IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
-v-	)	CAUSE NO.
	)	3AN-06-5630 CIV
ELI LILLY & COMPANY,	)	
	)	
Defendant.	)	

The videotaped deposition upon oral examination of ROBIN PITTS WOJCIESZEK, a witness produced and sworn before me, Nancy M. Kottenstette, Notary Public in and for the County of Marion, State of Indiana, taken on behalf of the Plaintiff at the offices of Ice Miller, One American Square, Suite 3100, Indianapolis, Indiana, on December 11, 2007, at 9:37 a.m., pursuant to all applicable rules.

C O N F I D E N T I A L

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A And Symbyax.
Q Okay. Let's first talk about the first item in the notice of deposition, which is regarding Lilly's responses to a letter from FDA in March of 2007, which was the subject of Plaintiff's Second Set of Interrogatories and Document Requests to Defendants in the Alaskan litigation. And I'm going to hand you -- I'll hand you what we'll have marked as Plaintiff's Exhibit 2.
(Plaintiff's Exhibit 2 was marked for identification.)
Q And this appears to be a copy of a fax of a letter. It bears several dates on the front page, the earliest in time of which was March 28, 2007, and I noticed that on the very last page there is an electronic signature of Thomas Laughren at FDA that's dated March 28, 2007. Do you see that?
A Yes, I do.
Q Was this letter faxed to you on March 28, 2007?
A Yes, it was.
Q Okay. And once you received this letter, who did you distribute copies to?
A I distributed to individuals within the regulatory affairs department in addition to those key individuals on the team who are responsible for

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this supplemental application.
Q And who were those key members responsible for the supplemental application?
A They would be the medical director of the Zyprexa team.
Q Who was?
A Sara Corya.
Q Okay. How does she spell her last name?
A C-O-R-Y-A.
Q Okay.
A The Zyprexa global brand development team leader at the time was Eric Baclet.
Q Anyone else?
A Of course, my supervisor, Greg Brophy.
Q Okay.
A And, again, those -- there was a core team of probably over 20 individuals, too, who are involved in just the overall data package who were also communicated, but those were the key individuals.
Q Now, the letter from FDA makes reference to a number of regulatory filings with FDA by Lilly regarding Symbyax; correct?
A Correct.
Q And Symbyax is a combination drug containing both Zyprexa and Prozac; correct?

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A That's correct.
Q Or, I guess, the generic terms would be containing both olanzapine and fluoxetine; correct?
A That's correct.
Q Did I pronounce that last one correctly?
A Yes, you did.
Q Okay. And in those regulatory submissions, Lilly was seeking approval from FDA to market the combination drug Symbyax for use in treatment resistant depression or TRD; is that correct?
A That's correct.
Q Okay. And it indicates that these prior submissions had occurred in September of 2006, in November of 2006, December of 2006, and February of 2007; correct?
A That's correct.
Q Okay. And am I correct that those submissions made by Lilly to FDA included information from clinical studies of the combination drug?
A That's correct.
Q Okay. And among other things, that clinical data included information regarding changes in the blood glucose of patients who were exposed to the combination drug as compared to people who were just receiving placebo; is that correct?

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A That's correct.
Q And since those submissions occurred in the fall of 2006, the studies that contained that data would have been concluded sometime before that; correct?
A That's correct.
Q And do you know when it was that those clinical studies were done which contained the data that was submitted to FDA in the submissions that are referenced here?
A They had completed over numerous years, but the last study that completed, which was to support the indication which was HDAO, completed in the fall of 2005.
Q Fall of 2005. And that was the latest of those studies; correct?
A That's correct.
Q And what was -- what would have been the earliest of those studies?
A I don't recall. They were -- some of the studies that we included in the submission were also submitted with the original application for Symbyax in 2002.
Q Okay. I want to make sure I understand. So that the submissions that occurred in the fall of 2006 to support the additional indication for

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treatment resistant depression included data from studies that had been conducted in support of the original Symbyax submission in 2002 as well as other studies after that point, the last of which had been completed by the fall of 2005. Is that a fair statement?
A That's a fair statement, yes.
Q Okay. And the earliest of those studies that had been done in support of the 2002 submission, I presume, would have been completed sometime before 2002; is that correct?
A That's correct.
Q Do you know when it was that they would have been completed?
A I don't know the exact dates, but, typically, they're done about six months prior to a submission.
Q So probably 2001 sometime?
A Some of them were, yes.
Q Okay. Do you know what the date -- at least a month, date of the 2000 submission for Symbyax?
A If I recall, it was November of 2002. It was prior to my responsibility --
Q Okay.
A -- around the application.

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Q Okay. So it'd be fair to say that the data that's being referenced here in this letter is the data that was generated between, say, early 2002 and 2005 in that time frame; correct?
A Majority of the data, yes.
Q Okay. Now, in order to approve Symbyax for use in treatment resistant depression, FDA needed to approve the labeling for the drug; correct?
A Correct.
Q Okay. And on the first page of the letter in -- there's a bolded heading that states "Updated Information on Risks of Weight Gain, Hyperglycemia, and Hyperlipidemia." Do you see that?
A Yes, I do.
Q In the first paragraph right after that heading, it states "A primary concern with this application and the primary basis for our not taking a final action is our view that we lack important safety information needed to adequately update the labeling with all relevant risk information. In particular, we are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine use, whether taken alone or in combination with fluoxetine. You

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must fully address these concerns before we will be able to take a final action on this application."
Do you see that language that I read?
A Yes.
Q And I read it correctly; correct?
A Yes, you did.
Q And it was clear, was it not, that the concerns about weight gain, hyperglycemia, and hyperlipidemia that it's referring to in connection with Symbyax had to deal with the Zyprexa portion of the drug and not the Prozac portion; correct?
A That's correct.
Q Okay. And, in fact, FDA has not requested any change in the labeling of Prozac regarding weight gain, hyperglycemia, and hyperlipidemia recently, have they?
A No, they have not.
Q Okay. Now, if I could direct your attention to the following page, in the first full paragraph on that page, FDA is talking about the data that they would like to see presented in the labeling; correct?
MR. KANTRA: Objection to the form.
A What they're asking for is regarding -- if you look at the previous paragraph, it's an extension of

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what type of information that they would like to see prior to making any labeling change.
Q Ah, okay. Good point. So the FDA is telling you before they can approve a labeling change to allow for a further indication of treatment resistant depression they wanted to see the type of data that they're referring to in the first full paragraph on page 2; correct? Is that a fair statement?
A That's -- that's a fair statement.
Q Okay.
A Yes.
Q And what they said in that paragraph was "Regarding data displays, an overall strategy will be to subgroup patients on the basis of their status at baseline so that clinicians can better understand the risks associated with treatment of patients falling into different risk categories.
For example, we note that your proposed Symbyax label includes information only on proportions of patients who are relatively normal at baseline with regard to random blood glucose (less than 140 milligrams per deciliter); i.e, 2.9 percent of such patients receiving OFC had on-treatment levels greater than or equal to