UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

JANINE ALI,
Plaintiff,

vs. Case No. 1:14cv-01615-AJT-JFA

ELI LILLY AND COMPANY,
An Indiana corporation

Defendant.

GILDA HAGAN-BROWN,

Plaintiff,

vs. Case No. 1:14cv-01614-AJT-JFA

ELI LILLY AND COMPANY,
an Indiana corporation
Defendant.

CONFIDENTIAL

VIDEOTAPED DEPOSITION OF MICHAEL CLARK, M.D.

Washington, D.C.
Tuesday, May 26, 2015

Reported by: Lori J. Goodin, RPR, CLR, CRR,
Realtime Systems Administrator

May 26, 2015

10:04 a.m.

Videotaped Deposition of MICHAEL CLARK, M.D., held at Covington & Burling, LLP, One City Center, 850 Tenth Street, Northwest, Washington, D.C. before Lori J. Goodin, RPR, CLR, CRR, Realtime Systems Administrator, a Notary Public in and for the District of Columbia.

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EXAMINATION INDEX

EXHIBITS

Clark

EXHIBIT	DESCRIPTION	PAGE
Exhibit 1	Clark's expert report for Hagan-Brown	10
Exhibit 2	Clark's expert rebuttal report for Hagan-Brown	10
Exhibit 3	Clark's expert report for Ali	10
Exhibit 4	Clark's expert rebuttal report for Ali	11
Exhibit 5	Clark's CV, 5/17/15	15
Exhibit 6	CYM-01188922, Pain on Demand Series CD	63
Exhibit 7	CYM-01188735, slide presentation	58
Exhibit 8	CYM-01720634, press release	66
Exhibit 9	CYM-00009871, Studio Anchor for Cymbalta	68

as part of promoting Cymbalta or whether that was given to speakers as part of speaker training?

A. Correct.

Q. Okay. Did you ever give presentations to other physicians as part of promotional activities for Cymbalta?

A. Yes.

Q. Okay. If you turn the page with the Bates stamp ending 754. Do you see that? It is double-sided, by the way.

A. Yes.

Q. All right. This is Cymbalta's safety profiles, warnings, and precautions, continued.

A. Yes.

Q. And this is the section of the presentation where you are sort of going over the very safety issues associated with Cymbalta; is that right?

A. Yes.

Q. And this is required by law; is that true?

A. I don't know.

Q. Okay. The first section says abrupt or tapered discontinuation; right?

into live use or was just a proposal.

Q. Okay. So do you recall whether or not there was in fact a webcast on Medscape for WebMD?

A. I don't.

Q. Do you recall preparing a video to that effect?

A. I don't.

Q. Take a look to that document and see if it refreshes your recollection. If it doesn't, that is fine.

A. Yeah, it really doesn't. It looks like the clip is only 45 seconds long, so it is not very long.

Q. Do you recall maybe doing a video invitation for people to come to a live webcast? Could that be what that is?

A. It could be. It could be, but I don't know.

Q. Okay. Giving live webcasts for Eli Lilly, that was something that you did for Eli Lilly; is that right?

A. Yes.

Q. Okay. Specifically with regards to Cymbalta?

A. Yes.
Q. And specifically you were promoting Cymbalta as a treatment for fibromyalgia; is that right?
A. Yes.
Q. Okay. One more.
(Clark Exhibit Number 12 marked for identification.)
BY MR. WISNER:
Q. All right, Doctor. I'm handing you what I have marked as Exhibit 12 to your deposition.
This is the document that is fairly lengthy one. It starts off with CYM-02832936.
Do you recognize this document?
A. Yes.
Q. What is this document?
A. It is a lecture on duloxetine and the treatment of diabetic peripheral neuropathic pain.
Q. And it has your name on the front; is that right?
A. Yes.
Q. Did you prepare this lecture?
A. No, I was simply the speaker.

A. Yes.

Q. Okay. Now, on Page 11 under the section, there is a sentence in the first paragraph of Section 8. It says, the sentence in the middle, it says, "Additionally, with rare exception, discontinuation symptoms quickly resolve when the patient resumes the previous dose then begins a more gradual tapering process."

You would agree that patients should be tapered off of Cymbalta upon discontinuing the medication, right?

MR. STEKLOFF: Object to form.

THE WITNESS: That is typically what I do when I am treating patients with it.

BY MR. WISNER:

Q. And what is your taper regimen?

A. Oh, it varies by individual. So, there is no algorithm or necessary stepwise process. But typically I would decrease somebody by 30 milligrams in their dose, maybe for a few days, to a week, and then go down by 30-milligram increments.

Again, it is influenced by other factors, not so much by the fear of

discontinuation symptoms.

But, larger concerns about whether somebody is going to relapse into depression or have their pain reemerge.

And, so, and it would also be influenced by whether or not I was switching somebody to another antidepressant.

So, in switching somebody, I might stop it cold.

And if I was worried about somebody being a fragile depression, or a fragile neuropathic pain state, I might go down once a month, or slower, to see, make sure that their depression wasn't worsening or the pain wasn't coming back.

Q. So, then, and tell me if I'm wrong here, but your primary concern in discontinuing a patient off of Cymbalta is not the emergence of discontinuation symptoms, as much as the reemergence of the underlying condition?

A. Yes.

Q. Okay. You had a chance to obviously review the medical records that have been discovered in, for Gilda Hagan-Brown, right?

A. Yes.

Q. And you understand she took what appears to be 30 milligrams a day for a period of several months?

A. Yes.

Q. And she subsequently decided she didn't want to take Cymbalta anymore.

MR. STEKLOFF: Object to form.

THE WITNESS: That is the assumption, yes.

BY MR. WISNER:

Q. Okay. Assuming what we just covered, what would you have advised her to be a proper taper regimen?

MR. STEKLOFF: Object to form.

THE WITNESS: Well, I mean it is hard to know, because I wasn't taking care of her and I don't have all of the information that I would have if I was treating somebody.

But, if I were to think about a patient taking 30 milligrams for a couple of months, I would just tell them to stop the medicine.

BY MR. WISNER:

Q. You would just say abrupt, just stop taking the drug?

A. Yes.
Q. And why is that?
A. Because in my experience, I haven't had anybody have difficulty doing that.
And, and, you know, you have to stop sometime.
So, 30 milligrams, once a day, it is a pretty low dose of Cymbalta.
Q. What is the lowest available dose of Cymbalta?
A. 20 milligrams.
Q. And that is a day, right?
A. Well, they make a 20-milligram size capsule.
Q. Right. And so the smallest dose would be 20 milligrams a day?
A. For a daily regimen, yes.
Q. Fair enough. I guess you could do 20 milligrams every other day.
A. Yes.
Q. Now Cymbalta's half life is about 12 hours, right?
A. Yes.
Q. If you were taking Cymbalta every other day, you would have experienced

A. Yes.
Q. Do you have any data specifically relating to Cymbalta that supports that statement?
A. I don't think so.
Q. So, this opinion is based then upon your general understanding of tapering?
MR. STEKLOFF: Object to form.
THE WITNESS: Yes.
BY MR. WISNER:
Q. In other words, it is based on the conventional wisdom associated with discontinuing antidepressants?
A. Yes.
Q. In preparing your reports did you evaluate any clinical trial data wherein Lilly specifically measured abrupt versus tapered discontinuation from Cymbalta?
A. Let's see. I don't think I looked at that data.
Q. If, in fact, Lilly had conducted clinical trials to measure this exact difference, and observed that there was no difference between tapered or abrupt discontinuation in their clinical trials, would that surprise you?

MR. STEKLOFF: Object to form.
THE WITNESS: Would that surprise me? No.
BY MR. WISNER:
Q. Is that information as a prescriber, you would want to know?
A. Well, again, when you see data from, and conclusions from trials like that, from any trial, you are used to seeing things that are conflicting, and you recognize that you are looking at data in an artificial context. So, it would be one piece of information that you would want, but it would not necessarily be surprising to you.
Q. If, in fact, Cymbalta's clinical trial showed that there was no difference between abrupt versus tapered discontinuation of Cymbalta, specifically by 30 milligrams a day, is that information that you think should have been in the label?
MR. STEKLOFF: Object to form.
THE WITNESS: Well, again, to preface, I don't know what is allowed to be put in the label, versus what is not allowed to be put in the label.

But, certainly if there is no difference between tapering versus stopping 30 milligrams, that wouldn't surprise me, since that has been my experience.

BY MR. WISNER:

Q. Well, wasn't that kind of contradicting conventional wisdom?

A. How so?

Q. Well, conventional wisdom said tapering helps ameliorate the symptoms that a patient may suffer when stopping an antidepressant, right?

A. Yes.

Q. If Lilly's historical data showed that in fact that was not true, that would go against conventional wisdom?

A. But if you are talking about stopping 30 milligrams versus tapering 30 milligrams, that is not what they are talking about. And that is certainly not what I'm talking about.

I'm talking about when somebody is on 60, 90, 120 milligrams.

I mean there comes a point at which you just, it really becomes, for lack of a better

word, silly to try to create smaller and smaller decrements and extend the taper out in an exponential fashion.

And most patients will tell you at some point they just want to stop the medicine, move on.

So, no, it wouldn't surprise me at all if there was, nor is it a contradiction to say that beyond a certain threshold you don't need to taper anymore to stop the medicine.

Q. Let me pose a different question to you.

Assuming Lilly did conduct a clinical trial where patients who were taking 120 milligrams -- strike that.

60 milligrams a day, one group stopped abruptly, the other group tapered, via 30-milligram increments over a period of two weeks. And that study showed, in fact, that there was no difference in the emergence of discontinuation symptoms.

Is that a clinical trial -- is that data that you would want to have known as a prescriber?

A. Not necessarily.

MR. STEKLOFF: Object to form.
BY MR. WISNER:
Q. And it says 1 percent or greater.
A. Correct.
Q. And that is referring to a bunch of different potential symptoms that could occur upon discontinuation, right?
A. Yes.
Q. Now in your report you stated that you think that it would be unreasonable for a physician to think that that 1 percent meant that the risks were about 1 percent; is that right?
A. Correct.
Q. And, you are aware that both of the physicians in this case understood that the risk was about 1 percent when they read that label.
MR. STEKLOFF: Object to form.
THE WITNESS: Yes.
BY MR. WISNER:
Q. And so it is your opinion and testimony that the physicians, in understanding and reading the prescribing insert in this case, were unreasonable?
MR. STEKLOFF: Object to form.
THE WITNESS: I'm sorry, could you

at 1 percent or greater and at a significantly higher rate in the duloxetine treated patients compared to those discontinuing from placebo."

Do you see that?

A. Yes.

Q. On Page 18, you quote a portion of that sentence. You say the first -- this is the second full paragraph, three sentences in. It says, "The first paragraph of the warning states the discontinuation of the symptoms occurred at a significantly higher rate in duloxetine treatments patients compared to those discontinuing from placebo." Right?

A. Yes.

Q. What do you understand that phrase, at a significantly higher rate, to mean?

A. I'm not sure how to make it more clear.

But, basically that when you -- significantly refers to a statistical comparison.

And, so, basically what it means is that you don't think it is a chance difference.

Q. Okay. That is kind of what I want to get at.

So, when it says significantly

higher, it is not using significantly in the colloquially sense. It is using significantly in the statistical sense?

A. Correct.

Q. Okay. And on the last sentence of your report in that -- sorry, that paragraph in your report, Page 18, it says, "A reasonable physician would understand that the 1 percent figure reflects the reporting threshold listing each specific symptom that occurred above that threshold, and that it does not reflect a specific frequency of the symptom."

Do you see that?

A. Yes.

Q. Have you seen any studies that Lilly may or may not have conducted measuring whether physicians understood that 1 percent figure to reflect the reporting threshold?

A. No.

MR. STEKLOFF: Object to form.

BY MR. WISNER:

Q. Okay. Would you agree, though, that a specific frequency of the symptom would have been helpful in the label?

MR. STEKLOFF: Object to form.

Before you began preparing your report for this case, you believed that discontinuation symptoms were rare for Cymbalta, correct?

A. Yes.

Q. And during the course of your evaluation, has that opinion changed?

A. No.

MR. WISNER: No further questions.

THE VIDEOGRAPHER: This concludes today's videotaped deposition of Dr. Michael Clark. We are going off the record. The time is 16:11 p.m.

(Whereupon, signature not having been waived, the deposition concluded at 4:11 p.m.)

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CERTIFICATE OF COURT REPORTER

UNITED STATES OF AMERICA)

DISTRICT OF COLUMBIA)

I, LORI J. GOODIN, the reporter before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was sworn by me; that the testimony of said witness was taken by me in machine shorthand and thereafter transcribed by computer-aided transcription; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, or financially or otherwise interested in the outcome of this action.

Lori J. Goodin

LORI J. GOODIN
Notary Public in and for the
District of Columbia

My Commission expires: May 14, 2016

DEPOSITION ERRATA SHEET

Case Caption: Ali, Janine vs. Eli Lilly and Company

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the _____ day of

_____, 20___.

_____

Michael Clark, M.D.