UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN,	)	
	)	
Plaintiff,	)	
	)	
-v-	)	CAUSE NO.
	)	1:14-CV-01614-AJT-JFA
	)	
ELI LILLY AND COMPANY, AN INDIANA CORPORATION,	)	
	)	
Defendant.	)	

and

JANINE ALI,	)	
	)	
Plaintiff,	)	
	)	
-v-	)	CAUSE NO.
	)	1:14-CV-01615-AJT-JFA
	)	
ELI LILLY AND COMPANY, AN INDIANA CORPORATION,	)	
	)	
Defendant.	)	

A.M.-P.M. SESSIONS

The videotaped deposition upon oral examination of MADELAINE M. WOHLREICH, a witness produced and sworn before me, Michele K. Gustafson, CRR-RPR, Notary Public in and for the County of Marion, State of Indiana, taken on behalf of the Plaintiffs at the offices of Ice Miller, One American Square, 29th Floor, Indianapolis, Indiana, on April 29, 2015, at 10:11 a.m., pursuant to the Federal Rules of Civil Procedure.

Pages 1-224 A.M.
Pages 225-449 P.M.

APPEARANCES

FOR THE PLAINTIFFS:

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ALSO PRESENT: Shawn Weyerbacher, Videographer
Stephanie M. Tartaglia, Esq.
Michael Lynch, Esq. (by telephone)

INDEX OF EXAMINATION

MR. STEKLOFF: Object to form.

A I don't know that.

Q Okay.

(Exhibit 1 was marked for identification.)

Q Doctor, I'm handing you what the court reporter has marked as Exhibit 1 to your deposition. The first page here says the Declaration of Sarah L. Helgeson. See that?

A I'm sorry. Where? On the front page?

Q Yeah.

A Yes, okay.

Q Do you know who Sarah L. Helgeson is?

A No, I don't.

Q Okay. If you turn the page on the first page. On Paragraph 1 it reads, "Since 2011, I have served as Director, Global Medical Information at Eli Lilly and Company."

Do you see that?

A Yes.

Q All right. And if you turn the page on page 3, Paragraph 7. Under the section titled Medical Information Letters on Cymbalta DEAEs, right, it reads, Since October 2004, Lilly has in effect a Medical Information Letter on possible DEAEs related to the use of Cymbalta.

Do you know what a medical information letter is?
A Yes.
Q And what is that?
A It is a letter summarizing relevant data and other information that is developed by our medical information specialists, whom I mentioned before, to address a specific question that comes up from external clinicians.
Q It says letter on possible DEAEs. DEAEs, that stands for discontinuation-emergent adverse events; correct?
A Discontinuation-emergent adverse events, yes.
Q Did you have any role in drafting or reviewing these medical information letters?
A There were two sets of medical letters. There were letters that were developed for use globally and letters that were developed for use in the U.S., and my role would have been to work with the medical information specialists developing letters for the U.S. affiliate.
Q If you continue reading here, it says, "Lilly has regularly updated this Medical Information Letter to incorporate new clinical trial data on DEAEs and new information from the relevant medical

literature."

Is that your understanding of what Lilly has done with regards to the medical information letters?

A Yes.

Q Okay. "Attached hereto are true and correct copies of the Medical Information Letters on Cymbalta DEAEs, revised as of the following dates".

You see that?

A Yes.

Q And it lists a bunch of different dates here with exhibit numbers; is that correct?

A Yes.

Q Okay. I want to draw your attention to Exhibit 3, which is the September 2006 Medical Information Letter. See that? On that list right there it says Exhibit 3.

A Oh, yes.

Q All right. Let's go to Exhibit 3. Specifically if you look at the bottom right-hand of your document, page 19 is -- sorry -- page 12 is where it starts.

MR. STEKLOFF: Mine says page 17.

MR. WISNER: That's correct. Page 17. Sorry. I was off by one.

Q You see that?

A Yes.
Q And then you see up there it says entered September 27, 2006?
A 2005? The -- I'm sorry. On page 12?
Q I'm sorry. Page 17. I was mistaken.
A Okay. Yes.
Q All right. See it says entered September 27, 2006?
A Yes.
Q Okay. And this is -- appears to be a fair and correct copy of the medical information letter that existed as of 2006; is that right?
A To my knowledge, yes.
Q And it says Discontinuation Symptoms on the top; right?
A Yes, it does.
Q Now, this letter was given to physicians who made inquiries about discontinuation; isn't that correct?
MR. STEKLOFF: Object to form.
A If it was a medical letter, the purpose of its development would -- and use would be to respond to questions relevant to the content of this particular letter.
Q This letter was not sent proactively to all physicians in the United States; correct?

A Correct.
Q And you would agree with me that this letter contains -- this letter, which is, I believe, one, two, three, four, five, six, seven, eight pages long, contains information in addition to the information contained in the U.S. product insert?
A Yes, it does.
Q Okay. If you turn the page on the page -- it says page 18 down at the bottom. It's the second page of the letter. It's double sided, so it's a little tricky. Under the section here that says Etiology; right?
A Etiology.
Q Etiology, what does that mean?
A It means origin.
Q Okay. In the first paragraph -- I'm just going to read it to you -- it says, Down-regulation of the serotonin transporters by SSRIs and SNRIs tends to enhance synaptic levels of serotonin in the brain. The serotonin system undergoes adaptive changes --
Doctor, are you reading along with me?
A Yes. I was also checking a reference.
Q Fair enough. I'm going to ask if I read that correctly, so I want to make sure you read along with me. So I'll start from the top.

changing it?
A No. We all share in the conceptualization. Usually our writer is kind of like a project manager and gets the ideas from all of the authors and then writes up a draft, which the other authors then work on and add their corrections or their own comments to.
Q Now, this one has some Cymbalta warning information in front of it. Do you see that?
A Yes. And that's not part of the article.
Q Yes. Why is that?
A I don't know for sure, but I believe this is a reprint. So if this was handed out proactively, in other words, either by sales reps or mailed by the company, then it needed to include appropriate -- this information about the drug.
Q Now, is that a common practice at Lilly, sending reprints of journal publications?
A It is done occasionally. Typically the article has to meet a number of criteria. It -- and if it's sent out, sometimes medical will send them out and sometimes marketing will, but it has to meet some pretty strict criteria depending on what it's used for as a -- and who's it's going to.
Q And what are those criteria?

A They vary. We had different types of classifications for these memberships. It couldn't contain any off-label information and it had to be something that there was good reason to believe it could be justified of why you were sending this to clinicians.

Q What is your understanding of off-label information?

A That's a long dissertation. But for the purposes of this context, off label means it shouldn't include discussions about uses that aren't approved, other indications, for instance, and shouldn't contain substantial information that isn't consistent with the label. And there are tight or looser definitions depending on what context you're talking about.

Q So it'd be fair to say that you couldn't state something in a journal article that was distributed by Lilly that contradicted the label?

A That's correct.

Q But you could expound upon certain piece of information in the label?

A Yes, yes, yes.

Q Okay. So there might be information in here that goes beyond what the label says, but it doesn't --

it's still consistent with what the label says?
A Absolutely.
Q Okay. And how was it determined which ones were going to be distributed as a reprint and which ones were not?
A We would have team meetings in which we discussed the -- if medical was driving it -- and I can really speak to that better -- we -- somebody would bring up and say, hey, I think we should send out an article on, or we should send out a particular article, if we thought that it was relevant and useful to clinicians.
Q You said if medical was driving it. What else could drive it?
A Marketing. There were occasions -- and it was -- where marketing could disseminate an article theoretically. This one, I'm not sure if it was -- whether this was sent out through the medical or marketing channel.
Q Okay. Why would marketing want to send out a publication?
MR. STEKLOFF: Object to form. Lacks foundation. Calls for speculation.
A My assumption would be to increase awareness of the drug or some aspect of the drug.

MR. STEKLOFF: I'm going to have some questions.

(Exhibit 27 was marked for identification.)

THE WITNESS: Thank you.

Q All right, Doctor. I'm handing you an e-mail exchange. It's a e-mail from Dr. Perahia. You see that?

A Yes.

Q And it's addressed to a bunch of people including yourself?

A Yes.

Q Okay. And the subject matter is CYMBALTA: Slides and Study Citation for 30 mg "down titration" dose. See that?

A Yes.

Q Okay. It reads from Dr. Perahia, it says, Hi John, We've only directly compared abrupt discontinuation versus tapered discontinuation in one study. The study question was one of the GAD registration trials. I have a slide showing the outcomes of this comparison which I can send to you on Monday -- I can send you on Monday, together with the study protocol. We've not conducted such a comparison in any MDD studies including HMBU and HMCQ.

See that?
A Yes.
Q Is that your under -- is it your understanding that there had not been by 2007 of April any clinical trials designed to measure abrupt versus tapered discontinuation for MDD?
A I don't recall.
Q Okay. Do you have any reason to disagree with Dr. Perahia's statement here?
A Which statement?
Q That we've not conducted such a comparison in any of the MDD studies including HMBU and HMCQ.
A I have no reason to disagree.
Q Okay. Do you recall ever yourself designing a protocol designed to measure abrupt versus taper discontinuation in MDD?
A No.
Q Do you recall ever doing the same design for a protocol designed to measure taper versus abrupt for fibromyalgia?
A I don't recall.
Q Have you ever designed a protocol designed to measure --
A I don't -- not that I recall.
Q Okay. Doctor, isn't it true that you never

proposed to conduct a phase 4 clinical trial to measure abrupt versus taper discontinuation?

A That's correct.

Q Isn't it true that you've never -- and even though -- Strike that.

But you had physicians that you respected suggesting that we -- that Lilly should study this issue; right?

MR. STEKLOFF: Object to form.

A I'm aware of the e-mail that we reviewed earlier in which Dr. Perahia says this is something we might think about doing.

Q But you never went about yourself designing a protocol to do that?

A In the U.S. affiliate the question did not arise to a level of frequency or urgency during the years that I was designing clinical studies for the U.S. affiliate that we thought to include that or study it.

Q And isn't it true you never designed a protocol specifically attempting to determine how long Cymbalta discontinuation symptoms could last?

A Yes. Because it wasn't arising as a question that was frequent enough or that we thought we needed to develop an answer from a clinical trial. Clinical

trials are certainly not the only way we answer questions, and they're the slowest way and don't always give you results that are meaningful or useful.

MR. WISNER: Pass the witness.

A Most people asking questions don't want to wait two to three years for you to give them an answer.

MR. WISNER: Move to strike the testimony. It's speculative and nonresponsive.

THE WITNESS: Strike away.

MR. STEKLOFF: I'll oppose striking. Can we go off the record?

MR. WISNER: Sure.

VIDEOGRAPHER WEYERBACHER: Off the record at 6:53.

(A recess was taken from 6:53 p.m. to 7:05 p.m.)

VIDEOGRAPHER WEYERBACHER: Back on record at 7:05 p.m.

MR. STEKLOFF: Good evening. I just want to cover a few topics that Mr. Wisner covered with you and follow-up on them.

CROSS-EXAMINATION

BY MR. STEKLOFF:

Q Do you recall a series of questions about how at

Cymbalta?

MR. WISNER: Objection. Lacks foundation. Vague. Ambiguous. Speculation.

A Providing complete and accurate medical information has always been the goal of medical team's work on Cymbalta.

Q And does that include discontinuation-emergent adverse events?

A Yes, absolutely.

MR. STEKLOFF: Pass the witness.

REDIRECT EXAMINATION

BY MR. WISNER:

Q Just stated a second ago, Doctor, that Lilly has always tried to be proactive; is that right?

A No, I didn't say always. I said Lilly has tried to be proactive about Cymbalta in terms of information about adverse events, yes.

Q And you include under that trying to be proactive, you're including issues related to discontinuation symptoms?

A Yes.

Q Lilly never proactively studied the risk of discontinuation beyond two weeks; correct?

A Lilly did not.

MR. STEKLOFF: Object to form.

Q Lilly never --
A I'm not sure that proactive -- what you mean by proactive study.
Q They never designed a study to measure whether or not discontinuation symptoms could last longer than two weeks?
A No.
Q They never conducted a study to specifically measure the difference between taper and abrupt discontinuation outside of the GAD and SUI indications?
MR. STEKLOFF: Object to form.
A I'm sorry. Repeat the question. Did we study abrupt versus tapered discontinuation in every indication that Cymbalta has? No. But apparently from your statement I understand it was studied in two of the indications. And SUI is not a Cymbalta indication. It's a duloxetine indication but not Cymbalta.
Q So Lilly never conducted a study to specifically measure the difference between taper and abrupt discontinuation outside of the GAD and SUI indications?
A That's right.
Q Okay. You stated one of the reasons why Lilly

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 7th day of May, 2015.

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Michele K. Gustafson, CRR-RPR
Notary Public

My commission expires:
August 31, 2017
Job No. 97560

ERRATA SHEET FOR THE TRANSCRIPT OF:

Case Name: Gilda Hagan-Brown v. Eli Lilly and Company, an Indiana corporation
Case Number: 1:14-CV-01614-AJT-JFA
Dep. Date: April 29, 2015
Deponent: Madelaine M. Wohlreich - AM-PM Session
Place: Indianapolis, IN.

CORRECTIONS:

Pg.	Ln.	Now Reads	Should Read	Reasons Therefore

Signature of Deponent