UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF VIRGINIA

ALEXANDRIA DIVISION

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JANINE ALI,

Plaintiff,

v.

ELI LILLY AND COMPANY,

an Indiana corporation,

Defendant.

----------x

Case No.

1:14-CV-01615-AJT-JFA

Hon. Anthony J. Trenga

Video Deposition of NAVERA R. AHMED, M.D.

McLean, Virginia

Monday, April 20, 2015

3:52 p.m.

Pages: 1 - 172

Reported by: Amy E. Sikora-Trapp, RPR, CRR,

Former CSR-NY, CLR

Video Deposition of NAVERA R. AHMED, M.D.
held at the offices of:
Sands Anderson
1497 Chain Bridge Road, Suite 202
McLean, Virginia 22101

Pursuant to notice, before Amy E. Sikora-Trapp, Registered Professional Reporter, Certified Realtime Reporter, Former Certified Shorthand Reporter (NY)(license unrenewed), Certified LiveNote Reporter, and Notary Public within and for the Commonwealth of Virginia.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:

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A P P E A R A N C E S

(Continued)

ON BEHALF OF THE WITNESS:

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ALSO PRESENT:

Ellen Hibbert, Videographer

April 20, 2015

C O N T E N T S

E X H I B I T S

C O N T E N T S

(Continued)

E X H I B I T S

independent of the record, meaning without the medical record would you remember the patient and your interactions with her.

A. Some, but not all. I mean, most of it is what's in the record is what I remember mostly.

Q. But do you remember Ms. Ali?

A. Oh, yes. I do.

Q. And do you remember generally treating her over the period of several years?

A. Yeah, uh-huh.

Q. What -- do you recall what you were treating her for?

A. Yes. I was treating her for fibromyalgia, and she had some osteoarthritis. These are the main conditions that I was treating her for.

Q. Before we go into the details of that treatment, can you walk us briefly through your educational background, starting in -- with undergraduate degree and then continuing on?

A. I did my medical school in Bangladesh

Medical College, then I came here and I did my residency at Prince George's Hospital Center, Maryland, and I did my fellowship at Washington Hospital Center, Georgetown University. And then I've been practicing here for the last 10 years or more.

Q. What year did you come to the United States and go to Prince George's County Medical Center?

A. I started at Prince George's County, my residency, in 1999.

Q. And where did you say you studied overseas?

A. Bangladesh.

Q. Did you focus on any -- any particular areas in your studies in Bangladesh?

A. No. I just did my medical school, finished my medical school. Straight out of medical school I came here, and then I took -- I did my residency here.

Q. And did you have any areas of focus during your residency?

A. My residency is internal medicine.
Q. What was your fellowship in?
A. Rheumatology.
Q. What year did you complete your fellowship?
A. 2004.
Q. Are you board certified?
A. Yes.
Q. In what?
A. Rheumatology. And I was board certified in internal medicine, too, but I -- that was 10 years back, so the second board certification I just retook my rheumatology boards because I don't practice internal medicine, my practice is rheumatology.
Q. And when you began practicing following your fellowship in 2004, can you walk us through your employment, where it was and what year it was?
A. Well, after I completed by fellowship, I started at the Arthritis Clinic of Northern Virginia, and have been there since

time frame and then continuing through to 2009, and again feel free to review your records, what types of treatment did you provide to Ms. Ali for her fibromyalgia?

A. Physical therapy, Lidoderm patches, Flexeril, tramadol, NSAIDs but she was taking over the counter, and she had gastritis so she couldn't take them anymore.

Q. Were those treatment options successful for Mrs. Ali?

A. For time being, but just a general way for fibromyalgia patient may help for a while, but then . . .

Q. Jumping ahead to the 2009 time frame, was Mrs. Ali still experiencing symptoms associated with fibromyalgia?

A. Yeah. 2009, she saw me because she was going to the pilgrimage, the Hajj pilgrimage, and wanted to take something. Other things obviously were not working, and so she wanted -- so we -- I gave her -- from my note, I feel like I gave her the sample with the package insert for

her to read about it, and if she thought that she would want to try the medication, then we would prescribe it. And she -- I think this was in October time frame, if I recollect from my chart.

And I think a few weeks later she came back and had decided not to try Cymbalta. She read the package insert. And I think we gave her -- I think the way I recall, is Flexeril and some tramadol to tide her through the pilgrimage process and to help her with any pain management.

Q. When you discussed -- when you provided the patient insert for Cymbalta to Mrs. Ali in the October 2009 time frame, do you recall whether you discussed the information in the patient insert with her?

MR. WISNER: Objection to the phrase "patient insert."

A. More likely --

MR. MARR: Go ahead.

A. More likely than not, because it is custom, as I said, in my practice that I review the risk/benefits of medication.

Q. Is one of the things with Cymbalta that you review the possible side effects associated with discontinuation of the drug?

A. More likely than not, the package insert was reviewed. If it was part of the package insert, then more likely than not, yes.

Q. And is it your understanding, sitting here today, that discontinuation symptoms are discussed in the label for Cymbalta?

A. The current label has -- it has to be tapered off, so . . .

Q. And was that true in 2009 as well?

A. If it was in the package insert, yes. If it was in the package insert in 2009.

Q. But as of 2009, beyond the package insert or the label, did you also have that understanding from your practice and your experience as a rheumatologist?

A. Yes. Your question is again that it has to be tapered off, is that your question?

Q. Yes.

A. Yes.

trial --

MR. STEKLOFF: Strike that.

Q. What value would you place on a placebo-compared trial, as opposed to a nonplacebo-controlled trial?

MR. WISNER: Objection, vague.

A. What do you mean by "a nonplacebo"?

Q. What about -- what value would you put on a placebo-controlled trial versus an open-label trial where there was no placebo to compare?

MR. WISNER: Objection. Objection. Vague as to "value."

A. A good value. Better than any -- I mean, a randomized double-blinded placebo-controlled trial is better than an open-label trial.

Q. And when you see the language "the following symptoms occurred at one percent or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo," does that mean to

you that those symptoms only occurred at one percent in that trial?

MR. WISNER: Objection. Move to strike as leading, as well as lacking foundation.

A. Repeat your question.

Q. When you see the language that says, "following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at one percent or greater, and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo," does that mean to you --

A. So in hundred patients, one patient had the symptom.

Q. And my question is, where it says, "the following symptoms occurred at one percent or greater and at a significantly higher rate," does that mean to you that those symptoms only occur in one -- one percent of patients?

A. Yes.

Q. Does that language suggest to you

that the symptoms could have occurred at a rate greater than one percent?

A. It says, yes.

Q. And based on your experience --

MR. STEKLOFF: Strike that.

Q. Based on your knowledge of class labeling of antidepressants, was it your understanding that some of those symptoms, such as dizziness, do occur in patients at a rate greater than one percent when -- when they discontinue?

A. Yes.

Q. And so is it fair to say that you did not, based on your knowledge of antidepressants, in your experience treating patients with antidepressants, that you did not need the label to tell you that some of these symp -- that the following -- that the symptoms listed in this paragraph occurred at more than one percent when patients discontinued from Cymbalta?

MR. MARR: Objection to form and foundation.

MR. WISNER: Join.

THE WITNESS: I can answer?

MR. MARR: Yup.

A. Yes, a little bit -- a little bit greater than one percent. Cannot be a hundred percent you know. Has to be slightly over one percent. You wouldn't expect it to be 90 percent, when you say greater than one percent, so . . .

Q. Right. But it might be reasonable to say -- it wouldn't surprise you to hear 12 percent of patients experienced dizziness, based on what you've told us about dizziness; correct?

MR. WISNER: Objection. Move to strike as leading, as well as lacking foundation.

A. I would expect the label to say about 12 percent had dizziness. I wouldn't expect it to say one percent had dizziness.

Q. What does it mean -- what does it mean to you that in clinic -- placebo-controlled clinical trials the symptoms occurred at a

significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo?

A. It means that -- exactly what it says, it means that they had -- when you compared it to placebo, then it was higher in duloxetine-treated patients, withdrawal symptoms, versus the placebo group. Just what it says, it's higher rate.

Q. And do agree that it says significantly higher as well?

MR. MARR: Objection.

A. Yes.

MR. STEKLOFF: I'm going to mark --

(Ahmed Exhibit Number 4, Journal of Affective Disorders article entitled: Symptoms following abrupt discontinuation of duloxetine treatment in patients with major depressive disorder, by Perahia, et al., marked for identification as of this date.)

(Witness and counsel confer.)

mean, I -- I have to look at the article. I can't just say would affect me, would not affect me. I have to look at it.

Q. If -- if a patient with -- not Ms. Ali, but a patient came to you and had the exact same experience as Mrs. Ali, and you treated her for the same number of years that you treated Mrs. Ali and had the same results, as of today, would you still prescribe Cymbalta for that patient?

MR. WISNER: Objection. Lacks foundation, speculation.

A. I -- I still prescribe Cymbalta to some of my patients now. I can't say exactly like Mrs. Ali because no patient is exactly the same. So -- I mean, there are patients that are taking Cymbalta, yes, and doing well on it, yes.

MR. STEKLOFF: I pass the witness.

MR. WISNER: Do you need a break or are you willing to keep going?

THE WITNESS: Yeah, I think we can.

MR. WISNER: Take a short break?

THE WITNESS: No, no. I think we can continue.

MR. STEKLOFF: Oh, okay. Great.

EXAMINATION BY COUNSEL

FOR THE PLAINTIFF

BY MR. WISNER:

Q. Good afternoon, Doctor.

A. Yeah.

Q. Early evening. My name is Brent Wisner. I represent Mrs. Ali in this case.

Earlier you testified you had a chance to look at the complaint; is that right?

A. I did, yes.

Q. You didn't carefully study it, did you?

A. No, I looked.

Q. Okay. So you have a general understanding, then, of what this case is about?

A. Yes.

Q. You understand that Mrs. Ali has not filed any complaint or lawsuit against yourself, you're aware of that?

A. Yes.

Q. Okay. The first thing that I want to talk about is, I want to delve a little bit into how you go about discussing a drug with a patient.

You testified on direct examination that you discuss the risks and benefits with -- with the patient; is that right?

A. Yes.

Q. And you previously testified that your understanding of the risks and benefits of a drug are at least in part determined upon what's in the prescriber insert; is that right?

A. Yes.

Q. Why do you rely upon a prescriber insert in trying to understand the risks and benefits of a drug?

A. Because it's a compilation of the data, and we feel like it's accurate. It tells you what symptoms and side effects we should be looking out for and counseling our patients about and what we can expect.

Q. And it would be fair to say that you would expect the prescriber insert to give you the most common or frequent adverse effects to expect from a drug?

MR. STEKLOFF: Object to form.

A. Yes.

Q. Based on your experience with Cymbalta and having reviewed the product insert at some point in your career, what do you understand to be the most common side effects of taking Cymbalta?

A. I mean, apart from, you know, headaches, dizziness, nausea, some GI side effects, the things that we worry about, even though it's rare, you know, it's like rare complication for seratonin symptoms and some things that come with the class effect. But commonly most patients will complain of somnolence, drowsiness, dizziness, and sometimes GI effects. In my practice, that's what I have seen.

Q. And would it be fair to say that in

your experience with patients who discontinue Cymbalta who experience withdrawal side effects, that that's pretty uncommon?

MR. STEKLOFF: Object to form.

A. It varies from patient to patient. I mean, I have had a few patients who have had to have a gradual taper, and then after that they've tolerated it. But then there are some patients who've done very well with -- with tapering off their medication. Sometimes I think some of them have even stopped it and not told me about it and haven't had any problems with it.

Q. Would it -- would it be fair to say that when you decide to prescribe a medication with a patient, it's a joint decision-making process?

A. Yes.

Q. And, in fact, with Mrs. Ali, you previously discussed Cymbalta with her and she decided not to take it; right?

A. Sure.

Q. You didn't prescribe it to her

anyway?

A. No. At that time we said no. In 2009, when she read about it and she said no, I don't want to go on it, that's fine, I prescribed her something else.

Q. And that's because you can never force a patient to take a drug?

A. No.

MR. MARR: Make sure you let him finish his question. Even though he's talking slowly, they must talk slower than Virginians do in California, but let him finish his question before you answer it. That way it will be a clean transcript for Madam Court Reporter.

THE WITNESS: Okay.

MR. SEKLOFF: Have you ever been told you talk slowly?

MR. WISNER: I've never, but I appreciate it. And I'm sorry -- can you just repeat the last question. I want to make sure --

(Discussion off the record.)

(Record read.)

Q. That's right?
A. Yes, I cannot.
Q. Okay. You also stated on your direct examination that you, at least with Mrs. Ali and your notes, it reflects that you gave her a copy of the prescriber insert; is that right?
A. Yes.
Q. Is that a common practice of yours?
A. Yes.
Q. Why do you have patients review the prescriber insert before they start a medication?
A. Just gives them something to look through. There's the Internet, they read about stuff in the Internet. I discuss things. And when you discuss things with your patients, oftentimes they may not remember, so it's good to have something in writing so they can go ahead and read at home and think, oh, maybe I can go back and ask my doctor about this or I didn't understand this or something like that.
So they have a chance to review the literature and ask me questions so that I can

answer them for them -- answer it for them before they start a medication. And then they are aware of the risks and the benefits.

Q. And with Mrs. Ali in 2009 she reviewed it, came back and said she didn't want to take the drug; right?

A. Yes.

Q. She wasn't willing to take on the risks or the benefits of the medication?

A. Sure.

Q. Now, I want to draw your attention to Exhibit 3. This is the product insert that we were talking about. I think it's on page seven, so you can just keep it there. Page seven on the top right?

A. Okay.

Q. And we're under section 5.7, "Discontinuation of Treatment with Cymbalta"; right?

A. Uh-huh.

Q. Now, opposing counsel asked you some questions about this, but the sentence -- the

second sentence in that paragraph reads, "Following abrupt or tapered discontinuation of placebo-controlled clinical trials the following symptoms occurred at one percent or greater." We'll stop right there.

When you read that, Doctor, do you understand -- what do you understand the risks of discontinuation symptoms or withdrawal to be?

MR. STEKLOFF: Object to form.

A. Repeat your question. What do I understand or --

Q. Yeah. If I -- if I'm a patient -- let me rephrase.

If I'm a patient and I ask you, Doctor, what is the likelihood that I'm going to suffer from discontinuation, what would you tell them?

MR. STEKLOFF: Based on the whole section or based on --

A. One percent. In 100 patients, you can have one, one percent.

Q. So it would be fair to say, and if

I'm wrong, please correct me, that it was your understanding when you read this label that the general risk of discontinuation symptoms is about one percent?

A. Yeah.

Q. Now, Doctor, what percentage of -- let's assume for a second that the percentage is not one percent. Let's assume the percentage is something higher.

At what point -- at what number would you believe that if it was above that number this warning be misleading?

MR. STEKLOFF: Object to form.

A. I can't say really. I mean, obviously, I would not expect it to be way higher than one percent, you know.

Q. Well, right there. What do you consider to be way higher?

MR. STEKLOFF: Object to form.

THE WITNESS: Should I guess, Michael?

MR. MARR: Well, you shouldn't -- you

shouldn't guess. But you -- you gave a verbal statement of way higher, and -- and if you have a numerical equivalent that you can give without speculating or guessing, then give it.

A. Probably -- I don't know, five percent or higher.

Q. So if the actual risk of discontinuation is significantly higher than five percent, would you agree with me that this warning as it's written is misleading?

MR. SEKLOFF: Object to form.

A. Yes.

Q. And if I say significantly higher, such as 45 percent, would that qualify as significantly higher?

A. Yes.

MR. STEKLOFF: Object to form, lacks foundation, calls for speculation. Incomplete hypothetical.

Q. Could you please turn your attention, to Exhibit 4. This is this medical journal article that opposing counsel showed to you.

Now, Doctor, I understand you've never seen this before; right?

A. No.

Q. You've never read this over?

A. No.

Q. And so you don't feel qualified to be offering opinions about the accuracy or validity of this publication; right?

A. Yes.

Q. Now, if I could just drawing your attention to a couple of points here. If you look at the bottom of the first page, and that says, "Declaration of interest."

Do you see that?

And it says, "David Perahia," and it lists several other individuals, and it says, "are employees of Eli Lilly and Company."

Do you see that?

A. Yes.

Q. So that footnote suggests that this publication was in fact written by Eli Lilly employees; is that right?

A. Who are the authors, yes. Seems like the authors, yes.

Q. Okay. Now, I want to draw your attention -- if you turn to page 209. Oh, I'm sorry, Doctor. The page before that. 208. It says under the section of "Results" here, right. I'm going to read you a sentence, and I don't want you to opine about what that means. I'm just going to ask you a very simple question afterwards, okay. It says, "Significantly more duloxetine treated patients (44.3 percent) report at least one DEAE," and I'll represent to you that that stands for discontinuation of emergent adverse event. So I'll read that, "Significantly more duloxetine-treated patients (44.3 percent) report at least one DEAE than placebo-treated patients (22.9 percent), with dizziness being the most common symptom."

Do you see that?

A. Yes.

Q. And it refers you to table two; right?

A. Uh-huh.
Q. Now --
A. Yes.
Q. -- in the drug label that we looked at a second ago, the U.S. prescriber insert, nowhere does it say 44.3 percent, does it?
A. No.
Q. You would agree with me, that's a piece of information, as a prescriber, that you would want to know?
MR. STEKLOFF: Object to form.
A. Yes.
Q. Why is that information you would want to know?
A. It would -- you know, it would give me an idea as to what the actual percentage of the side effect it was producing was. If it's -- yeah, it's more than one percent but it's 44 percent so I would like to know.
Q. Okay. And would it be fair to say that if this clinical trial -- if that statement that I read is true, and please just assume that

it is true, I don't need you to take my word on it, okay, but assuming that's true, would it be fair to say that this is information you would want to relay with your patients moving forward when you prescribe Cymbalta to them?

MR. STEKLOFF: Object to form.

MR. MARR: Objection, form.

A. Can I assume?

Q. Assuming it's true.

A. I don't know this art -- assuming.

MR. MARR: He's asking you to assume it's true. So based upon that assumption.

A. Yes.

Q. And so it would be fair to say, then, that if this information is true, it would affect the way you go about discussing the risks and benefits of Cymbalta to your patients?

MR. STEKLOFF: Object to form. Calls for speculation.

A. Yes.

Q. Doctor, if you need a break, you let me know, okay, because I like to go quick. Okay.

amitriptyline but, you know, not SSRI and SNRIs, no.

Q. Do you ever prescribe Paxil?

A. No. Because we treat fibromyalgia and Cymbalta is approved for fibromyalgia. The others are -- I don't treat depression or anything.

THE REPORTER: "I don't treat"?

MR. MARR: "Depression or anything."

Q. I'm going to hand you, Doctor, what I'm going to mark as Exhibit 6.

(Ahmed Exhibit Number 6, copy of U.K. drug label for Cymbalta, 52 pages, marked for identification as of this date.)

Q. This is a copy of the drug label for Cymbalta as it exists in the United Kingdom. As a doctor who has had some foreign training, I'm sure you're familiar with other countries have different types of drug labels.

A. Uh-huh.

Q. Now, if I could have you turn your attention to page six. I'd also ask that you

have the drug label, which I believe is Exhibit 3, with the section "Discontinuation Readily Available," because we're going to go back and forth between these labels; okay?

All right. So on page six, do you see the section -- and this is referring to Exhibit 6, the -- the European label.

Do you see the section that reads, "Discontinuation of treatment"?

A. Yes.

Q. Okay. Now, it starts off --

MR. STEKLOFF: Hold on. Just put a standing objection to relevance to this European label questioning.

Q. "Withdrawal symptoms when" treated is discont -- "when treatment is discontinued are common, particularly if discontinuation is abrupt."

Do you see that?

A. Yes.

Q. Now, if I could you turn your attention to the U.S. label. Nowhere in the U.S.

label does it state that discontinuation is common, does it?

MR. STEKLOFF: Object to form.

A. You want me to read the entire paragraph to say where it says nowhere?

Q. Please take a second and just review the U.S. label, but nowhere in that -- those three paragraphs under section 5.7 does it say that discontinuation is a common phenomena?

MR. STEKLOFF: Object to form.

A. Yes.

Q. Okay. On the European label, it says, in clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45 percent of patients treated with Cymbalta and 23 percent of patients taking placebo."

Now, you'd agree with me, Doctor, that 45 percent or approximately 45 percent, that comports with the 44.3 percent I showed you earlier; right?

MR. STEKLOFF: Object to form. Calls

for speculation.

A. Yes.

Q. And again, nowhere in the U.S. label does it say about approximately 45 percent?

MR. STEKLOFF: Object to form.

A. Agreed.

Q. And previously we -- I already asked you this, but -- I think I asked you about 44.3 percent, but if it is actually in fact approximately 45 percent, that's information you'd want to know as a prescriber?

MR. SEKLOFF: Object to form. Calls for speculation. Incomplete hypothetical.

You're reading her portions of that.

Q. Yes?

A. Yeah.

MR. SEKLOFF: Do you want her to read all of the information or just portions?

MR. WISNER: I'm actually asking questions. If you could really just object to information, I'd appreciate it.

Q. All right. So let's continue.

"The risk of withdrawal symptoms seen with SSRI's and SNRI's may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction."

Do you see that?

A. Yes.

Q. Now, nowhere in the U.S. label, particularly under "Discontinuation of Treatment with Cymbalta," does it say that discontinuation symptoms are correlated with dose of therapy?

MR. STEKLOFF: Object to form.

A. Yes.

Q. Nowhere in the discontinuation section in the U.S. label does it say the longer that you take Cymbalta, the more likelihood or increased risks of withdrawal you may have?

MR. STEKLOFF: Object to form again.

A. Yes.

Q. It's not in the label; right?

A. Yes.

Q. Okay. Now, the European label continues. It says, "The most commonly reported"

indications -- "reactions are listed in section 4.8. Generally these symptoms are mild to moderate, however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there" may -- there have been rare reports of such symptoms in patients who have inadvertently missed a dose.

Do you see that?

A. Yes.

Q. Now, Doctor, did you know before today that if you inadvertently missed a dose you could suffer withdrawal with Cymbalta?

MR. STEKLOFF: Object to form.

A. Can you say your question again? So if somebody forgot to take the dose?

Q. Sure.

A. Yeah. I have not thought about that, yes.

Q. You've never -- you've never been told that before; right?

MR. STEKLOFF: Object to form.

A. No.
Q. And you'd agree that missing a single dose can lead to withdrawal reactions, that's a piece of information you would have wanted to know as a prescriber?
MR. STEKLOFF: Object to form again.
A. Yes.
Q. And this is a piece of information you probably would share with your patients when you're prescribing the drug; right?
MR. STEKLOFF: Object to form.
A. Yes.
Q. And, Doctor, just so you know -- well, never mind. We'll continue with this.
The next sentence says, "Generally these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged," two to three "months or more."
Do you see that?
A. Yes.
Q. Nowhere in the U.S. label does it say

that discontinuation reactions can last two to three months or more, does it?

MR. STEKLOFF: Object to form.

A. I have to read the whole thing, but no, I don't recall.

Q. Sorry, I'm going to rephrase the question.

A. Just in that paragraph?

Q. Yeah. In section 5.7, nowhere does it say that discontinuation reactions can last two to three months?

A. No, it doesn't.

Q. Did you know before today that it was possible that discontinuation reactions could last two to three months?

MR. STEKLOFF: Object to form.

A. No.

Q. And that's a piece of information you would like to know as a prescriber; right?

MR. STEKLOFF: Object to form. Calls for speculation.

A. Yes.

Q. And when discussing the treatment option with a patient, this is something you might apprise them of, if they ever want to discontinuation -- discontinue the drug; correct?

MR. STEKLOFF: Object to form.

A. Yes.

Q. One more sentence. It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient's needs."

Do you see that?

A. Yes.

Q. Now, again, nowhere in the U.S. label does it say you must taper for at least two weeks, does it?

MR. STEKLOFF: Object to form.

A. No, it doesn't say the exact time.

Q. In fact, in this warning in the U.S. label, there is no indication of how long you should taper whatsoever?

MR. STEKLOFF: Object to form.

A. You're right.

Q. Doctor, you would agree that knowing that you should taper for a minimum of two weeks, that's a piece of information that you would like to know --

MR. STEKLOFF: Object to form.

Q. -- as a prescriber?

A. We usually taper it off during that period or a little while longer. On -- on a regular basis when we -- we taper off antidepressants like Cymbalta, I usually recommend to taper it off for two to four weeks or something like that.

Q. And that's based upon your own experience with it; correct?

A. Yeah. From my knowledge of it.

Q. You didn't get that from the U.S. label?

A. No.

Q. Okay.

MR. WISNER: Can we go off the record.

A. I push around, but not like this.
Q. Do you see that last paragraph there, it reads -- starts off with "Dear Fugan and all"?
Do you see that?
A. Uh-huh.
Q. Now this paragraph reads, "my point was not so much what events should be included, but concern that the implication from the wording is that tapering eliminates the risk of discontinuation symptoms. None of the individual studies specifically designed to look at this (SUI or GAD) have shown a benefit to tapere compare with abrupt discontinuation. I just believe that the sentence that concludes the first paragraph is not accurately reflecting the lack of benefit" -- "the lack of benefit (or lack thereof) of tapering in studies designed to look at this specifically."
Do you see that?
A. Yes.
MR. STEKLOFF: Objection.
Q. Doctor, it was your understanding,

when you prescribed Cymbalta to Mrs. Ali, that tapering a medication reduced the risk of suffering from withdrawal; right?

A. Yes.

Q. And based on the sentences that I just read you it would appear that these individuals within Eli Lilly and Company are stating that the studies show that there is no difference between tapering abruptly or taping -- tapering or abrupt discontinuation?

MR. STEKLOFF: Object to form.

A. These are parts of emails. I just don't know the entire story. I can't really comment based on what you're showing me right now. I can tell you what my understanding was, but who knows what has gone on. I don't know. This is just three part -- just three emails that you're showing me.

Q. Let me ask this question a different way. Sorry, did I cut you off, Doctor? I didn't mean to.

A. No, no. Go ahead. Ask me.

Q. Assume for a second that Lilly conducted clinical trials to see if abrupt discontinuation or if tapering made a difference on whether or not people suffered from discontinuation symptoms. And assume for a second that the study shows that there was no difference.

MR. STEKLOFF: Object to form.

A. Okay.

Q. Assuming those two pieces of information, is that information that you would have wanted to know as a prescriber?

MR. STEKLOFF: Object to form.

A. Yes.

Q. And that's information you would have expected to be in the label; correct?

MR. STEKLOFF: Object to form.

A. Yeah. I expect things that are important to be in the label, yes.

Q. And the risk that a patient could potentially suffer from discontinuation, that's important?

A. Yes.
Q. And let's assume that you were speaking -- well, let's not assume. At some point you discussed the risks and benefits with Mrs. Ali of Cymbalta; right?
A. Yes.
Q. And during that discussion, assuming that the risk really is 45 percent --
MR. STEKLOFF: Object to form.
Q. -- is that something you would have shared with her as part of the discussion of the risks and benefits of the drug?
MR. STEKLOFF: Object to form.
A. If it's in the package insert, yes.
Q. And if Mrs. Ali had told you, I will not take on that risk, would you still prescribe Cymbalta to her?
A. Of course not.
Q. Why not?
MR. STEKLOFF: Object to form.
A. I just don't do that. I don't force any medications on any patients. Patients are

told to make an informed consent. It's a mutual thing. It is their body, and they can refuse any medication they don't want to be on. I may, in my clinical, judgment, feel that it may be the next step. But if she doesn't want to take it, that's fine. We'll have to find another alternative step. Nobody's forcing anything on anybody.

Q. Would it be fair, then, Doctor, if she said, I refuse to take on this risk, or I refuse to take Cymbalta, that you would have tried to explore possible alternative treatments for her?

A. Yes. Probably would have done more Flexeril, tramadol, more physical therapy, yes.

Q. And you would have done that, even if you did not have another drug to prescribe, you still would not have prescribed the drug; right?

MR. STEKLOFF: Object to form.

A. Of course not.

Q. Okay. Doctor, I want to wrap up my questioning in a minute. If you could turn to

A. Yes.

Q. And so that's why, in part, it would be important to know what the placebo patients were experiencing; right?

A. Yes.

Q. And do you agree that when the label talks about placebo-controlled clinical trials and says that -- that the following symptoms occurred at one percent or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo, it's telling you that in these studies the patients who were taking Cymbalta experienced them -- experienced the symptoms listed here at significantly higher rates?

A. Obviously, it means that the discontinuation symptoms with Cymbalta were higher than those from the placebo, and that's why that's a drug and that's the placebo.

I mean, there can be sometimes statistically insignificant changes between the placebo and the drug, and that's possible. But

you're saying that they were. Yeah, that I understand here, but --

Q. And do you agree --

MR. WISNER: Hold on. Please let her finish her answer.

Q. Go ahead, please.

A. Go ahead. What was your question?

Q. No, no. I did not mean -- I didn't mean to cut you off.

A. That doesn't -- you know, what I mean is that -- so the breakdown gives you a clarification, like 21 percent of placebo had dizziness, 44 percent in -- in the duloxetine group had dizziness. So the percentage is like double the amount of patients had dizziness in the medication group versus the placebo group. And that's -- that I can understand.

But when you ask me to guess greater than one percent, that's guesswork. I understand it's higher, of course, that's why the drug -- in most of the cases, the drug has a, you know, higher rate of side effects than the placebo, and

that's understandable. But I don't see -- I don't -- you can't tell me to say, well, you just guess, then, what the percentage is.

Q. And I'm not asking you to guess what the percentages are. My question is, without -- you have no idea, without reviewing this whole study and potentially other studies --

A. True.

Q. -- to understand the details on whether it would have had any impact on your prescribing decision for Mrs. Ali?

A. True.

Q. And so when Mr. Wisner asked you a bunch of questions about whether you would have given her different advice, if you knew that 45 percent of patients experience a symptom, do you agree that that's not a complete hypothetical, because you don't have all -- you don't have the placeb -- he didn't ask you about the placebo numbers, he didn't ask you to go over the details, you didn't review the details?

A. That's not what he asked me. He

asked me if it was -- if there was 44 percent, if someone came, and drug reps came and asked you, there is a 44 percent, would you know about it, if it's in the package insert, would you pay attention to it, and I said yes.

Q. And understanding that you, of course, would pay attention to it, do you know whether it would have changed your prescribing decision for Mrs. Ali?

MR. WISNER: Objection, speculation.

A. I would have reviewed it with her. Whether she would have taken the medication or not, that is speculation. I can't -- but she would have had a package insert to review it, and I would have reviewed it with her.

Q. Do you know whether you would have -- but is it fair to say that you would be speculating, if -- if I asked you whether you would have made a different recommendation to Mrs. Ali, putting aside what her decision would have been?

A. I would have -- yes. I would be

speculating. It depends what was in the package insert, what the information is, what she would have decided, what I would have decided, based on whether she would have wanted to go on the medication, you know.

It's all speculation because you're asking me hypothetical questions. I can't answer those things.

Q. And so -- well, let me ask a different question.

Do you agree that the language that is in the label about the one percent or greater and at a significantly higher rate in the duloxetine patients versus the placebo, that you would have reviewed that with Mrs. Ali?

A. If this was in the package insert, I said this many times. More likely than not, we reviewed it, and it says in my documents I gave her the package insert. I don't know how many times I have to answer that question, though. But I did say that many times, yes.

MR. STEKLOFF: No further questions.

MR. WISNER: Thank you, Doctor.

MR. STEKLOFF: We're done. Thank you.

MR. MARR: We'll read.

THE VIDEOGRAPHER: This concludes today's videotape deposition of Dr. Navera Ahmed.

Going off the record. The time is 1847 p.m.

(Signature not having been waived, the deposition of NAVERA R. AHMED, M.D. was concluded at 6:47 p.m.)

* * *

ACKNOWLEDGMENT OF DEPONENT

I, NAVERA R. AHMED, M.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached Errata Sheet signed by me.

_____ _____

(DATE) NAVERA R. AHMED, M.D.

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, AMY E. SIKORA-TRAPP, RPR, CRR, Former CSR-NY (license unrenewed), CLR, and Notary Public within and for the Commonwealth of Virginia, hereby certify that the foregoing deposition of NAVERA R. AHMED, M.D. was taken before me on the 20th day of April, 2015.

That the said witness was duly sworn before the commencement of the testimony; that the said testimony was taken stenographically by me and then transcribed.

I further certify that I am not kin to any of the parties to this action nor am I interested directly or indirectly in the matter in controversy; nor am I in the employ of any of the counsel in this action.

IN WITNESS WHEREOF, I have hereunto set my hand this 21st day of April, 2015.

_____

AMY E. SIKORA-TRAPP, RPR, CRR,
Former CSR-NY (license unrenewed), CLR
Notary Public
within and for the Commonwealth of Virginia
My Commission expires: 7/31/19