We do not.

BY MR. ANDREWS:

Q Could it have anything to do with the S enantiomer or the R enantiomer?

MR. IPSARO: Objection.

THE WITNESS: I don't -- I don't know the answer to that. I would have to speculate. I don't know.

However, we have already made the judgment that all antidepressants, regardless of mechanism, have the risk of inducing suicidality. So the warning applies to all antidepressants regardless of the mechanism whether it's, you know, through serotonin reuptake or norepinephrine reuptake or even recently atypical antipsychotics that have been approved for antidepressant use have gotten this class warning.

BY MR. ANDREWS:

Q Let me ask you to -- well, yes, let me ask you to pick up Exhibit 6. We're going way back in time here. It's your memo about Celexa.

A Okay.

Q All right. And then Exhibit 7 you remember was the Hearst -- the first three pages of the Hearst

memo. Would there be documents like this at the FDA regarding the FDA's investigation into pediatric approval of Lexapro?

A Oh, yes.

Q And we can make a FOIA request and say -- what would you suggest we ask for?

A The, you know, the relevant reviews and memoranda related to the approval of and the approval letter for -- you have the supplement number. I forget what the supplement number was.

Q I do, too. It's probably in Exhibit -- well, no. It wouldn't be. Anyway. Okay. That helps me.

Focusing on Exhibit 6, Page 3, about two-thirds of the way down on the page, there is a note from you. Do you see that?

A Yes.

Q And it says, There was a packaging error resulting in tablets being distinguishable for drug and placebo for nine patients (although still blinded).

That is a representation of the reality that

there was at the beginning of the Study 18 trial a potentially unblinding event. Correct?

A Potentially. Correct.

Q I mean, that's what we're calling it. There was a potentially unblinding event. Correct?

A Yes. With an emphasis on potential.

Q Yes, sir. We don't know one way or the other whether it would have unblinded the study.

MR. IPSARO: Objection. Right.

BY MR. ANDREWS:

Q Right?

A Correct.

Q And then you say, A reanalysis without these patients yielded a P value of .52 in favor of Citalopram. Correct?

A Correct.

Q And .52 would be not statistically significant. Correct?

A That's correct.

Q So if this potentially unblinding event, if these patients were removed, this would no longer be a

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positive study?
A That's correct.
Q So the approval of Lexapro was based on -- for pediatric use was based on an Escitalopram positive study and a Citalopram positive study where if you removed nine patients who were potentially unblinded, it was actually a negative?
A If you remove nine patients. We considered the issue and made a judgment that they should not be removed.
Q Seems like a lot of hoops to jump through to approve this drug for pediatric use.
A I didn't consider this a huge hoop. I considered this a nonissue. That there is no reason to believe that -- the fact that tablets have a different color. Any one patient would only get one color tablet.
Q I'm saying you're making exception and using a different drug and a different drug study had a potentially unblinding event that would have made the study negative. Is Forest getting some type of

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special treatment regarding pediatric depression?
A Absolutely not.
Q What was your personal involvement in the approval of Lexapro for pediatric use?
A Again, I was the -- well, at that point, I was -- I believe I was the division director. I would have to go back and look at the dates of when it was approved.
Q Did you have a role in making that decision?
A Sure. Ultimately, it was my decision, but there would have been a reviewer and very likely a team leader. I mean, we can get that package. And there probably would have been a review by a primary reviewer, a team leader, and then probably a memo of some sort from me.
Q Do you believe that pharmaceutical manufacturers such as Forest have a duty to warn doctors of any potential dangers associated with their drugs?
MR. IPSARO: Objection.
THE WITNESS: I mean, they have a duty to

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provide labeling that includes the information that FDA considers to be important to provide clinicians with the information they need to prescribe the drugs.
BY MR. ANDREWS:
Q And I'm going to stick on this one. Do you hold the opinion that pharmaceutical manufacturers such as Forest have a duty to warn doctors of any potential dangers associated with their prescription drugs?
MR. IPSARO: Objection.
BY MR. ANDREWS:
Q Yes, no, or you can't answer the question the way it's phrased?
MR. IPSARO: Objection.
THE WITNESS: I can't answer the question the way it's phrased.
BY MR. ANDREWS:
Q Let me ask you to look at the label again. It's Exhibit 21. Let me ask you to look at Page 4?
A Okay.
Q Under warnings, the first one is clinical

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worsening and suicide risks. Correct?
A Correct.
Q And then the middle paragraph begins, The discussion of pooled analysis. Correct?
A Correct.
Q Let me ask you to look in the middle of that paragraph, a sentence near the right that begins, There was considerable variation. Do you see that?
A Yes.
Q What it says is, There was considerable variation in risk among drugs, but a tendency toward an increase for almost all drugs studied. Correct?
A Correct.
Q Does that leave open the interpretation to a physician that some of the drugs studied did not have an increase?
A That's not the way I read it. The way I read that initial clause in that sentence is that -- this is what it was intended to convey: That despite the considerable variation and risk among drugs, almost all of them show an increase.