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.	)	

The videotaped deposition upon oral examination of MICHAEL J. DETKE, 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 28, 2015, at 10:10 a.m., pursuant to the Federal Rules of Civil Procedure.

APPEARANCES

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Stephanie M. Tartaglia, Esq.
Michael Lynch, Esq. (by telephone)

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quote, SSRI discontinuation events, end quote, held December 17, 1996, in Phoenix, Arizona. The symposium and the supplement were sponsored by an unrestricted educational grant from Eli Lilly and Company. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the publisher or the sponsor, period, end quote. You see that?

A Yes.

Q Have you seen this document, Exhibit 1, prior to my handing it to you?

A I don't recall. I may have seen it or read it at some point in the relatively distant past.

Q And I recognize that you were at Harvard at the time. But did you attend this symposium in December of 1996?

A No.

Q You will see, if you go to -- two more pages, there's a table of contents. The Journal of Clinical Psychiatry and then there's page numbers to the left. Do you see that page?

A Yes.

Q And there's a number of titles of doc -- of studies, papers that are in here with the names of authors. Can you just look through this, call it,

table of contents and tell me if you're -- if you've ever worked with any of the authors who are named on these various papers?

A I've worked with Alan Schatzberg.

Q On what?

A Several things. He was a member of the Cymbalta Global Depression Advisory Board for --

Q Was he a Lilly employee or . . .

A No.

Q Okay.

A He's a -- he's a, for the past many years, a professor of psychiatry at Stanford. And I've worked with him in several other capacities. Peter Haddad was an -- is an academic in England and was an advisor, I think, on Cymbalta and, I think, on some other things to Lilly. Jerry Rosenbaum was -- he was and is a -- the chairman of the psychiatry department at Massachusetts General Hospital, which was one of the hospitals where I did my residency, so I knew him initially there. He was a member of the Cymbalta Global Depression Advisory Board. And I've worked with him in a few other capacities since leaving Lilly.

Q Was he in any way a teacher of yours when you were

at Massachusetts General?
A Yes.
Q Okay.
A He was a faculty member at Mass General.
Q Okay.
A He was the chairman of my four years there. You know, direct teaching from him was probably a handful of hours or something like that, something relatively minor. John Zajecka was also a member of the Cymbalta Global Depression Advisory Board, and I've worked with him in various capacities since. I think the A. H. Young refers to Alan Young, and I've -- I know him. I don't know if he was ever an advisor to Lilly, but I -- he may have been. And those are the only names that I recognize.
Q You used the term the Global Depression Advisory Board. Did I get that right?
A Yes.
Q What is that?
A It was a group of all academics, about 25, who met about twice a year to provide advice and feedback on Cymbalta data on -- in the psychiatry indications, the depression and anxiety indications.

Q What affiliation, if any, did these 25 academics have with Lilly?
A They were -- I guess they were consultants of some sort or another. I'm not sure if that's the term Lilly used, but -- or advisors. So they were on a scientific advisory board.
Q Did they receive any monetary compensation or grants for their work on the Cymbalta Global Depression Advisory Board?
MR. DURAISWAMY: Objection. Lack of foundation.
A My understanding is that they were compensated for the time they spent on the board, yes.
Q And what was your role on that board? Or were you on that board?
A I attended that board very regularly. When I was a -- the first few years when I was a clinical research physician, I would attend those boards and sometimes present data, if it was a clinical trial that I had run. And then when I was medical director, I usually ran those board meetings, those scientific advisory board meetings, and there were several other Lilly attendees.
Q So at some point were you officially a member of this board?

A We didn't -- usually the -- we -- we referred to the 25 academics as members of the board and referred to ourselves as Lilly attendees or something like that.
Q Was there one or more of the 25 academics who were in charge or leaders of the Cymbalta Global Depression Advisory Board?
A There was not a board member who was chair or co-chair. That's a -- no.
Q Do you know how long the Cymbalta Global Depression Advisory Board existed?
A It existed for -- we started to put it together soon after I joined. It probably sort of formally gelled in 2001. It existed until -- until I left the team, and beyond that I don't know.
Q So roughly 2001 through 2007 you know the board existed?
A Yes.
Q If you would now turn to the first article, which begins at page 3. Excuse me. It's referred to as, Antidepressant Continuation Syndrome: An Update on Serotonin Reuptake Inhibitors. Do you see that?
A Uh-huh.
Q By Alan Schatzberg?
A Yes.

VIDEOGRAPHER D'ANGELO: Going off record. It's 4:21.

(A recess was taken from 4:21 p.m. to 4:33 p.m.)

VIDEOGRAPHER D'ANGELO: We are back on record. It's 4:33.

(Exhibit 13 was marked for identification.)

Q The court reporter has marked as Exhibit 13, a two-page document, CYM-01813088 and 89. You'll see on the back there's only just somebody's signature name block there. Can you take a look at this e-mail exchange and let me know when you're ready for me to ask you questions?

A Sure.

(Witness reviewing document)

A Go ahead.

Q Okay. You'll see that the bulk of this document is an e-mail from Walter Debbert, D-e-b-b-e-r-t, is it?

A Yes, Walter Debbert.

Q Right. Dated November 11, 2002, at 6:44 p.m. and you're copied on it. First of all, who is Walter Debbert?

A Walter is a clinical research physician who was working in one of the European countries or the

European region, I believe, at this time.
Q Okay. And you'll see in the next to the last paragraph of this e-mail, there's a reference to Mike, and I assume that's to you. And I'll just read the whole paragraph. Quote, discontinuation symptoms are a big deal in MDD (thanks to ourselves with Prozac promotion), period. Mike, comma, can you confirm that for MDD we would propose a gradual tapering, question mark? It would seem logic that if we propose this for MDD, comma, we would recommend it also for SUI, period, end quote. Do you see that?
A Yes.
Q Do you know what Walter was referring to in the first sentence of that paragraph when he said, discontinuation symptoms are a big deal and MDD (thanks to ourselves with Prozac promotion)?
MR. DURAISWAMY: Objection. Lack of foundation. Form. Calls for speculation.
A Since I didn't write it, I don't know exactly what he meant, but I assume he was referring to the longer half-life with Prozac and the relatively fewer DEAEs with Prozac.
Q What was the Prozac promotion dealing with discontinuation symptoms?

MR. DURAISWAMY: Objection. Lack of foundation.

A I wasn't directly involved with Prozac promotion, but my general understanding is that the relatively fewer DEAEs with Prozac compared to most of the other drugs in the class was promoted.

Q So Lilly was promoting Prozac as having fewer discontinuation symptoms than Paxil and other drugs in that category?

MR. DURAISWAMY: Objection. Lack of foundation. Asked and answered.

Q Is that correct?

A I think that's essentially accurate.

Q Then he asks you a question, can you confirm that for MDD we would propose a gradual tapering? You see that?

A Yes.

Q Do you recall answering that question?

A No, I don't recall.

Q Do you know what he's talking about there?

A I don't know --

MR. DURAISWAMY: Objection. Foundation. Form. Speculation.

Go ahead.

A Again, I didn't write it, so I don't know exactly

what he's referring to, but that -- my guess is that, you know, a general recommendation that we taper, meaning in the label language and in other recommendation.

Q All right. And he was from Europe?

A Yes.

Q So the gradual tapering recommendation was made in the European label; correct?

MR. DURAISWAMY: Object to the form. Ambiguous. Foundation.

A There's a tape -- a recommendation to taper in the U.S. label and the European label, correct.

Q And the recommendation in the U.S. label is simply a gradual reduction; correct?

A I don't remember the exact wording, but that's approximately correct.

Q You can go back if you want to be certain. It's Exhibit 6 at page 12, roughly at lines 466 through 470.?

MR. DURAISWAMY: Are you asking him what it says about tapering in that paragraph or what it says about tapering in the entire label?

MR. WOERNER: I asked him in the recommendation in the U.S. label is simply a gradual reduction. He answered I don't remember

Q All right. And then number two, he says, Consider running a trial which might add to the evidence base on how best to manage stopping the drug. Example: Over how long should drug be tapered, question mark. (Open label treatment, then perhaps three arms looking at abrupt discontinuation versus two-week taper versus four-week taper in a double-blind fashion with frequent visits). Do you see that?

A Yes.

Q Was that ever done?

A We did go on to design a study. One of the generalized anxiety disorder studies, which compared a randomized double-blind comparison between abrupt discontinuation and taper, and then I believe there were some other studies, but I know there was at least that one that did a, as I said, randomized double-blind comparison, which was, I believe, one of the very first studies in the literature of any SSRI or SNRI that did that.

Q All right. And he says, Abrupt discontinuation versus two-week taper versus four-week taper. In the study you're referring to in which abrupt discontinuation was compared to taper, was it the two-week versus four-week?

A It was abrupt discontinuation versus two-week.
Q So why was a four-week taper not included in that study?
MR. DURAISWAMY: Object to the form. Asked and answered several times today.
A The -- we did that study and we also compared pool data of studies that had abrupt discontinuation and other studies that had taper and saw that there was a relatively modest difference between an abrupt discontinuation and a taper, so we didn't -- we did not believe that further analyses of different durations of taper would be -- provide significant additional information.
Q Who wrote the protocol for that study?
MR. DURAISWAMY: Object to the form. Ambiguous.
A It was one of the core generalized anxiety disorder studies. Early on I think I was the lead physician on those -- that study, and then that transitioned to Dr. Russell when I was promoted to medical director and hired Dr. Russell, Jim Russell.
Q Okay. I guess what I don't understand is I took his e-mail to say that he was suggesting one study that included abrupt discontinuation, a two-week taper and a four-week taper all in one study. Is

reference 2, data on file. Hmm. So at the time of this paper that study wasn't published apparently, at the time of writing this medical letter. So, no, I can't say off the top of my head exactly which study that was. It would have been one of the early depression studies prior to February 11, '05, obviously, but it's not clear to me from this information exactly which study it was.

Q It's my understanding from your earlier testimony that you ultimately decided that a two-week taper was as long as a taper as you needed to study; is that correct? You didn't need to study longer than a two-week taper?

A That's correct. We had no reason to believe that that would have provided additional material information.

Q And I realize that this was drafted some years ago and additional studies were done. But did you ever reach a conclusion that a three-day taper was sufficient to substantially decrease the incidence of discontinuation-emergent adverse events for Cymbalta?

A Not to my knowledge.

MR. WOERNER: Okay. Now we have five minutes left on the tape, so let's take a break. Where am

context, again, speaking as a clinician, around tapering is that with very few exceptions, there's -- there's no disadvantage to tapering. So even in a setting where the scientific data supporting tapering is modest or weak, there's almost no reason not to do it. There are rare exceptions to that, which we could talk about if you want to.

Q Doctor, did the data that you compiled across many studies regarding tapering when discontinuing Cymbalta, did that data suggest that there would be a significant difference in the risk of DEAEs based on the precise duration over which the medication was tapered?

MR. WOERNER: Object to form.

A No. Having -- having looked at the pool of data that I referred to earlier showing 10 percent drug versus placebo difference in DEAEs after abrupt discontinuation and 7 percent after taper, we had no reason to believe that looking at finer gradations of tapering in dose or duration of tapering would have been likely to show significantly different results on average.

Q Doctor, do you recall being asked some questions about Exhibit 2, what has been referred to during

tapering substantially improves tolerability, which does not represent the data accurately, period, end quote. Do you see that?

A Yes.

Q Why did it not represent the data accurately?

A As I've testified earlier today, the -- the full body of the data that we had available by, I think, this time indicated that -- the data we had on Cymbalta seemed to indicate that there was probably a modest improvement -- a modest reduction in DEAEs when you taper as opposed to discontinue abruptly, and other data from drugs in the class were consistent with that. We were concerned that putting that sentence in the label might suggest to prescribers that if they tapered, it would solve the problem completely, and we thought that that would be inappropriate reassurance.

Q Okay. Because, in fact, patients could still suffer from DEAEs even if they were tapering the?

A Exactly. That's what the data show.

Q And when you said we, what -- who did you mean by we?

A Well, I proposed striking that sentence, but it -- you know, as the e-mail chain shows, others, like Jim Russell, were in agreement.

Q All right. And then the --

MR. DURAISWAMY: Michael, I think you're out of time. Obviously I'm not going to cut you off if you got a few more minutes, but I think you're out of time.

Q The next sentence says, To Rick's point, it (perhaps more weakly) implies that tapering solves all tolerability problems entirely, which would be an even worse representation of the actual data.

Why would that be an even worse representation of the actual data?

MR. DURAISWAMY: Objection. Asked and answered.

A You wouldn't want to reassure prescribers that if you taper there's no chance of discontinuation-emergent adverse events. That would -- that would -- it's false information and it would falsely reassure people.

MR. WOERNER: That's all the questions I have.

THE WITNESS: Okay.

MR. WOERNER: Thank you very much.

THE WITNESS: Thank you.

VIDEOGRAPHER D'ANGELO: This concludes testimony. It is now 8:21.

(The deposition concluded at 8:21 p.m.)

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EASTERN DISTRICT OF VIRGINIA
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GILDA HAGAN-BROWN, Plaintiff, -v- ELI LILLY AND COMPANY, AN INDIANA CORPORATION, Defendant.	)	CAUSE NO. 1:14-CV-01614-AJT-JFA
and		
JANINE ALI, Plaintiff, -v- ELI LILLY AND COMPANY, AN INDIANA CORPORATION, Defendant.	)	CAUSE NO. 1:14-CV-01615-AJT-JFA

Job No. 97558

I, MICHAEL J. DETKE, state that I have read the foregoing transcript of the testimony given by me at my deposition on April 28, 2015, and that said transcript constitutes a true and correct record of the testimony given by me at said deposition except as I have so indicated on the errata sheets provided herein.

_____
MICHAEL J. DETKE

STATE OF INDIANA

COUNTY OF MARION

I, Michele K. Gustafson, CRR-RPR, a Notary Public in and for said county and state, do hereby certify that the deponent herein was by me first duly sworn to tell the truth, the whole truth, and nothing but the truth in the aforementioned matter;

That the foregoing deposition was taken on behalf of the Plaintiffs; that said deposition was taken at the time and place heretofore mentioned between 10:10 a.m. and 8:21 p.m.;

That said deposition was taken down in stenograph notes and afterwards reduced to typewriting under my direction; and that the typewritten transcript is a true record of the testimony given by said deponent;

And thereafter presented to said witness for signature; that this certificate does not purport to acknowledge or verify the signature hereto of the deponent.

I do further certify that I am a disinterested person in this cause of action; that I am not a relative of the attorneys for any of the parties.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this_____day of May, 2015.

_____

Michele K. Gustafson, CRR-RPR

Notary Public

My commission expires:

August 31, 2017

Job No. 97558