Case 1:14-cv-13848-NMG Document 227-20 Filed 10/14/17 Page 2 of 5

Page 1 1 2 IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA 3 4 HEATHER BROWN, a Disabled Minor, by and through Her 5 5 Parents and Next Friends, . . 6 Plaintiffs, : : Civil Action No.: : CV 09-900734 7 v. : GEORGE W. DEMUTH, M.D., 8 : et al., 5 9 . Defendants. : 10 Х 11 Tuesday, July 9, 2013 12 Rockville, Maryland 13 Videotaped Deposition of 14 THOMAS LAUGHREN, M.D. 15 a witness, called for examination by counsel for the 16 plaintiffs, pursuant to notice, held at the Hilton 17 Washington DC/Rockville Hotel, 1750 Rockville Pike, 18 Rockville, Maryland, beginning at 8:09 a.m., before 19 Frances M. Freeman, a Notary Public in and for the 20 State of Maryland, when were present on behalf of the 21 respective parties:

Page 2 Page 2 1 APPEARANCES: 1 E X H I B I T S (Continued) 2 For the Plaintiffs: 2 Deposition Exhibit No. Page 3 3 RIP ANDREWS, ESQUIRE 3 15. 1/5/2004 memo 181 4 Marsh, Rickard & Bryan, P.C. 4 16. Advisory committe transcript 245 5 800 Shades Creek Parkway 5 17. Hammad article 235 6 Suite 600-D 19. Review and Evaluation of Clinical Data 261 26 8 205/879-1981 22. 5/22/2008 memo 290 11 JOHN R. IPSARO, ESQUIRE 11 23. Study report 291 12 Ulmer & Berne 12 24. Study report 293 14 Suite 2800 14 26. Agreement with Forest 311 15 Clininati, Ohio 45202 15 27. FDA's website 335 16 SUIte 2800 14 26. Agreement with Forest 311 17 9. Article on placeb-controlled trials 337 16 C O N T E N T S </th <th>-</th> <th></th> <th></th> <th></th> <th></th> <th></th>	-					
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Page 3Page 31CONTENTS1PROCEEDINGS2WITNESSEXAMINATION BY2THE VIDEOGRAPHER: This marks the beginning3Thomas Laughren, M.D.Mr. Andrews: 53of Videotape Number 1 in the Deposition of Dr. Thomas4EX H I B I T S3July 9th, 2013, in the matter of Heather Brown, et1, versus George W. Demuth, et al., before the5Deposition Exhibit No.Page5July 9th, 2013, in the matter of Heather Brown, et61. Notice176al., versus George W. Demuth, et al., before the71(a). Notes on Glenmullen documents817Circuit Court of Montgomery County, Alabama, Civil82. 11/16/2006 memo928Action Number CV 09-900734.93. 10/25/1996 memo939At this time, would all attorneys please104. Citalopram study report10710115. Premarking Studies report11311126. 9/16/2002 memo12412137. Review and Evaluation of Clinical Data 12713MR. IPSARO: John Ipsaro on behalf of the148. 12/13/2001 memo17215Theeupon,159. 9/4/2003 memo17716THOMAS LAUGHREN, M.D.1411. Letter17417a witness, called for examination by counsel for the1812. 8/21/2003 memo17818plaintiffs, and after having been first duly sworn by1913. Senate Committee on Finance memo20319the No	20	STEVEN JONES, Videographer		20	32. Witness' stack of documents	372
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FREEDOM COURT REPORTING 2015 3RD AVENUE NORTH BIRMINGHAM, AL 35203 1-877-373-3660 2 (Pages 2 to 5)

Case 1:14-cv-13848-NMG Document 227-20 Filed 10/14/17 Page 4 of 5

	Page 298		Page 300
1	drug. And I can elaborate on that.	1	memo. Would there be documents like this at the FDA
2	It turns out that even though the	2	regarding the FDA's investigation into pediatric
3	R-Citalopram is not active at all at the serotonin	3	approval of Lexapro?
4	transporter, both the R and the S-Citalopram are	4	A Oh, yes.
5	active on cardiac function.	5	Q And we can make a FOIA request and say
6	And we recently FDA recently modified the	6	what would you suggest we ask for?
7	labeling for Citalopram to limit the dose because of	7	A The, you know, the relevant reviews and
8	a concern about a particular cardiac effect that	8	memoranda related to the approval of and the approval
9		9	
	occurs at roughly twice the frequency with Citalopram because both the R and the S contribute to it.		letter for you have the supplement number. I
10		10	forget what the supplement number was.
11	And so in that sense, they are different	11	Q I do, too. It's probably in Exhibit well,
12	drugs. But from the standpoint of activity at the	12	no. It wouldn't be. Anyway. Okay. That helps me.
13	serotonin transporter, they are essentially the same	13	Focusing on Exhibit 6, Page 3, about
14	drug.	14	two-thirds of the way down on the page, there is a
15	BY MR. ANDREWS:	15	note from you. Do you see that?
16	Q Do we know the mechanism by which	16	A Yes.
17	antidepressants, SSRIs, can cause suicidality in	17	Q And it says, There was a packaging error
18	adolescents?	18	resulting in tablets being distinguishable for drug
19	MR. IPSARO: Objection.	19	and placebo for nine patients (although still
20	THE WITNESS: We do not.	20	blinded).
21	BY MR. ANDREWS:	21	That is a representation of the reality that
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	Page 299		Page 301
1	Page 299 O Could it have anything to do with the S	1	Page 301 there was at the beginning of the Study 18 trial a
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76 (Pages 298 to 301)

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3	Page 302		Page 304
1	positive study?		provide labeling that includes the information that
2	A That's correct.	2	FDA considers to be important to provide clinicians
3	Q So the approval of Lexapro was based on	3	with the information they need to prescribe the drugs.
4	for pediatric use was based on an Escitalopram	4	BY MR. ANDREWS:
5	positive study and a Citalopram positive study where	5	Q And I'm going to stick on this one. Do you
6	if you removed nine patients who were potentially	6	hold the opinion that pharmaceutical manufacturers
7	unblinded, it was actually a negative?	7	such as Forest have a duty to warn doctors of any
8	A If you remove nine patients. We considered	8	potential dangers associated with their prescription
9	the issue and made a judgment that they should not be	9	drugs?
10	removed.	10	MR. IPSARO: Objection.
11	Q Seems like a lot of hoops to jump through to	11	BY MR. ANDREWS:
12	approve this drug for pediatric use.	12	Q Yes, no, or you can't answer the question the
13	A I didn't consider this a huge hoop. I	13	way it's phrased?
14	considered this a nonissue. That there is no reason	14	MR. IPSARO: Objection.
15	to believe that the fact that tablets have a	15	THE WITNESS: I can't answer the question the
16	different color. Any one patient would only get one	16	way it's phrased.
17	color tablet.	17	BY MR. ANDREWS:
18	Q I'm saying you're making exception and using	18	Q Let me ask you to look at the label again.
19	a different drug and a different drug study had a	19	It's Exhibit 21. Let me ask you to look at Page 4?
20	potentially unblinding event that would have made the	20	A Okay.
21	study negative. Is Forest getting some type of	21	Q Under warnings, the first one is clinical
-			
	Page 303		Page 305
1	special treatment regarding pediatric depression?		worsening and suicide risks. Correct?
2	A Absolutely not.	2	A Correct.
3	Q What was your personal involvement in the	3	Q And then the middle paragraph begins, The
4	approval of Lexapro for pediatric use?	4	discussion of pooled analysis. Correct?
5	A Again, I was the well, at that point, I	5	A Correct.
6	was I believe I was the division director. I would	6	Q Let me ask you to look in the middle of that
7	have to go back and look at the dates of when it was	7	paragraph, a sentence near the right that begins,
8	approved.	8	There was considerable variation. Do you see that?
9	Q Did you have a role in making that decision?	9	A Yes.
10	A Sure. Ultimately, it was my decision, but	10	Q What it says is, There was considerable
11	there would have been a reviewer and very likely a	11	variation in risk among drugs, but a tendency toward
12	team leader. I mean, we can get that package. And	12	an increase for almost all drugs studied. Correct?
13	there probably would have been a review by a primary	13	A Correct.
14	reviewer, a team leader, and then probably a memo of	14	Q Does that leave open the interpretation to a
15	some sort from me.	15	physician that some of the drugs studied did not have
16	Q Do you believe that pharmaceutical	16	an increase?
17	manufacturers such as Forest have a duty to warn	17	A That's not the way I read it. The way I read
18	doctors of any potential dangers associated with their	18	that initial clause in that sentence is that this
19	drugs?	19	is what it was intended to convey: That despite the
20	MR. IPSARO: Objection.	20	considerable variation and risk among drugs, almost
21	THE WITNESS: I mean, they have a duty to	21	all of them show an increase.

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